

DASH2 Forms Manual

Table of Contents

Number	Description	Current Version
1	Prescreen Eligibility Form	1.2
2	SV1 Blood Pressure Form	1.3
3	SV1 Visit Form	1
4	SV2 Blood Pressure Form	1
5	SV2 Visit Form	1
6	Eligibility Questionnaire	1.9
7	SV3 Blood Pressure Form	1.1
8	SV3 Visit Form	1
9	Instruction for Completing the Food Frequency Questionnaire	1.1
10	Physical Activity Questionnaire	1.3
11	Symptoms Form	1.4
12	Adverse Events	1.2
13	Eligibility Review	1.7
14	Local Lab Worksheet	1.3
15	Generic Blood Pressure Form	1.2
16	Run-In Flow Form	1.1
17	Medication Questionnaire	1.1
18	Participant Closeout Form	1.5
19	Patient History Questionnaire	1.1
20	Intervention Flow Form	1.3
21	Brief Physical Activity Questionnaire	1.1
22	Premature Study Termination Form	1.3
23	BP Escape Tracking Record	1.4
24	Daily Diary	1.4
25	Anonymous Survey	1.1
26	Participation Survey	1.1
27	ABPM Placement Form	1.1
28	ABPM Participant Questionnaire	1.1
29	Participant Information Sheet	1.1
30	Central Lab Collection Form- 24-Hour Urine	1.4
31	Central Lab Collection Form - Fasting Blood	1.5
32	Recruitment Activities Log	1.1
33	Case Conference Form	1.2
34	Reason for Non-Enrollment	1
35	DASH2 Diet Acceptability Questionnaire	1.3
36	Shipping Log	1.1
37	Initial Run-In Blood Pressure Form	1.3

DASH2 Forms Manual

Table of Contents

Number	Description	Current Version
38	Central Lab Shipping Log - Urine	1.1
39	Central Lab Shipping Log - Blood Samples	1.1
50	Quarterly checklist for monitoring Blood Pressure Observers	1
51	Blood Pressure Written Examination	1.2
52	Blood Pressure Certification Form	1.4
53	Blood Pressure Observation Checklist Form	1.1
54	Standard, RZ and Cuffs Inspection and Maintenance Log	1.3
55	Standard, RZ Manometer and Cuffs Inspection and Maintenance Log	1.2
56	Quarterly Cleaning, Inspection and Comparison Log	1.1
57	Standard Manometer Quarterly Cleaning and Inspection Log	1.1
58	DASH2 Videotape Test Sheet	1
59	ABPM Initialization/Downloading/Transfer Checklists	1
60	ABPM Instructions to Participants	1
61	ABPM Certification Written Test	1.1
62	Certification Form: ABPM placement	1.1
63	Weight Observation Checklist Form	1.1
64	Weight Certification Form	1.3
65	Weight Scale(s): Accuracy Check and Yearly Certification Log	1.2
66	Height Observation Checklist Form	1.1
67	Height Certification Form	1.3
68	Waist Circumference Observation Checklist Form	1.1
69	Waist Circumference Certification Form	1.3
70	Ambulatory Blood Pressure Observation Checklist	1.1
72	Proposal for a DASH2 Paper	1.3
73	PASC Review Form for a DASH2 Publication Proposal	1.4
74	DASH2 Ancillary Study Request Form	1.4
75	DASH2 Data Analysis Request Form	1.4
76	DASH2 Data Release Request Form	1.4
77	DASH2 Abstract Review Form	1.2
78	DASH2 Manuscript Review Form	1.3
79	DASH2 Data Application Error Log	1
80	Dietary Screening Certification	1.1
81	Dietary Screening Quality Assurance Checklist	1.1
82	Participant Orientation Certification (Module 3)	1
83	Compliance Assessment Quality Assurance Checklist (Not Available)	
84	Kitchen Staff Certification Checklist: Food Preparation	1.1
85	Exit Interview Quality Assurance Checklist	1

DASH2 Forms Manual

Table of Contents

Number	Description	Current Version
86	Exit Interview Certification	1
87	Spot Checking of DASH Recipes, Meals, and Food Items	1
88	ABPM Monitor Inspection & Maintenance Log	1
89	Request for Additional Lab Supplies	1
90	Kitchen Scale(s): Weekly Accuracy Check	1
91	Food Service Sanitary Inspection Checklist and Action Plan	1
92	DASH2 Food Preparation and Distribution Test	1
93	Kitchen Quality Control Schedule	1.1
94	Participant Orientation Checklist (Module 3)	1
95	Participant Orientation Test (Module 3) (Not Available)	
96	Participant Orientation Test Answer Key (Module 3) (Not Available)	
97	Food Acquisition Certification (Module 2) (Not Available)	
98	Food Acquisition Checklist (Module 2) (Not Available)	
99	ABPM Placement Certification	1
100	General Dietary Information Questionnaire	1.1
101	Study Food Checklist	1.3
102	Study Menus	1.2
103	How to Fill out the Food Questionnaire	1
104	Diet Orientation Form (version 1)	1
104	Diet Orientation Form (version 2)	1
105	Weekly (Layman's) Detailed Menu	1.3
106	Guidelines for Beverages and Seasonings	1.1
107	Safe Foods to Go	1
108	Recipes	1.9
109	Food Substitution Record	1
110	Standardized Portion Guidelines for Assessing Compliance (Not Available)	
111	Master Menus (Not Available)	1.3
112	Production Menus (Not Available)	1.3
113	Tray Assembly Forms (Not Available)	1.3
114	Clinical Measurements	1.1
115	Daily Diary Information (version 1)	1
115	Daily Diary Information (version 2)	1
116	Medications Allowed During DASH2	1
117	Donation Tracking Form	1
118	Flower Form - CONFIDENTIAL	
119	SV3 Follow Up Form	1
120	Food Substitution List (Not Available)	

DASH2 Forms Manual

Table of Contents

Number	Description	Current Version
121	Food Substitution FAX	1
122	Exit Interview Action Planning Worksheet	1
123	Exit Interview Script	1
124	Exit Interview Height/Weight Table	1
125	Health Risk Assessment Report (Access) (Not Available)	
126	Health Risk Assessment Cover Letter	1
127	Food List and Recipe Ingredients (Not Available)	
128	Food Preparation Checklist	1
129	Salt in the DASH2 Diet	1
130	Clean Plate Form	1.2
131	Food Questionnaire Test (FFQ) (Not Available)	
132	Blood Pressure Medication Follow Up form	1
133	Adverse Events Classification Form	
134	Storage Specimen Request Form	



PSV
 ID # _____
 Visit Date ___ / ___ / _____

Prescreen Eligibility Form

Thank you for your interest in the DASH2 study! Your answers to the following questions will help to determine if you can become part of this important study. Any information you provide will be kept strictly confidential.

Please print your name, address, and phone number.

First name	MI	Last name		
Address	City	State	Zip	
Daytime phone	Evening phone			
			Yes	No
1.	Are you 22 years old or older?		<input type="checkbox"/>	<input type="checkbox"/>
2.	Do you take insulin?		<input type="checkbox"/>	<input type="checkbox"/>
3.	<i>For women only:</i> Are you pregnant, planning to become pregnant, or breastfeeding?		<input type="checkbox"/>	<input type="checkbox"/>
4.	Have you taken any medications to control your blood pressure in the last three months?		<input type="checkbox"/>	<input type="checkbox"/>
5.	Are you currently taking diet pills or any medications to control your weight?		<input type="checkbox"/>	<input type="checkbox"/>
6.	Do you currently chew tobacco or use snuff?		<input type="checkbox"/>	<input type="checkbox"/>
7.	On the average, how many drinks of alcohol do you have in a week? <i>If you don't drink alcohol, enter 0.</i> <i>(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)</i>	_____	drinks per week	
8.	Have you ever had a stroke or heart attack?		<input type="checkbox"/>	<input type="checkbox"/>
9.	Do you have any other heart problems? If yes, what? _____		<input type="checkbox"/>	<input type="checkbox"/>
10.	Do you have any other serious illness such as cancer, HIV, or liver or kidney disease? If yes, what disease? _____		<input type="checkbox"/>	<input type="checkbox"/>
11.	Are you on a special diet or planning to go on one? If yes, what kind of diet? _____		<input type="checkbox"/>	<input type="checkbox"/>
12.	Are there any foods that you cannot or will not eat? If yes, what and why? _____		<input type="checkbox"/>	<input type="checkbox"/>

13. How tall are you? _____ ft. _____ inches
14. How much do you weigh? _____ pounds
15. What is your **primary** race?
(check one answer only)
- American Indian or Alaskan Native 1
- Asian/Pacific Islander 2
- Black/African American 3
- White 4
- Other (specify) _____ 5
16. Do you consider yourself to be Hispanic?
- Yes 1
- No 2
17. What is your sex?
- Male 1
- Female 2
18. How did you hear about DASH2?
(check one answer only)
- Mailed letter/brochure/flier 1
- Non-paid radio story 2
- Screening events/health fair 3
- Word of mouth/friends 4
- Non-paid print story/newspaper 5
- Non-paid TV story 6
- Presentations 7
- Other _____
19. What is your date of birth?
- _____
- mm dd yyyy
20. What is your mothers maiden name?
- _____

For Office Use Only

21. Optional SBP ___ ___ ___ Optional DBP ___ ___ ___

22. PSV eligible Yes 1 No 2

23. What cohort is participant being screened for? _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Administration and Coding Instructions for Prescreen Eligibility Form

The Prescreen Eligibility Form may be completed in one of three contexts: over the phone, during a community screening activity or in the clinic. It is recommended that this form be administered in an **interview format** due to the detailed information that the recruitment committee is capturing for the “hear about study” question (Q18). If this form is given to the respondents to complete on their own, question 18 must be explained to the respondents.

Some of the questions on this form will result in immediate exclusion from the study, others are intended to gather demographic information, to aid in recruitment monitoring, and some are used as a flag to be reviewed by a clinician or dietitian. As soon as a participant is determined to be ineligible, the staff person should check the “No” box under PSV eligible in the “office use only” section. The interview may then be concluded at this point or continued (at local discretion).

In addition to the questions asked on the form, the prescreening visit includes an optional blood pressure assessment. Space is included in the “office use only” section to record this information. The blood pressure assessment may be taken either before or after completing the questionnaire. If it is done before and the participant is not eligible, the remainder of the questionnaire need not be completed.

Record the visit date (be sure to write in a four digit year) in the upper right corner. If the participant is still eligible to continue at the end of the visit, the computer will assign a study ID number upon entry of the form and this should also be recorded on the form.

Record respondent’s name, address, and phone number. Please print legibly to facilitate entry later.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Questions 1-14 will NOT be entered:

- Q1. Only individuals aged 22 years or older as of PSV date are eligible to participate
- Q2. Respondents taking insulin are excluded from participation.
- Q3. Question 3 is asked only of women. Those who answer “yes” should be excluded. Inform the woman that, because of the effects of pregnancy on blood pressure, she is not eligible for the study at this time. Women who plan to deliver in the near future can be rescreened again after delivery, but cannot be checked as “no” based on an anticipated delivery date.
If respondent is breastfeeding, inform the woman that she is not eligible for the study because of the effects of breastfeeding on blood pressure. Those women who are excluded only on the basis of this question can be invited back for rescreening if they plan on stopping breastfeeding prior to completion of the study. This question may not be checked “no” however, based on the anticipation that this will happen in the near future.
- Q4. If respondents have taken blood pressure medications in the past three months, they are excluded.
- Q5. Respondents taking any diet pills or medication to control weight are excluded.
- Q6 Respondents using chewing tobacco or using snuff are excluded.
- Q7 Probe to get a specific number of drinks per week. If more than 14 drinks in a week, the person is ineligible.
- Q8 Respondents who have had a stroke or a heart attack are excluded.
- Q9 Respondents having any heart problems may be excluded. Record the problem and then consult your clinician for those respondents answering “yes”. The clinician will determine if the problem is cause for exclusion according to local protocol. If the clinician decides that the person is eligible, change the response to “no”.
- Q10 Respondents having any other serious illness such as cancer, HIV, or liver or kidney disease may be excluded. Record the problem and then consult your clinician for those respondents answering “yes”. The clinician will determine if the problem is cause for exclusion. If the clinician decides that the person is eligible, change the response to “no”.
- Q11 Respondents who are planning to go on or are on a special diet may be excluded. Record the problem and then consult your dietitian for those respondents answering “yes”. The dietitian will determine if the problem is cause for exclusion. If the dietitian decides that the person is eligible, change the response to “no”.
- Q12 Respondents who can not eat certain foods may be excluded. Record the problem and then consult your dietitian for those respondents answering “yes”.

The dietitian will determine if the problem is cause for exclusion. If the dietitian decides that the person is eligible, change the response to “no”.

Q13. Record height in feet and inches.

Q14. Record weight in pounds.

Body mass index - To determine if the participant is BMI eligible, first locate the participant’s height (from Q13) on the PSV reference chart (attached) and note the accompanying weight threshold. If the participants weight (from Q14) equals or exceeds this threshold, the participant is ineligible based on BMI.

The following questions CANNOT be left blank.

Questions 15-20 and 22-23 will be entered if eligible. Entry is optional if respondent is ineligible.

Q15 This question is intended for demographic purposes. Record the primary race. This should be the one the participant identifies with the most. Check only one answer. If the respondent enters “Hispanic” under “other”, code Q16 as “yes”, ask participant if they consider themselves to be white Hispanic, black Hispanic, or other Hispanic. Code Q15 as appropriate based on the answer. The “other” category should not be checked simply because the participant lists Hispanic.

1=American Indian, Alaskan Native

2=Asian/Pacific Islander

3=Black/African American, Ethiopian, Mulatto

4=White, Spanish, Capeverdian, Lebanese, Spanish, Persian, Jewish,
Brazilian, Portuguese, Milano, Russian, German-Arab, Arab

5=Other, (anything coded as “other” will not be classified as a minority by NIH. Contact the CC for “other” races that you are unable to recode into the above categories.)

Q16. Although often used as a racial category, “Hispanic” actually relates more closely to ethnicity and is thus complementary to Q15. If Hispanic is written in above or Q16 is “yes”, probe for primary race code.

Q17. Self-explanatory.

Q18 Check only one answer. The item that prompted the respondent to call or come in should be used. The respondent can write in other responses if they want. If a response is written in “other” it will need to be coded. Use the following definitions and categories as a guideline to determine which code you will use. This is a two digit field, you will need to write in leading 0’s.

01=Mailed letter/brochure/flier: any mass mailing of DASH2 information that requests a mail or phone response. This does not include calls or cards returned as a result of distributing brochures by other means (i.e. hand distribution at stores, malls). These should be coded as **(09)**.

02=Non-paid radio story: any free radio announcement, ad, interview or program that gives information about DASH2

- 03=Screening events/health fair:** any gathering or event that occurs outside a DASH2 clinic. It may last one or more days. Screening could include , churches, shopping malls, special events, etc.
- 04=Word of mouth/friends:** any referral or recommendation to DASH2 by friend or family that cannot be linked by the caller to target mailing. This would also include referral from a physician or health care provider or public clinic.
- 05=Non-paid print story:** any free local or national newspaper or magazine article or public service announcement or newsletter (church, worksite, hospital, HMO, MCO, and professional organization) that gives information about DASH2. This would also include payroll stuffers that are placed without a fee.
- 06=Non-paid TV story:** any free TV announcement, ad, interviews, or program that gives information about DASH2.
- 07=Presentations:** any presentations other than screening done outside a DASH2 center.

Additional codes:

- 08=Valpack:** any mass mailing through companies which include DASH2 brochure or special coupons with other coupons.
- 09=Brochure/flier distributed other than mailing:** this includes brochures left on display at sites, libraries, grocery stores, and pharmacies. These should be coded to distinguish them from other brochures. Be sure staff answering phones are aware of posting of information or distribution of fliers and brochures
- 10=Paid print advertisement:** any print (newspaper, circular, magazine, etc.) ad that is paid for by a DASH2 site. This could include inserts in newspapers or utility bills (if it was paid to be inserted).
- 11=Paid radio advertisement:** any radio ad or announcement that is paid for by a DASH2 site.
- 12=Paid TV advertisement:** any TV ad or announcement that is paid for by a DASH2 site.
- 13=Email:** any information obtained through e-mail.
- 14=Person was in prior study:** anyone who has been in a prior research study at the clinical center, including prior DASH participants. Later, we will specifically identify prior DASH1 participants.
- 15=Web page:** any information obtained from the internet or DASH web page

Q19 Self-explanatory. Use a four digit year(e.g. 12/10/1960).

Q20. Record the participant's mothers maiden name. This field is used to help distinguish multiple people with the same name.

“For Office Use Only” section

SBP - If a blood pressure measurement is taken, record the SBP and mark either eligible or ineligible to indicate whether the participant was excluded on the basis of this measurement. No eligibility limits are established for PSV blood pressure measurement. It is recommended however, that individuals with a SBP less than 116 be excluded. In addition individual clinics should establish their own upper eligibility limits, and participants whose blood pressure exceeds these limits should be excluded and referred to a physician for further follow-up.

DBP - If a blood pressure measurement is taken, record the DBP and mark either eligible or ineligible to indicate whether the participant was excluded on the basis of this measurement. No eligibility limits are established for the PSV blood pressure measurement. It is recommended however, that individuals with a DBP less than 76 mm Hg be excluded. In addition individual clinics should establish their own upper eligibility limits, and participants whose blood pressure exceeds these limits should be excluded and referred to a physician for further follow-up.

PSV Eligible:

This section should be filled out after reviewing all the participant responses on the form. Only one outcome status should be checked.

PSV eligible - The Eligible box should be checked “yes” if all of the following are true:

Question 1 is answered “yes”;

Questions 2, 3, 4, 5, 6, 8, are answered “no”;

Question 7 indicates the person drinks \leq 14 drinks per week.

Question 9, 10, 11, 12 are answered “no” or if answered “yes” the clinician or dietitian DID NOT determine the problem to be a reason for exclusion.

SBP and DBP are within the eligible range;(if measured)

“Body mass index” is within the eligible range (Questions 13,14);

If any of the above are NOT true, code PSV eligible as “no”.

What cohort is participant being screened for - Write the number of the cohort that the participant will be placed in. In most cases the participant will be placed in the current cohort. However, in some cases the participant may be screened for the following cohort.

Reviewed by: - Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank.

Entered by - At data entry time record the staff ID of the person entering the form. This can not be left blank.

PSV Reference Chart

Body Mass Index Table (for use with Prescreen Eligibility Form)

Locate participants height (from Q13) on the table below and note the accompanying threshold weight. If participants weight (from Q14) equals or exceeds this threshold, the participant is ineligible based on BMI.

threshold		threshold		threshold	
height	weight (lbs.)	height	weight (lbs.)	height	weight (lbs.)
46"	165.9	55"	240.4	64"	328.6
47"	172.1	56"	247.8	65"	337.3
48"	178.4	57"	255.4	66"	346.1
49"	184.8	58"	263.1	67"	355.1
410"	191.4	59"	270.9	68"	364.1
411"	198.0	510"	278.8	69"	373.3
5	204.8	511"	286.8	610"	382.5
51"	211.7	6	294.9	611"	391.9
52"	218.7	61"	303.2	7	401.4
53"	225.8	62"	311.5		
54"	233.0	63"	320.0		

CHEATSHEET: CODES FOR Q18 OF PSV

Brochures

- 01=Mailed letter/brochure/flier:** any mass mailing of DASH2 information that requests a mail or phone response.
- 08=Valpack:** any mass mailing through companies which include DASH2 brochure or special coupons with other coupons.
- 09=Brochure/flier distributed other than mailing:** this includes brochures left on display at sites, libraries, grocery stores, and pharmacies.

Radio

- 02=Non-paid radio story:** any free radio announcement, ad, interview or program that gives information about DASH2
- 11=Paid radio advertisement:** any radio ad or announcement that is paid for by a DASH2 site.

Print

- 05=Non-paid print story:** any free local or national newspaper or magazine article or public service announcement or newsletter (church, worksite, hospital, HMO, MCO, and professional organization) that gives information about DASH2. This would also include payroll stuffers that are placed without a fee.
- 10=Paid print advertisement:** any print (newspaper, circular, magazine, etc.) ad that is paid for by a DASH2 site. This could include inserts in newspapers or utility bills (if it was paid to be inserted).

Television

- 06=Non-paid TV story:** any free TV announcement, ad, interviews, or program that gives information about DASH2.
- 12=Paid TV advertisement:** any TV ad or announcement that is paid for by a DASH2 site.

Events

- 03=Screening events/health fair:** any gathering or event that occurs outside a DASH2 clinic. It may last one or more days. Screening could include , churches, shopping malls, special events, etc.
- 07=Presentations:** any presentations other than screening done outside a DASH2 center.

Other

- 04=Word of mouth/friends:** any referral or recommendation to DASH2 by friend or family that cannot be linked by the caller to target mailing. This would also include referral from a physician or health care provider or public clinic.
- 13=Email:** any information obtained through e-mail.
- 14=Person was in prior study:** anyone who has been in a prior research study at the clinical center, including prior DASH participants. Later, we will specifically identify prior DASH1 participants.
- 15=Web page:** any information obtained from the internet or DASH web page



SV1
 ID # _____
 Name _____
 BP Date ____ / ____ / ____

SV1 Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of Blood Pressure measurements: _____ : _____ AM or PM
 (noon = 12:00 pm)

b. Cuff size Small adult (< 24 cm) _____ (1) Adult (24-32 cm) _____ (2) Arm circumference _____ cm
 Large adult (33-41cm) _____ (3) Thigh (42-52 cm) _____ (4)

c. Able to obtain valid reading (see instructions) _____ yes (1) _____ no (2)

Wait five minutes seated

d. Resting 30-second pulse _____ / 30 seconds

e. Pulse obliteration pressure (POP) _____ mm Hg
 + 6 0

f. Random zero peak inflation level (PIL), minimum 180 mmHg _____ mm Hg

g. Blood Pressure device # _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value _____ / _____ mm Hg

b. Zero Value _____

c. Corrected value (a - b) _____ / _____ mm Hg

Wait 30 seconds

3. SECOND RANDOM ZERO BLOOD PRESSURE

a. Uncorrected value _____ / _____ mm Hg

b. Zero value _____

c. Corrected value (a - b) _____ / _____ mm Hg

4. SUM OF 2 SBPs AND 2 DBPs, Items 2c + 3c _____ / _____ mm Hg

Sum of 2 SBPs (item #4) <236 or >340; sum of 2 DBPs, (item #4) <156 or >200, candidate is INELIGIBLE. Check ineligible on SV1 visit form.

If sum SBP (item #4) >360 or sum DBP (item #4) >220, refer participant to personal physician and complete form #23.

Collected by (staff ID): _____
 Entered by (staff ID): _____

Administration and Coding Instructions for SV1 Blood Pressure Form

USE FOR: Blood pressure screening of potential participants.

PURPOSE: Determine eligibility.

The SV1 Blood Pressure Form must be filled out during each SV1 visit. ID # labels should be printed and placed on the SV1 forms.

Some data collected on the form will indicate immediate exclusion and ineligible should be checked on the SV1 Visit Form (#03). Additionally, some data may require that participants be referred to site medical staff for consultation and the BP escape tracking form (#23) be completed.

Type of Visit - Verify that the correct blood pressure form is being used for this visit by checking the visit code in the upper right corner. It should say "SV1". This is form #02.

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further. If an ID # number has not yet been assigned, leave blank and fill in later after the computer assigns an ID #.

Name - Clearly enter the participant's name and check carefully to make sure it is copied correctly.

BP Date - Clearly enter the date when the blood pressure measurements are obtained, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

1. Preparation for Blood Pressure Measurements

Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 11.

- a. This should be the time the person is seated and the process is begun. Noon is 12:00 pm.
- b. Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement.

- c. Indicate here whether you were able to obtain a valid blood pressure reading. If the brachial artery is occluded by the cuff, the participant is excluded from participating in DASH2 (see MOP Chapter 11. If this is so or if you were unable to obtain a valid blood pressure reading for any reason, Check No, note the reason, and check Ineligible on the SV1 Visit Form (#3). If you were able to obtain the reading, check Yes.
- d. Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
- e. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
- f. Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level and record the result. If this value is less than 180, enter 180.
- g. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a one digit field.

2. **Blood Pressure Readings**

Obtain two sitting blood pressure measurements using the random-zero device. Wait at least 30 seconds between each reading. Both readings and zero values are recorded to the nearest **even** number. Subtract the zero value from the corresponding reading with a hand calculator AFTER BOTH MEASUREMENTS ARE OBTAINED. Record the resulting corrected value for both of the measurements obtained. If DBP goes to 0 mmHg, use the 4th phase DBP for all BP measurements. Be sure to write in leading zeros if less than 100.

Add the two corrected SBP and DBP measurements (2c and 3c) together and record the sum in item #4. The ineligible ranges are summarized at the bottom of the form. If ineligible, check ineligible on the SV1 visit form (#3). The escape BP levels are also shown at the bottom of the page. If these latter thresholds are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#23) should be filled out. Refer to MOP Chapter 6 for details and complete form #23.

3. **DASH Identification Number of Person Taking and Entering BP**

Collected by: record the Staff ID # of the person performing the blood pressure measurements.

Entered by: record the Staff ID # of the person entering the data into the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns. .
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Coding Instructions for SV1 Blood Pressure Form

Visit and participant identification data:

ID

ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant’s name (e.g. ABCD*12345)

Name

Check for the participants correct name.

BP Date

Check for leading zeros and four digit year. If a date is missing, illegible, or the time frame is not within the cohort’s dates, flag the form and resolve with clinic coordinator before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

1. Preparation for Blood Pressure Measurements

- a. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- b. Check for the correct cuff size. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). The circumference should correspond to the cuff size. Use the cuff size obtained at SV1 to record all of a participant’s blood

pressure measurements during screening. If the cuff size is not marked, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

- c. Check whether valid blood pressure was obtained. If No is checked, the fields that follow (1.d. through 4.) will be blank and no audit will be created. If Yes is checked, all the following fields must be filled in. Any missing data in these fields will generate an audit.
- d. The resting pulse is a two digit field and, if item 1.c. is marked yes, cannot be missing. If the resting pulse is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- e. The pulse obliteration pressure is a three digit field and, if item 1.c. is marked yes, cannot be missing. If the (POP) is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- f. Check for correct addition. The random zero peak inflation level should equal the sum of the (POP) plus 60. If the sum is less than 180, write in 180 for the (PIL). If the (PIL) is missing or is outside the normal range, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- g. This is a one digit field. If the BP device # is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

2. First Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

3 Second Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
4. Sum of 2 SBPs and 2 DBPs. Check for addition accuracy of $2c + 3c$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

5. DASH Identification Number of Persons Taking and Entering BP

Staff ID number of person performing the blood pressure measurements cannot be left blank. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

Staff ID number of person entering the data cannot be left blank. This value should not be on the form until everything else on the form has been entered. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.



SV1
ID # _____
Name _____

SV1 VISIT Form

DONE ?

- Informed Consent (if applicable)
- Participant Information Sheet (if not on file)
- Distribute Eligibility Questionnaire
- Review Eligibility Questionnaire (optional) **eligible** 1
ineligible 2
N/A 3
- Complete SV1 Blood Pressure Form **eligible** 1
ineligible 2
- General Dietary Information Questionnaire **eligible** 1
ineligible 2

Optional:

Height ___ ___ ___ . ___ cm Weight ___ ___ ___ . ___ kg
--

- **eligible** 1
- ineligible** 2
- N/A** 3

- SV1 Visit Outcome: **eligible** 1
- ineligible** 2
- incomplete** 3
- refused** 4

SV2 visit date _____

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Administration and Coding Instructions for SV1 Flow Form

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

SV1 Flow Form

Be sure you have the appropriate form for the visit. Fill out the participant ID number, name, and the visit date at the top of the form. The participant should take the SV1 Flow Form with them to the different stations to be sure all screening tasks are completed. At each station, the staff person needs to check that the task was completed and, if applicable, enter the appropriate eligibility result.

Informed Consent:

The need for a consent to be done at a specific visit will vary by site. If consent is being done at this visit, check the “Done?” box.

Participant Information Sheet:

After completing form #29, mark “Done?”.

Distribute Eligibility Questionnaire:

The Eligibility Questionnaire (form #6) is designed to identify persons who are ineligible for medical or behavioral reasons. Remove the last page (“office use only” section) from the form, store it in the participant’s study chart, and give the rest of the form to the participant to take home and return at the SV2 clinic visit. This form may also be administered as a part of the SV1 visit. If the participant is not eligible for SV2, he should not receive this form. Be sure to place a label with the participant’s study ID on each page of the form. If an ID has not yet been assigned, write the participant’s name on each page of the form.

Review Eligibility Questionnaire:

After the participant has completed form #6 review the form, mark “Done?” and the eligibility result. Mark the “NA” box if the form will be completed at home and returned at the next visit.

Complete SV1 Blood Pressure Form:

After completing the blood pressure form, check the “Done?” box and mark whether the participant is eligible to continue or ineligible

General Dietary Information Questionnaire:

After completing, mark “Done?” and the eligibility result.

Optional:

The participant’s weight and height measurement may be collected at SV1 or SV2, as long as it is completed by SV2. Measure the participant’s weight and height per the protocol outlined in MOP chapter 13 and record height to the nearest .10 cm and weight to the nearest .10 kg. Refer to the SV1 Reference Chart (located in the back of chapter 6 of the MOP) to determine if the participant is BMI eligible. Indicate if the person is eligible or ineligible based on BMI. Mark the “NA” box if the measurements will be completed at the next visit.

SV1 Visit Outcome:

This section is used to summarize the participant’s eligibility status at the end of the visit. A single result is checked, entered into the computer, and subsequently used to generate recruitment monitoring reports. A participant is either eligible to continue on to SV2, ineligible, incomplete, or refused. “Refused” should be used for participants who appear otherwise eligible but refuse to continue in the study. “Incomplete” should **only** be checked as a **final** outcome (if the participant is a no show and you are not able to contact the participant for any further visits). If a participant is excluded due to investigator discretion (i.e., not as part of the regular screening activities for this visit), check “ineligible” and complete the Participant Closeout Form (#18) to record the reason for the exclusion. Place the completed form in the participant’s folder.

SV2 Visit Date

If participant is SV2 eligible, note the scheduled SV2 date.

Reviewed By:

Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank

Entered By:

Record the staff ID of the person entering the form. This can not be left blank

Administration and Coding Instructions for SV2 Blood Pressure Form

USE FOR: Blood pressure screening of potential participants.

PURPOSE: Determine eligibility.

The SV2 Blood Pressure Form must be filled out during each SV2 visit. ID # labels should be printed and placed on all pages of SV2 forms.

Some data collected on the form will indicate immediate exclusion and ineligible should be checked on the SV2 Visit Form (form #05). Additionally, some data may require that participants be referred to site medical staff for consultation and BP escape tracking form (#23) completed.

Type of Visit - Verify that the correct blood pressure form is being used for this visit by checking the visit code in the upper right corner. It should say "SV2". This is form #04

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further. If an ID # number has not yet been assigned, leave blank and fill in later after the computer assigns an ID #.

BP Date - Clearly enter the date when the blood pressure measurements are obtained, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

1. Preparation for Blood Pressure Measurements

Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP, Chapter 11.

- a. This should be the time the person is seated and the process is begun. Noon is 12:00 pm.
- b. Use the same cuff size as used for this participant for SV1.
- c. Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
- d. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
- e. Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level and record the result. If this value is less than 180, enter 180.
- f. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a one digit field.

2. **Blood Pressure Readings**

Obtain two sitting blood pressure measurements using the random-zero device. Wait at least 30 seconds between each reading. Both readings and zero values are recorded to the nearest **even** number. Subtract the zero value from the corresponding reading with a hand calculator **AFTER BOTH MEASUREMENTS ARE OBTAINED**. Record the resulting corrected value for both of the measurements obtained. If DBP goes to 0 mmHg, use the 4th phase DBP for all BP measurements. Be sure to write in leading zeros if less than 100.

Add the two corrected SBP and DBP measurements (2c and 3c) together and record the sum in item #4. Record the sum of the SV1 SBPs and DBPs in item #5. Add the sums of the SV1 and SV2 SBPs and DBPs (items #4 & #5) and record in item #6. The ineligible ranges are summarized at the bottom of the form. If ineligible, check ineligible on the SV2 visit form (#5). The escape BP levels are also shown at the bottom of the page. If these latter thresholds are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#23) should be filled out. Refer to MOP Chapter 7 for details and complete form #23.

3. **DASH Identification Number of Person Taking and Entering BP**

Collected by - record the Staff ID # of the person performing the blood pressure measurements.
Entered by - record the Staff ID # of the person entering the data in the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Coding Instructions for SV2 Blood Pressure Form

Visit and participant identification data:

ID

ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

BP Date

Check for leading zeros and four digit year. If a date is missing, illegible, or the time frame is not within the cohort's dates, flag the form and resolve with clinic coordinator before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

1. Preparation for Blood Pressure Measurements

- a. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- b. Check for the correct cuff size. The cuff size should correspond to the circled cuff size in the SV1 cuff size box. Use the same cuff size throughout the study. If the cuff size is not marked or does not correspond to the SV1 cuff size, flag the form and resolve with the clinic

coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

- c. The resting pulse should be a two digit field and cannot be missing. If the resting pulse is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- d. The pulse obliteration pressure is a three digit field and cannot be missing. If the (POP) is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- e. Check for correct addition. The random zero peak inflation level should equal the sum of the (POP) plus 60. If the sum is less than 180, write in 180 for the (PIL). If the (PIL) is missing or is outside the normal range, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- f. This is a one digit field. If the BP device # is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

2. First Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

3. Second Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
4. Sum of SV2 2 SBPs and 2 DBPs. Check for addition accuracy of $2c + 3c$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
 5. Sum of SV1 2 SBPs and 2 DBPs. Enter the value from SV1 Form #02, item #4. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
 6. Sum of SV1 and SV2 4 SBPs and 4 DBPs. Check for addition accuracy of $4 + 5$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
 7. DASH Identification Number of Persons Taking BP and Entering Data

Staff ID number of person performing the blood pressure measurements cannot be left blank. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

Staff ID number of person entering the data cannot be left blank. This value should not be on the form until everything else on the form has been entered. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic

coordinator. An audit will be created if data entered are outside the normal range or if data are missing.



SV2
ID # _____

SV2 Visit Form

DONE ?

- Check Visit Window
- Informed Consent (if applicable)
- Complete SV2 Blood Pressure Form **eligible** 1
ineligible 2
- Collect Blood Specimen
- Initiate Local Lab Worksheet
- Complete Urine Dip Stick
Protein and glucose **eligible** 1
ineligible 2
- Distribute Food
Frequency Questionnaire
- Distribute 24-Hour
Urine Materials
- Review Eligibility Questionnaire (if completed at
at SV1, do not repeat) **eligible** 1
ineligible 2
N/A 3

If height/weight taken at SV1, do not repeat:

Height ___ ___ .___ cm
Weight ___ ___ .___ kg

- **eligible** 1
ineligible 2
N/A 3

Visit Outcome: **eligible** 1
ineligible 2
incomplete 3
refused 4

SV3 Visit date _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Administration and Coding Instructions for SV2 Flow Form

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

SV2 Flow Form

Be sure you have the appropriate form for the visit. Fill out the participant ID number, at the top of the form. The participant should take the visit flow form with them to the different stations to be sure all screening tasks are completed. At each station, the staff person needs to check that the task was completed and the eligibility result is checked, if appropriate.

Visit Window:

Check to make sure visit is at least 7 days after blood pressure measurement during SV1 visit. If not, the remainder of the SV2 visit cannot be conducted and must be rescheduled to comply with this requirement. No upper limit exists for the SV2 window, except that Run-in cannot begin more than 150 days past SV1.

Check the "Done?" box if at least seven days have expired since SV1.

Informed Consent:

The need for a consent to be done at a specific visit will vary by site. If the consent is being done at this visit or was done at an earlier visit, check the "Done?" box.

Complete SV2 Blood Pressure Form:

After completing the blood pressure form, check the "Done?" box and mark whether the participant is eligible to continue or ineligible.

Collect Blood Specimen:

Mark "Done?" after collecting the blood specimen.

Initiate Local Lab Worksheet

If the results from the UA are not acceptable and the participant will not be retested, check the "ineligible" box under Visit Outcome on the SV2 Visit Form. If the results are acceptable or the participant will be retested, initiate the Local Lab Worksheet, enter the results and details of retesting (if appropriate). The participant is considered eligible for purposes of the SV2 Visit Form. Check the "Done?" box when completed.

Complete Urine Dip Stick:

Mark "Done?" after collecting the urine specimen. Note the glucose and protein urine dipstick results on this form next to the check box and enter dipstick eligibility status.

Food Frequency Questionnaire:

Mark "Done?" after distributing the FFQ and instructing participant on how to complete it.

24-Hour Urine Materials:

Mark "Done?" after distributing 24 Hour Urine Materials and instructing participant on how to collect specimen.

Review Eligibility Questionnaire:

After the participant has completed form #6 review the form, mark "Done?" and the eligibility result.

Weight/Height:

If the participant's weight and height measurements were completed at SV1, mark the "NA" box, **do not** repeat. If not completed at SV1, measure the participant's weight and height per the protocol outlined in MOP chapter 13 and record the height to the nearest .10 cm and weight to the nearest .10 kg. Refer to the SV1 Reference Chart (located in the back of chapter 6 of the MOP) to determine if the participant is BMI eligible. Indicate whether participant is eligible or ineligible based on BMI.

SV2 Visit Outcome::

This section is used to summarize the participant's eligibility status at the end of the visit. A single result is checked, entered into the computer, and subsequently used to generate recruitment monitoring reports. A participant is either eligible to continue on to SV3, ineligible, incomplete, or refused. "Refused" should be used for participants who appear otherwise eligible but refuse to continue in the study. "Incomplete" should **only** be checked as a **final** outcome (if the participant is a no show and you are not able to contact the participant for any further visits). If a participant is excluded due to investigator discretion (i.e., not as part of the regular screening activities for this visit), check "ineligible" and complete the Participant Closeout Form (#18) to record the reason for the exclusion. Place the completed form in the participant's folder.

SV3 Visit Date

If the participant is SV3 eligible, note the scheduled SV3 date.

Reviewed By:

Record the staff ID of the person reviewing the form for completeness and eligibility. This cannot be left blank.

Entered By:

Record the staff ID of the person entering the form. This cannot be left blank.



SV2
ID# _____
Date ___/___/___

Eligibility Questionnaire

NAME: _____
(First) (Last)

Please review and answer all of the questions on this form. Indicate your answers by placing an "x" in the appropriate box. Depending upon your answers, some of the questions may be skipped.

At your next visit, please return this form and also bring in all of the medications you currently take. Bring in not only prescription medications, but also any non-prescription medications (including vitamins and other food supplements) that you take on a regular basis.

Thanks very much for your cooperation.

	Yes	No	Unsure	Comments
1. Have you ever had any of the following?				
a. Stroke -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Heart attack -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
c. Heart failure-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
d. Angina -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
e. Coronary bypass surgery or angioplasty -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
f. Prescription for nitroglycerin tablets for heart pain -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
2. Do you have asthma or another chronic obstructive lung disease, such as chronic bronchitis, emphysema or COPD, etc.? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
<i>If yes, within the past 6 months have you:</i>				
a. Changed breathing medications or increased the dosage of your breathing medication? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Been to the emergency room or been hospitalized for breathing problems?-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
3. Have you ever had cancer?-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
<i>If yes, was it: Active within the past 6 months or treated with radiation or chemotherapy within the past 6 months? -----</i>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____

	Yes	No	Unsure	Comments
4. Have you ever had any of the following stomach or gastrointestinal (GI) conditions?				
a. Chronic GI disorder (such as Inflammatory Bowel Disease, Crohn's Disease, malabsorption)-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Colostomy or history of bowel resection (removal) -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
5. Have you ever had kidney failure, a kidney transplant, or dialysis?-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
6. Do you have any medical conditions or special dietary requirements that might interfere with your ability to eat study foods or attend the clinic for at least one meal a day five days each week? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
7. Do you regularly take any of the following?				
a. Tums -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Rolaids -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
c. Other non-prescription antacid -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
d. Vitamins -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
e. Calcium, magnesium or potassium supplements -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
f. Salt substitutes -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
g. Over the counter products or medications containing sodium (see attached list)-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
h. Metamucil-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
8. <i>If you checked yes next to any of the medicines in question 7, would you be willing to stop taking them during the study?</i> -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
9. Have you taken any medications to control your blood pressure in the past 3 months? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
10. Do you regularly take any of the following medications?				
a. Steroid or corticosteroid pills -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Cholestyramine or colestipol -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
c. Breathing medicines other than inhalers -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
d. Dilantin or phenytoin -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
e. Digitalis -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
f. Lithium -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
g. Insulin -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
h. Diet pills/weight loss medication (see attached list) -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____

ID# _____

	Yes	No	Unsure	Comments
11. Do you regularly take medications for psychological or emotional problems? <i>If yes, have you changed medications or the dosage of the medications you take within the past 6 months?</i>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
12. Do you currently use smokeless tobacco products (e.g. chew, snuff)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
13. Are you currently taking any lipid lowering medications on the attached list. <i>If yes, have you changed your dosage in the past month?</i>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
14. Are you planning to leave the area within the next year?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
15. On average, how many drinks of alcohol do you have in a week? If you don't drink alcohol, enter 0. (one drink = 1 can of beer <u>or</u> 1 glass of wine <u>or</u> 1 shot of liquor)				_____ drinks per week

For women only

16. Are you pregnant, planning to become pregnant or breast feeding?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
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Over-the-counter Drugs and Products Containing Sodium (Question 7, part g)

Baking soda toothpaste
Baking soda for upset stomach
Alka Seltzer
Bisodol powder
Bromo-seltzer

Weight-loss Drugs (Question 10, part h)

This list includes some but not all the over the counter products found in drug stores or health food stores. Please respond yes if you use any product for this purpose.

<u>Generic name</u>	<u>Brand name</u>
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate
	Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim
	Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex
	Mazanor
phendimetrazine	Plegine, X-trozone, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Lipid-lowering drugs that are exclusionary only if the dosage has changed (Question 13)

<u>Generic name</u>	<u>Brand name</u>
lovostatin	Mevacor
pravastatin	Pravachol
simvastatin	Zocor
fluvastatin	Lescol
atorvastatin	Lipitor
nicotinic acid	Niacin, Slo-Niacin, Niacor, Nicobid, Niacinamide, Nicotinamide
gemfibrozil	Lopid
clofibrate	Atromid-S
bizafibrate	Bezalip
dextrothyroxine sodium	Choloxin
probucol	Lorelco

ID# _____

OFFICE USE ONLY - DO NOT GIVE TO PARTICIPANT

List all participant prescription medications, over-the-counter medications, vitamins and other food supplements here:

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____
- 7. _____
- 8. _____

17. Is the participant taking any of the following class of medications? **Yes** **No**

- a. lipid lowering medications (see attached list and Q10b, Q13)----- 1 2
- If yes, are they automatically exclusionary? ----- 1 2
- If no, is the dosage unstable? ----- 1 2
- b. weight loss medications (see attached list)** ----- 1 2
- c. over the counter products not allowed (see attached list)* ----- 1 2
- d. estrogen replacement therapy medications ----- 1 2
- e. any other excluded medications----- 1 2

* If participant is willing to stop medications, code response as "no".

** Participant may stop these medications and be screened for another cohort. If the product is not on the attached list, make a copy of the ingredients and have the clinician review

Clinician signature: _____

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Administration and Coding Instructions for Medical Eligibility Questionnaire

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered..

Eligibility Questionnaire

This questionnaire will begin the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate. The following information is intended to help you assist applicants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician.

Ultimately, all “Unsure” responses must be resolved and coded either “Yes” or “No”.

This form will typically be completed by the participant at home between the SV1 and SV2 visits. When distributing the form to the participant, be sure to remove the last page (“for office use only” section) and store it in the participant’s study chart. The participant should receive page 4, however, which lists specific medications and products that are referred to in three of the questions.

In addition, remind the participant to bring all of his/her medications, including nonprescription medications such as vitamins, allergy preparations, and food supplements, with them to his/her next visit. Finally, review the instructions for completing the form with the participant..

Participant and Visit Identifying Data

ID # - Clearly enter the ID number that has been assigned, and check to be sure the numbers and letters have been copied correctly. If an ID number has not been assigned yet, leave blank and fill in later.

Date - Clearly enter the date when this form **is reviewed with the participant**. If the form is completed at home, the participant should be instructed to leave it blank. It will be filled in at the SV2 visit. As appropriate, use leading zeros for numbers less than 10 (08/14/1994 represents the date of August 14, 1994).

Q1a-f. These questions are intended to screen for cardiovascular disease other than hypertension. An individual with only hypertension should answer No to each question.

If any question is answered Yes, participant is ineligible for the study.

Q2. This question is intended to screen for individuals with obstructive airways disease that is unstable and thus could interfere with the study. A person who is currently being treated for asthma or COPD, or who has been treated for one of these conditions as an adult, should answer Yes. If an individual has a history of childhood asthma only, with no recurrences as an adult, they may answer No and skip to question 3. If Yes or uncertain, proceed to second part of question.

The second part of this question refers to the past six months. It is important to find out if there has been a worsening in the individual's asthma or COPD, and that should guide the answers to these questions. Any change in medication, including an increase in dose, should be noted as a Yes for Q2a. A decrease in dose of a regular medication, if no other changes have been made, is not significant and should be answered as No. A refill does not constitute a change in medication.

An asthmatic or COPD episode that resulted in a visit in the last six months to the emergency room, urgent/immediate care clinic, or an admission to the hospital should be noted as a Yes to Q2b.

If Yes to either Q2a or Q2b, participant is ineligible.

Q3. Answer Yes to initial inquiry if a person has ever had a diagnosis of cancer. If there is no history of cancer, answer No and skip to question 4.

Inactive cancers are those which have (1) been in remission for over six months or were removed over six months ago AND (2) have not resulted in any further treatment within the past six months. Active cancers include those that have been present within the past six months OR which have required treatment within the past six months. For instance, a woman with breast cancer who had the tumor removed eight months ago, but who was treated with chemotherapy that ended four months ago, would answer Yes to the question "was (your cancer) active in the past six months?"

If Yes to the second part of question 3, participant is ineligible.

Q4. This question is intended to ascertain the presence of a chronic GI disorder that could interfere with bowel function (absorption, fluid and mineral balance). Acute infectious disorders are not of significance and need not be noted (answer No if no other problems present).

The “chronic GI disorders” of interest include those listed and any other that could interfere with bowel function. Answer Unsure if a question arises as to the significance of a condition not listed and refer it to a study clinician after the visit.

Surgery that could influence absorption or fluid and mineral balance should be indicated by answering Yes to the question about colostomy or bowel resection. Minor surgery, such as polyp removal, localized removal of a portion of the colon, or hemorrhoidectomy, is not important. An individual with these minor procedures but no other surgery may answer No.

If yes to either Q4a or Q4b, participant is ineligible.

Q5. This question is for documentation purposes only.

Q6. If Uncertain, list condition in comment field and refer to a study clinician after the visit.

If Yes, the participant is ineligible.

Q7-8. If yes to any item in a - h, Q8 should be answered.

If Q8 is answered No, participant is ineligible.

Q9. If the participant has taken blood pressure medications within the past three months, this question should be answered Yes. If this question is answered Yes, further exploration can be done to determine eligibility using the Blood Pressure Medication Follow Up form (# 132). The new eligibility requirements are that participants must be off blood pressure medications at least three months prior to randomization and one month prior to their SV1. Do NOT enter form #6 until eligibility is resolved on form # 132.

Q10. If Yes to any of items a - h, participant is ineligible. If the answer to h (diet pills/weight loss medications) is yes, the participant may be screened for a subsequent cohort if they go off the medication. Participant must be off diet pills/weight loss medications 21 days prior to SV1.

Q11. This question is intended to identify individuals who are taking unstable doses of psychotropics and/or phenothiazines. If Q11 is answered Yes, ask the second part of the question.

If Yes to the second part of Q11, participant is ineligible. Participants should be on a stable dose of psychotropics for 6 months prior to SV1.

Q12. If Yes, participant is ineligible.

Q13. This question is intended to identify individuals who are taking unstable doses of otherwise permissible lipid lowering medications. If Q13 is answered Yes, ask the second part of the question.

If Yes to the second part of Q13, participant is ineligible. Participants should be on a stable dose of otherwise permissible lipid lowering medications for one month prior to SV1

Q14. If Yes, participant is ineligible.

Q15. If participant consumes 15 or more drinks per week, he/she is ineligible. Participants who do not drink alcohol should enter zero.

Q16. This is completed only by women. If Yes, participant is ineligible.

OFFICE USE ONLY SECTION:

This page of the form should not be handed to the participant. They receive only the first four pages.

Medication Information

Participants are required to bring in all of their medications when they return/complete this form. If they fail to do so, a staff person needs to call them at home to obtain the information.

All medications taken should be listed. Please emphasize the importance of including non-prescription medications such as vitamins, food supplements, and allergy preparations in this list. Medications taken sporadically or on an “as needed” basis should also be included.

This review is done to ensure that any exclusionary medications have not been overlooked by the participant. If the participant is taking any medications, or if any box is checked unsure on pages 1-3, a clinician must review the form and sign the bottom of page 5 in order for the participant to continue participating in the study.

Q17. This is included as a prompt to facilitate the review of the medications. If any shaded boxes are checked, the participant is ineligible.

The staff person reviewing the form with the participant should write in his/her staff ID # at the bottom of page 5.

If any of the shaded boxes on this form are checked, the participant is ineligible.

Medications **ALLOWED** during DASH2.

Medical condition or symptom

Aches and pains	Tylenol Aspirin Ibuprofen (but not within 48 hours before BP measurement)
Indigestion	Nephrox Amphogel
Cold/flu/allergy	Tylenol, Extra strength tylenol Chlortrimeton Benadryl Hismanal Seldane Tavist Afrin, otrivin or Ayr nasal spray Robitussin (NOT Robitussin DM) Claritin Beconase nasal spray
Constipation	Correctol Senokot
Infections	Antibiotics
Hormones	Estrogen and progesterone (but don't start these meds or change dose during feeding)
Other	Lactaid Beano

If you want to take any other medication, you must first discuss it with DASH2 study personnel. Many medications can interfere with the DASH2 study, so please ask first!

Estrogen replacement therapy drugs

Generic name	Brand name
conjugated estrogen	Premarin Prempro Milprim PMB
estradiol	Estrace Climara Vivelle
estradiol patch	Estraderm
medroxyprogesterone acetate	Provera
chlorotrianisene	Tace
diethylstilbestrol	diethylstilbestrol
est estrogens and methyltes	Estratest
esterified estrogens	Menest, Estratab
estradiol & testosterone	Depo-Testadiol
estradiol cypionate	Depo-estradiol Estradiol
estradiol val & test	Deladumone
estradiol valerate	Delestrogen Estradiol
estrone	Theelin Estrone
estropipate	Ogen Ortho-Est
estinyl estradiol	Estinyl Feminone
quinestrol	Estrovis

Administration and Coding Instructions for SV3 Blood Pressure Form

USE FOR: Blood pressure screening of potential participants.

PURPOSE: Determine eligibility.

The SV3 Blood Pressure Form must be filled out during each SV3 visit. ID # labels should be printed and placed on all pages of SV3 forms.

Some data collected on the form will indicate immediate exclusion and ineligible should be checked on the SV3 Visit Form (form #08) Additionally, some data may require that participants be referred to site medical staff for consultation and form #23 completed.

Type of Visit - Verify that the correct blood pressure form is being used for this visit by checking the visit code in the upper right corner. It should say "SV3". This is form #07

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further. If an ID # number has not yet been assigned, leave blank and fill in later after the computer assigns an ID #.

BP Date - Clearly enter the date when the blood pressure measurements are obtained, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

1. Preparation for Blood Pressure Measurements

Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP, Chapter 11.

- a. This should be the time the person is seated and the process is begun. Noon is 12:00 pm.
- b. Use the same cuff size as used for this participant for SV1.
- c. Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
- d. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
- e. Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level and record the result. If this value is less than 180, enter 180.
- f. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a one digit field.

2. **Blood Pressure Readings**

Obtain two sitting blood pressure measurements using the random-zero device. Wait at least 30 seconds between each reading. Both readings and zero values are recorded to the nearest **even** number. Subtract the zero value from the corresponding reading with a hand calculator **AFTER BOTH MEASUREMENTS ARE OBTAINED**. Record the resulting corrected value for both of the measurements obtained. If DBP goes to 0 mmHg, use the 4th phase DBP for all BP measurements. Be sure to write in leading zeros if less than 100.

Add the two corrected SBP and DBP measurements (2c and 3c) together and record the sum in item #4. Record the sum of the SV1 and SV2 SBPs and DBPs in item #5. Add the sums of the SV1, SV2 and SV3 SBPs and DBPs (items #4 & #5) and record in item #6. The ineligible ranges are summarized at the bottom of the form. If ineligible, check ineligible on the SV2 visit form (#5). The escape BP levels are also shown at the bottom of the page. If these latter thresholds are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#23) should be filled out. Refer to MOP Chapter 8 for details and complete form #23.

3. **DASH Identification Number of Person Taking and Entering BP**

Collected by - record the Staff ID # of the person performing the blood pressure measurements.
Entered by - record the Staff ID # of the person entering the data in the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Coding Instructions for SV3 Blood Pressure Form

Visit and participant identification data:

ID

ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

BP Date

Check for leading zeros and four digit year. If a date is missing, illegible, or the time frame is not within the cohort's dates, flag the form and resolve with clinic coordinator before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

1. Preparation for Blood Pressure Measurements

- a. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

- b. Check for the correct cuff size. The cuff size should correspond to the circled cuff size in the SV1 cuff size box. Use the same cuff size throughout the study. If the cuff size is not marked or does not correspond to the SV1 cuff size, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- c. The resting pulse should be a two digit field and cannot be missing. If the resting pulse is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- d. The pulse obliteration pressure is a three digit field and cannot be missing. If the (POP) is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- e. Check for correct addition. The random zero peak inflation level should equal the sum of the (POP) plus 60. If the sum is less than 180, write in 180 for the (PIL). If the (PIL) is missing or is outside the normal range, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- f. This is a one digit field. If the BP device # is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

2. First Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the

form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

3 Second Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
4. Sum of SV3 SBPs and DBPs. Check for addition accuracy of $2c + 3c$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
5. Sum of SV1 and SV2 SBPs and DBPs. Enter the value from SV2 Form #04 item #6. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
6. Sum of SV1, SV2 and SV3 SBPs and DBPs. Check for addition accuracy of $4 + 5$. The SBP field is a four digit field and a leading zero should be used if the value is less than four digits. The DBP field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

7. DASH Identification Number of Persons Taking BP and Entering Data

Staff ID number of person performing the blood pressure measurements cannot be left blank. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

Staff ID number of person entering the data cannot be left blank. This value should not be on the form until everything else on the form has been entered. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.



SV3
ID # _____

SV3 Visit Form

	DONE ?	
Check Visit Window	<input type="checkbox"/>	
Informed Consent (if applicable)	<input type="checkbox"/>	
Complete SV3 Blood Pressure Form	<input type="checkbox"/> eligible <input type="checkbox"/> 1 ineligible <input type="checkbox"/> 2
Review Local Lab Worksheet for possible additional specimens	<input type="checkbox"/>	
Collect 24-Hour Urine Specimen	<input type="checkbox"/>	
Collect Fasting Blood Specimen	<input type="checkbox"/>	
Complete Physical Activity Questionnaire	<input type="checkbox"/>	
Review Food Frequency Questionnaire	<input type="checkbox"/>	
Complete Symptoms Form	<input type="checkbox"/>	
Review Study Food Checklist & Menus	<input type="checkbox"/> eligible <input type="checkbox"/> 1 ineligible <input type="checkbox"/> 2
Weight		_____ kg
Visit Outcome:		eligible <input type="checkbox"/> 1 ineligible <input type="checkbox"/> 2 incomplete <input type="checkbox"/> 3 refused <input type="checkbox"/> 4

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Administration and Coding Instructions for SV3 Flow Form

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

SV3 Flow Form

Be sure you have the appropriate form for the visit. Fill out the participant ID number at the top of the form. The participant should take the visit flow form with them to the different stations to be sure all screening tasks are completed. At each station, the staff person needs to check that the task was completed and, if appropriate, the eligibility result is checked.

Visit Window:

Check to make sure visit is at least 7 days after blood pressure measurement during SV2 visit. If not, the SV3 visit cannot be conducted and must be rescheduled to comply with this requirement. No upper limit exists for the SV3 window, except that Run-in cannot begin more than 150 days past SV1.

Check the “Done?” box if at least seven days have expired since SV2.

Informed Consent:

The need for a consent to be done at a specific visit will vary by site. If the consent is being done at this visit or was done at an earlier visit, check the done box.

Blood Pressure:

After completing the blood pressure form, check the “Done?” box and mark whether the participant is eligible to continue or ineligible.

Review Local Lab Worksheet:

Check to see if participant requires additional lab work. If so, draw blood and/or collect urine as needed. If urine is collected, note dipstick protein result and eligibility. Otherwise, check “Done?” box.

Collect 24-hour Urine Specimen:

Check the “Done?” box after collecting the 24-hour urine specimen from the participant. If participant failed to return the sample, or if the sample was inadequate, it must be redone prior to start of run-in. Check “Eligible” under “Eligibility Summary” if participant is otherwise eligible to continue.

Collect Fasting Blood Specimen

The participant should have been instructed ahead of time to fast prior to the visit, and this should be confirmed at the time of the visit. A blood specimen is collected from the fasting participant and is shipped to the central lab to be analyzed for lipids. Check the “Done?” box when completed.

Physical Activity Questionnaire:

Complete the Physical Activity Questionnaire. The computer will compute an initial caloric level to be used to start the run-in feeding. This value will be printed out as part of the participant randomization report after the data has been entered. Check the “Done?” box after administering the Physical Activity Questionnaire.

Food Frequency Questionnaire:

Check the “Done?” box after reviewing the FFQ. If participant failed to return it, check “Eligible” under “Eligibility Summary” if participant is otherwise eligible.

Administer Symptoms Questionnaire

Complete the Symptoms Questionnaire with the participant. Check the “Done?” box on the SV3 Visit Form. If participant answers yes to question 17, the staff person fills out the serious AE form (#12).

Checklist of Study Foods and DASH2 menus:

Check the “Done?” box after reviewing the DASH2 menus and Study Foods Checklist. Also indicate eligibility by checking either the “Eligible” or “Ineligible” boxes.

Weight:

Record the weight measurement to the nearest .1 kg.

Visit Outcome:

This section is used to summarize the participant's eligibility status at the end of the visit. A single result is checked, and subsequently used to generate recruitment monitoring reports. A participant is either eligible to continue on to Run-In, ineligible, incomplete, or refused. "Refused" should be used for participants who appear otherwise eligible but refuse to continue in the study. "Incomplete" should **only** be checked as a **final** outcome (if the participant is a no show and you are not able to contact the participant for any further visits). If a participant is excluded due to investigator discretion (i.e., not as part of the regular screening activities for this visit), check "ineligible" and complete the Participant Closeout Form (#18) to record the reason for the exclusion. Place the completed form in the participant's folder.

Reviewed By:

Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank

Entered By:

Record the staff ID of the person entering the form. This can not be left blank



Instructions for Completing Food Frequency Questionnaire (FFQ)

Overview

The Block Food Frequency Questionnaire (FFQ, Version 1.0) is used to assess usual dietary habits. It is a self-administered assessment of the participant's usual food intake over the past year (12 months). The main purpose is to assess group and individual pre-study nutrient intake and eating habits.

The FFQ is divided into the following sections:

- The front page contains general instructions, a box to record the study ID, and boxes to fill in the participant's sex, age, weight, height, and, if female, breast feeding or not. The participant's sex, age, weight, height, and information about breast feeding is self-report data and will not be entered.
- The second page asks about vitamin supplements.
- The main body of the questionnaire begins on page 3 and ends on page 7. This section asks the participant to indicate the frequency with which he/she consumes selected food items by category and amounts consumed.
- Page 8 contains questions relating to food preparation, fat consumption, and other items used to adjust their reported intake from the main body of the questionnaire.

Frequency choices range from "never or less than once per month" to "every day." Some items have choices for up to five times per day. The portion allows the participant to choose small, medium, and large, with a few items having an "extra large" category. A medium serving size is given as an example on the questionnaire; small is one-half of the medium serving or less, and large is one-and-one-half times the medium serving or more. The nature of the questionnaire is such that many people record eating more fat, vegetables, fruits, and cereal than they actually consume. The summary questions on pages 8 of the questionnaire allow adjustment to a participant's responses to these food categories during analysis.

It is not possible for the FFQ to incorporate all the foods that people eat. The food items on the FFQ were chosen to include the most important foods in most people's diets. The purpose of the FFQ is to get an overview of a participant's usual pattern of food consumption rather than ascertaining his/her exact intake of foods and beverages.

A 20-minute videotape explaining the questionnaire and demonstrating how to administer it is provided along with the questionnaire. The tape is particularly useful in cases where the verbal administration of the FFQ is necessary. All personnel administering the FFQ should review the tape

before interviewing participants, in addition to completing a questionnaire for themselves and completing the training process.

Distribution of the questionnaire

The preparation of ready-to-use copies of the FFQ for all DASH2 participants is the responsibility of the coordinating center (CC). The CC will mail sufficient quantities of the questionnaire to each clinical center to last the entire study. The CC is also be responsible for scanning and analyzing the questionnaires once they are returned by the clinical centers.

The clinical centers are responsible for administering the questionnaires and reviewing them for completeness and accuracy with the participants once they return them, as well as mailing the original questionnaires to the CC for scanning and analysis.

After analysis some questionnaires may require further clarification with the participants. Copies of these questionnaires will be sent to the clinical sites.

Instructions

At SV2 record the participant's study ID on the front page on the first line of the section "For Office Use Only." Write the ID in the boxes and blacken the appropriate bubbles. Make sure that all the information is written in the appropriate space. In addition, paste a participant's study ID label in the upper right hand corner of the first page. Do not burst the questionnaire. Please leave it intact for the coordinating center. If a participant's ID contains one or more asterisks, mark the blank bubble.

Review the questionnaire with the participant as detailed in the instructions below and give the participant the questionnaire. Remind the participant that the form must be filled out with a #2 pencil.

Ask the participant if he/she needs assistance completing the questionnaire. If he/she indicates that he/she needs assistance, set aside time to assist him/her or schedule a time when they can come back and complete the questionnaire with your assistance. If the participant does not need assistance, ask him to complete the FFQ at home and return it at the SV3 visit. Review "How to Fill Out the Food Questionnaire," (Form #103) with the participant and give to participant to use as a guide when filling out the food questionnaire at home.

Completed questionnaires should be returned and reviewed by clinic personnel at SV3. If participants are called to remind them of the SV3 visit, the caller should include a reminder to bring in the questionnaire.

If a participant forgets to return the questionnaire at SV3, give him/her a another copy and ask to complete and return it on or prior to the start of run-in feeding. Mailed questionnaires that are incomplete or those that need clarification should be reviewed with the participant over the telephone.

Introducing the FFQ to the Participant

A brief (2 to 5 minute) introduction for the respondent is extremely important to obtain valid information from the questionnaire. Use the following guidelines for introducing the questionnaire to the participant.

1. Inform the participant that on average, it takes 40 minutes to complete the questionnaire. Suggest that he take a break halfway through the questionnaire and come back to it later if the scoring becomes tedious. Some people become careless in the second half of the questionnaire which can lead to poor estimates of nutrient intake.
2. Inform the participant that the questionnaire asks about his pattern of eating over the last year (12 months). If he objects that he cannot “remember,” explain that he need only approximate his usual pattern (“I eat eggs about twice a week”). The goal is to get an idea of the usual diet during the last 12 months. He doesn’t have to remember how many times he has eggs in the past year, but generally how often he eats eggs per week or month.
3. Point out that she should mark the small, medium, or large portion size for each food. She should check “small” or “large” for those foods that she usually eats substantially less or more than other people of her age and sex.

As an approximation, a “small” portion is about 1/2 the stated “medium,” or less. A “large” portion is about 1 1/2 times as much, or more.

4. Emphasize completeness. The participant should check “Rarely/Never,” not simply skip foods she rarely or never eats. If she does not recognize the food, she should assume she does not eat it. Each line should have an answer. If the food is not consumed, the bubble “never or less than once per month” is still filled in. Each line needs, at least, this bubble filled in.
5. Emphasize care and attention. He should be careful to record the numbers in the correct column. It will make a big difference in the estimate if he marks “hamburgers, once a day” when he means “hamburgers, once a week!” Point out that frequency categories for beverages on page 7 are different than for the previous sections.
6. Inform the participant that some foods such as eggs, milk, breakfast cereal, and bread require special attention. For eggs, explain that if she usually eats only one egg at a meal, she should mark “small.” Similarly, if she usually eat two eggs she should mark “medium.”
7. With milk, clarify that those items refer to milk consumed as a beverage and **not** milk added to breakfast cereal. Alert him to the fact that triple counts may occur for milk and bread and that he needs to be careful not to triple count these items. An example of triple counting would be a respondent who drinks milk three times a day alternating his/her choices between skim, 2%, and whole milk. In filling out the FFQ, the respondent may indicate a frequency of three times a day for each of the three milks, resulting in a total frequency of nine times a day.

Triple or double counting may also occur for breakfast cereals especially if a respondent usually mixes two kinds of cereal. In such cases, they should give each kind of cereal half the total frequency.

8. Demonstrate how to mark the form by reviewing the sample on page 2 under the “fruits and juices” subheading. It may help to go through a few questions so that, the participant is not intimidated by the lengthy, complicated form. She may make notes on a separate piece of paper if she wishes.

Other questions that may come up

1. For those items for which “in season” is printed on the questionnaire (peaches, watermelon, strawberries), **and for those items only**, the program assumes that the response is for the 2-to-3 month period when the food in question is in season. For all other items on the questionnaire, the program assumes that the response is for a 12-month average or pattern.
2. Summary question *a* on page 8 asks about the type of fat usually used in cooking. If the participant checks two, the program will divide up the nutrient values 50-50. **If three are checked, one saturated, and one unsaturated fat is selected.**
3. Summary questions *b* and *c* on page 8 ask broadly, “How many vegetables (or fruits) do you usually eat per day or week?” The purpose of these questions is not to collect information about variability (different kinds of vegetables and fruits) but about how often he eats vegetables. So if the participant never has a vegetable at lunch, but always has a potato and a green vegetable at dinner, his answer to “Not counting potatoes and salad, how many vegetables do you eat per day or per week?” would be “one per day.”

This information will be used by the computer to adjust the participant’s responses to the vegetable questions in the questionnaire as well as the fats used in cooking, fruits and juices, cereals, and milk. Many people, as they progress through the questionnaire, record more vegetables and fruits per day than they eat. This question permits the computer to adjust to more realistic levels, while preserving the proper distribution of vegetables the participant prefers.

4. In the single vitamin question on page 2, the participant is to record the nutrients in the single vitamins he takes, if he takes single vitamins, in addition to multiple. The vitamins in multiple vitamins are not to be recorded under the “Single Vitamin” question.

Procedures for the verbal administration of the questionnaire

Occasionally, a participant will request assistance completing the FFQ. Use the following suggested script and procedures to initiate the verbal interview.

“For the next 45 minutes, I am going to be asking you about the foods you eat.”

“Please tell me how often you usually eat each food, for example twice a week, three times a month, and so forth.”

“For each food, tell me whether you usually eat a small, medium, or large portion.”

“I am interested only in the foods **you** eat (not what your family eats).”

“The foods are listed in categories. I am going to start with fruits and juices.”

“During the past year (12 months) how many times did you eat oranges (or appropriate food)?”

“Was it a small, medium, or large portion?”

The introductory phrase “During the past year, or so, how many times did you...” followed by a probe for portion size should be repeated with every food item until you feel that the respondent understands the flow of the questions. Thereafter, use the introductory statement only when you start a new class of foods.

Reviewing and editing the questionnaire

Editing the FFQ involves a pre-scan edit with the participant, computer scanning of the FFQ, and a post-scan edit. When the questionnaire is returned to the clinical center, stamp the date received at the top of the form next to the ID (the space between the FFQ logo and the instructions). Review the questionnaire in the presence of the respondent using the procedures outlined below:

1. Do a pre-scan edit. Check for omissions, skipped foods, and missing information. This should take about 30 seconds. A few omissions are fairly benign. If many foods are skipped, it creates uncertainty about whether the respondent really never eats those foods, or whether it is a poorly executed questionnaire. Prevent this by careful instruction beforehand that the participant should mark “rarely/never,” not simply skip the food. If there are nevertheless omissions, fill out the blank spaces with the participant’s help.
2. Check for “unusual” frequencies, which suggest that the participant may have not been focusing when filling out the form, for example, orange juice, 3/day, 8 ounces/serving, or coleslaw, a large serving daily.
3. Check the dry cereals to see if the respondent overcounted. If he eats a large serving of each cereal daily, verify this with the participant. Check the three milks and bread products for the same possible error.
4. Hold up the questionnaire to look for patterns. If the questionnaire has mostly one per day, one per week, etc., verify that it is in fact what the participant means. The poor estimates arise when participants mark exclusively one frequency or portion size.
5. If portion sizes are omitted, considerable precision is lost. Avoid this by careful instruction beforehand, and probe after the questionnaire is returned.
6. Seasonal Issues

- a. A few foods on the main food list specify “in season.” What should be coded is the frequency during the three months or when the food item is in season. Do not average over the whole year for those foods. The computer program does this.
 - b. All the rest of the foods are assumed by the computer program to be year-long (12-month) averages. However, occasionally respondents will write in “in season,” e.g., corn “in season.” It is appropriate to use that volunteered information to help the respondent average those over the whole year. Thus, if the respondent indicates “corn once a week in season,” divide the reported frequency by 4 (3 of 12 months), and fill in the bubble that best approximates the new frequency.
7. Multiple marks refer to situations where the participant marks two adjacent items on a single line (e.g., two frequencies are marked for the same food) or more than one response for any question that requires a single response. Clarify multiple mark errors with the participant.
 8. If the participant marks the questionnaire with a pen instead of a #2 pencil ask him to go over the pen marks with the correct pencil lead.
 9. Make sure that any bubbles erased by the participant have been completely erased. Even a faint mark in the bubble will be detected by the scanner.

Mailing procedures

After the questionnaires have been checked for completeness, photocopy the originals, retain the copies, and mail the originals to the coordinating center. It is important to do this as soon as possible, so the coordinating center has time to scan the forms, run edit checks, and refer problem forms to the clinical site before the participants begin run-in. Wait until most of the questionnaires for a cohort are collected, but do not hold forms for all participants in the cohort.

To mail the forms, print and fill out the FFQ Shipping Log (Form #36) from the DASH2 file server. (Procedure for printing from file service is in development). To fill out the form:

1. Circle the appropriate study center.
2. Fill in the number of FFQs being shipped in the “Quantity Sent” column.
3. Fill in the date shipped in the area specified.
4. Check the method of shipment.
5. In the comments, write the ID number of the FFQ being shipped.

Make a copy of the completed Form #36 for your records and include the original with the FFQs being shipped. Send an electronic message via the file server to the attention of Lauren Haworth, indicating the date the shipment was sent and how many questionnaires were included.

When the coordinating center receives the shipment, the bottom of Form #36 will be completed, and a copy will be returned to the clinical center either by FAX or regular mail. If there were any problems with the shipment, that will be indicated in the comments section at the bottom of the form.

Post-coding error report and interview with participants

Following scanning of the FFQ at the coordinating center, an error report may be generated. The most common errors and the action you should take to resolve them are outlined below.

Common Errors on FFQ

Type of error	Possible cause of error and action to resolve error
Total breads consumed questionably high.	This includes the first four items under the “Breads, Snacks, and Spreads” category. One potential cause for over-counting could be a subject who alternates between white and wheat bread, and reports that they consume each type on a daily basis. Please clarify with the subject whether they actually consume both types daily, or whether they consume one bread per day, alternating types.
Total milks consumed questionably high.	This includes whole, 2%, and skim milks from the “beverages” section as well as milk/cream in coffee/tea. Milks may be double-counted by participants who alternate between types of milk and report consuming each type every day. Another source of double-counting could be a subject who reports milk in coffee/tea twice (in the dairy products section and the beverages section). Please clarify with the subject.
Total cereals consumed questionably high.	This includes the three cold cereal items from the breakfast foods section. Cereals may be double-counted by participants who alternate between brands of cereal and report consuming each type every day. Please clarify with the subject.
Too few foods eaten daily	When the subject’s responses are summed, the result is too few foods per day. This could be the result of a participant marking the wrong bubble (e.g. weekly instead of daily). You will have to go back to the subject, point out that the total foods per day seems low, and clarify their answers.

Type of error	Possible cause of error and action to resolve error
Too many foods eaten daily	When the subject’s responses are summed, the result is too many foods per day. This could be the result of the frequency being written in the wrong column (daily instead of weekly, for example). Otherwise, you will have to go back to the subject, point out that the total

	foods per day seems high, and clarify their answers.
Too many foods coded or imputed as small/medium/large serving size	This is probably the result of a subject rushing through the form without thinking carefully about each item. Ask the subject to think more carefully about each item and clarify their answers.
Error in skip pattern on vitamin questions	The answer to the vitamin summary question at the top of page 2 is inconsistent with the answers to the detail questions. Confirm vitamin intake with the participant.
Too many food items skipped	Clarify with the subject whether the items were accidentally skipped, or whether they were foods rarely/never consumed. Update the form with the correct response.

FFQ error report

If one of the completed forms has a problem that cannot be corrected without speaking with the participant, the CC will send a fax or e-mail message to the site contact person, outlining the problem and explaining what needs to be clarified.

Post-coding interview with participants

To correct the errors it will be necessary for the clinical site to contact the participant. In your conversation with the participant, it is essential that you clarify responses to the items in error by asking non-leading questions.

Use the following examples of non-leading questions as a guide:

Missing Food Items or Portion Size

- “There are several blank items on this page of the Food Frequency Questionnaire. It is important that each food item have a response. Please look at the foods you didn’t mark. Thinking back over the past year, please mark how often you ate these foods.”

Same Frequency Marked for a Substantial Number of Foods

- “Please look at the foods on this page of the Food Frequency Questionnaire again. Think about ‘how often’ you ate these foods over the past year. Be sure your answer shows how often you ate each food.”

Same Portion Marked for a Substantial Number of Foods

- “Please look at the ‘Medium Serving Size’ column for the foods on this page. Think about how it compares to the amount you ate. If you ate this amount, your serving size is ‘medium.’ If you ate half this amount (or less) your serving size is ‘small,’ if you ate 1 and 1/2 times (or more) than this amount, your serving size is ‘large.’ Please review the amounts you marked again.”

Multiple Marks

- “Each item on this page can have only one response in the ‘how often’ section. You have marked more than one box for this item. Please read this line again and choose one response.”

Sending corrections to the CC

Based on the participant’s answers, correct your copy of the FFQ as needed. Fax the corrected FFQ to Lauren Haworth at the CC. If no corrections are needed (there was no error), please notify the CC.



Physical Activity Questionnaire

Now I would like to know about your physical activity during a **typical week**. But first, let me ask you about your work and sleep habits.

1. On average, how many days do you work? _____ workdays
2. On average, how many hours do you sleep during each worknight (worknight would be the night before you go to work. For instance Sunday → Thursday for a typical workweek.) Record to nearest quarter-hour. _____.____ hours/night
3. On average, how many hours do you sleep each night before your days off (that is ___ and ___ nights)? _____.____ hours/night

Now I am going to ask you about your physical activity during a typical week; that is, your workdays and days off in a typical week. We are not going to talk about light activities, such as slow walking, light housework, or nonstrenuous sports such as bowling, archery, or softball. Please look at this Activity List, which shows some examples of what we consider moderate, hard, and very hard activities. (Interviewer: Hand subject list and allow time for the subject to read it over.) People engage in many other types of activities, and if you are not sure where one of your activities fits, please ask me about it.

4. First, let's consider moderate activities. During your workdays in a typical week, what activities do you do and how many total hours do you spend doing these moderate activities or others like them? Please tell me to the nearest half-hour. _____.____ hours/week
5. During your days off in a typical week, how many total hours do you spend on moderate activities and what do you do? Please tell me to the nearest half hour. (Probe: Can you think of any other sport, job, or household activities that would fit into this category?) _____.____ hours/week

6. Now let's look at hard activities. During your workdays in a typical week, what activities do you do and how many total hours do you spend doing these hard activities or others like them? Please tell me to the nearest half-hour. __ __. __ hours/week
7. During your days off, how many total hours do you spend on hard activities and what do you do? Please tell me to the nearest half-hour. (Probe: Can you think of any other sport, job, or household activities that would fit into this category?) __ __. __ hours/week
8. Now let's look at very hard activities. During your workdays in a typical week, what activities do you do and how many total hours do you spend doing these very hard activities or others like them? Please tell me to the nearest half-hour. __ __. __ hours/week
9. During your days off, how many total hours do you spend on very hard activities and what do you do? Please tell me to the nearest half-hour. (Probe: Can you think of any other sport, job or household activities that would fit into this category?) __ __. __ hours/week

Now I would like to ask you some questions about your activities in the **past month**.

10. For the past month, about how often have you taken part in moderate physical activity (such as golf, light sports or physical exercise, gardening, taking long walks)?
- More than 4 times a week 1
 2-4 times a week 2
 About once a week 3
 2-3 times over the month 4
 Rarely or never 5
11. For the past month, about how often have you taken part in hard or very hard physical activity (such as jogging, running, swimming, aerobics, strenuous sports)?
- More than 4 times a week 1
 2-4 times a week 2
 About once a week 3
 2-3 times over the month 4
 Rarely or never 5
12. How does the amount of activity you have done for the past month compare with your usual physical activity level?
- More active 1
 Less active 2
 About the same 3

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Administration and Coding Instructions for the Physical Activity Questionnaire

Interviewing Technique

Your technique should limit bias, and you should try to keep the interview from becoming tedious. It may be difficult for participants to remember their past week's activity. Some may not try very hard, and others may get bogged down in details. You should strive to achieve a happy medium. You should control the pace of the interview; extraneous talk should be avoided. If participants are going into excessive detail, you should remind them that they need not account for every minute but that an average or estimate is expected. You might ask, "How much time in general?"

It is important to remember that most of the participants you see will spend the vast majority of their waking hours in light activity. Many tiring and unpleasant household or occupational tasks do not have a very high energy cost. Clerks in a store, for example, may be on their feet all day and may feel fatigued, but the energy cost is in the light category. An exception to this example would be time spent in stocking shelves, which probably would be moderate activity. Also, for most occupational tasks that require at least moderate energy expenditure, it is important to accurately determine the time spent in the activity. In the stock clerking example, even though a person might do that activity for an entire shift, it probably would not equal 8 hours. You should try to subtract time spent on lunch, breaks, and the like.

Interviewing Suggestions

You will be handing people lists of moderate, hard, and very hard activities (Activity List). We have found it easier to give them all three lists to look at once, before we ask them any questions about their activity level in the past 7 days.

Explain the following things before you hand them the list of activities (otherwise, they may not attend to what you are saying because they'll be too busy looking at the list:)

1. They are to think of the past 7 days. Stress that this is a recall of actual activities for the past week, not a history of what they usually do.

2. Workdays and days off will be treated separately. You may even help them figure out which days to include. For example, Monday through Thursday this week and Friday of last week might comprise the past 5 workdays. The

exception to this is for homemakers, retired persons and people not working. Their activities will probably be the same across the week. Questions 1, 2, 4, 6, and 8 should be coded "0" because these questions refer to work days.

3. Workdays include evenings as well.
4. We are not considering light activities, such as desk work, standing, slow walking, light housework, softball, archery, bowling, and the like.
5. They should also consider types of activities that are not included on the lists but are similar in strenuousness.

Mention the following things before you ask them questions about their activity level:

1. You will ask them questions about each category of activities separately (because people tend to give stream-of-consciousness reports of their week).
2. You may ask them if the amount of activity they report is more, less or about the same as usual (because people tend to be defensive, exaggerate the numbers, or offer rationales for low activity levels). This may enable the participants to give more accurate estimates of their activity level. However record the actual amount, not the usual amount.

While they are reporting the frequency with which they engage in various activities, be aware of the following:

1. Don't let them sidetrack you.
2. You may wish to ask them about their days off first. This enables them to practice giving you the information you need in a smaller block of time.
3. Check if the amount of time they are reporting is per weekend, per week, or per day. Someone may say, for example, "I did one hour of digging this past weekend," when what is really meant is, "I did one hour of digging each of the two days this past weekend." Except for questions 2 and 3, the remaining questions refer to total hours, not hours per day.
4. Some people have trouble recalling or pinpointing the moderate to very hard activities they have engaged in, in the past 7 days. In such cases, try to cue them by asking, for example, "how about any housework that made you work up a sweat; do you take stairs at work; do you walk briskly to work; did you participate in any sports, any vigorous family activities; did you do any vigorous home repair or gardening?"
5. Some people have trouble quantifying the amount of time they spent doing moderate, hard, or very hard activities. In such cases, break down all of their activities into specific events and ask them how long they did each activity. Then sum up the amount of time relevant to each category. Finally, ask them if they agree with your calculations.

6. If you are unsure of the strenuousness of an activity that they may have participated in, ask them to describe the physical effort involved - for example, what does the activity entail, what other activity is it comparable to, do they work up a sweat? We have found that walking and running provide good frames of reference for classifying other activities. Everyone should be familiar with the relative intensity of brisk walking, which is at about the midpoint of the moderate activity category. Therefore, if some other activity subjectively seems to be about as strenuous to the individual as walking briskly, then the activity should be coded as moderate. Running at any speed falls into the very hard category. If some activity seems about as strenuous to the individual as running, classify the activity as very hard. If the activity in question seems harder than walking but not as strenuous as running, place it in the hard category. Be careful to be certain that the activity in questions is performed continuously for at least 5 minutes. Some activities may be quite strenuous, but if they are performed intermittently, the overall energy cost may place them in the moderate category. A good example of this is weight lifting.
7. If the last week was totally atypical - for example, in the hospital or in bed, or involving a family crisis, a work crisis, or travel - it is permissible to go to the previous week for the survey. Do not take this action lightly, use it only in unusual circumstances.
8. Be sure that the time reported for an activity was actually spent doing the activity. Being at the pool for 2 hours but only swimming for 15 minutes, for example, should be recorded as 15 minutes, not 2 hours. Working in the garden all day Saturday (8 hours) should mean actually working for 8 hours. Do not count the time on breaks, rest periods, meals, and the like.
9. For most activities, the rate at which they are performed can make a huge difference in the energy cost. It is possible to play singles tennis, for example, so as not to move around very much and not spend much energy. The rate of digging, for another example, could make the MET cost range from 3 to 12. Try to get some indication of how hard they are working at a particular task.
10. NOTE: Please be certain to review the accompanying Physical Activity Log with all participants so that they can use this to prepare for filling out the Physical Activity Questionnaire.

Activity List

Moderate Activities (similar to brisk walking)

Occupational Tasks:

1. Delivering mail or patrolling on foot
2. House painting
3. Truck driving (making deliveries-lifting and carrying light objects)

Household Activities:

1. Raking the lawn
2. Sweeping and mopping
3. Mowing the lawn with a power mower
4. Cleaning windows

Sports Activities (actual playing time):

1. Volleyball
2. Ping Pong
3. Brisk walking for pleasure or to work (3 mph or 20 min/mile)
4. Golf-walking and pulling or carrying clubs
5. Calisthenics exercise

Hard Activities (between brisk walking and jogging/running)

Occupational Tasks:

1. Heavy carpentry
2. Construction work-doing physical labor

Household Activities:

1. Scrubbing floors
2. Shoveling snow

Sports, Activities (actual playing time):

1. Doubles tennis
2. Disco, Square, or Folk dancing

Very Hard Activities (similar to jogging/running)

Occupational Task:

1. Very hard physical labor-digging or chopping with heavy tools
2. Carrying heavy loads, such as bricks or lumber

Sports Activities (actual playing time):

1. Jogging or swimming
2. Singles tennis
3. Racquetball
4. Soccer

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.

- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Physical Activity Questionnaire

Visit and participant identification data:

ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

1. The response to Question 1 must be between 0 and 7. Homemakers, retired persons and people not working should be coded as a 0. If a 0 is coded for question 1, questions 2, 4, 6 and 8 should also be coded a 0.
2. Question 2 must reflect the average hours of nightly sleep per worknight. Record to the nearest quarter of an hour (i.e. 07.25). If the participant does not work outside the home, this should be coded a 0.
3. Question 3 must reflect the average hours of nightly sleep each night before their days off. Record to the nearest quarter of an hour (i.e. 07.25). If the participant does not work outside the home, this must reflect the average hours of nightly sleep.
4. Enter to the nearest half of an hour. If the participant does not work outside the home, this should be coded a 0.
5. Enter to the nearest half of an hour.
6. Enter to the nearest half of an hour. If the participant does not work outside the home, this should be coded a 0.
7. Enter to the nearest half of an hour.
8. Enter to the nearest half of an hour. If the participant does not work outside the home, this should be coded a 0.

9. Enter to the nearest half of an hour .
10. Do not leave blank. Answer must be between 1 and 5.
11. Do not leave blank. Answer must be between 1 and 5.
12. Do not leave blank. Answer must be between 1 and 3.



ID# _____

Date ____ / ____ / ____

Visit (check one):

SV3 4

RI 5

IFP/I 6

IFP/II 7

IFP/III 8

SYMPTOMS FORM

Below is a list of problems and complaints people sometimes experience. For each item, check the box that best describes how bothersome the problem was for you **during the past month**.

Be sure to check one box on each line. If you did not have the problem, please check the box under "symptom did not occur". If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = symptom did not interfere with usual activities

Moderate = symptom interfered somewhat with usual activities

Severe = symptom was so bothersome that usual activities could not be performed

<u>Symptom</u>	Symptom		Symptom Occurred and was:		
	<u>Did not Occur</u>	<u>Occur</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>
1. Fatigue or low energy level	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
2. Excessive thirst	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
3. Poor appetite	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
4. Lightheadedness when standing up	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
5. Change in taste	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
6. Stuffy nose	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
7. Dry mouth	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
8. Itchy skin or hives	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
9. Wheezing	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
10. Diarrhea / loose stools	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
11. Constipation	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
12. Bloating / uncomfortably full	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
13. Nausea or upset stomach	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4
14. Headache	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 4

15. Overall, during the past month, I felt (check one)

- much worse than usual 1
- worse than usual 2
- the same as usual 3
- better than usual 4
- much better than usual 5

16. Other symptoms (specify): _____

17. In the past month, have you had any illness that you considered serious or significant (for example, an illness that led to a doctor's visit, new medication, diagnostic tests or hospitalization?)

- | | |
|----------------------------|----------------------------|
| Yes | No |
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

If participant answered yes to question 17, please complete form #12.

Clinician signature _____ Date _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Symptoms Form Administration and Coding Instructions

This form is designed to identify individuals who have symptoms that could either interfere with their further participation in the study or be a result of a food borne illness. Any positive responses should be immediately brought to the attention of a staff clinician, who takes whatever action seems appropriate and also signs the form.

Have each participant complete this form at SV3, during Run-In week 2; and at the end (days 24-30) of each of the 3 Intervention feeding periods. Mark the appropriate box in the upper right corner of the form. A clinic staff member should review the form for completeness write their ID number after "Reviewed by Staff ID." The Staff ID # of the person entering the data should be added to the form at the time the data is entered in the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made, by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g. RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Symptoms Coding Instructions

ID #: ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date: Enter the date when the form was completed, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four-digit year.

Type of Visit: Check whether the appropriate box has been checked to designate when form was completed (at SV3, during Run-in, Intervention feeding period 1, Intervention feeding period 2, or Intervention feeding period 3). Only one box should be marked.

Items 1-14. Symptoms:

Check to make sure only one response was marked for each symptom.

Item 15. Overall, during the past month, I felt:

Check to be sure only one response was marked.

Item 16. Other Symptoms:

If there is a response, make sure that it is legible. Review any other symptoms with clinician.

Item 17. Significant illness in past month:

If response is YES, Serious AE (form #12) must be completed.

Clinician Signature:

Must be filled in if responses to Items 1-14 include 2, 3 or 4

Must be filled in if response to Item 15 is 1 or 2

Must be filled in if there is a response to Item 16

Must be filled in if response to Item 17 is Yes

Date: Date reviewed by Clinician

Reviewed by: Record the Staff ID # of the person reviewing the form.

Entered by: Record the Staff ID # of the person entering the data in the computer.



ID# _____
 AE Date ____ / ____ / ____
 Visit (check current visit or last completed):

- PSV 1
- SV1 2
- SV2 3
- SV3 4
- RI 5
- IFP/I 6
- IFP/II 7
- IFP/III 8

Adverse Events

This form should be filled out if item 17 on Symptoms form (form #11) is answered "yes."

Describe event (Include as much detail as possible. Indicate whether the event is ongoing or resolved.)

Event Summary: (to be completed by Clinician)	DASH2 related event?	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
	Cardiovascular or gastrointestinal event?	Yes <input type="checkbox"/>
		No <input type="checkbox"/>

Event Outcome:	*Exclude from study?	Yes <input type="checkbox"/>
		No <input type="checkbox"/>

Reviewed by: _____
Clinician signature Date

* If excluded prior to randomization, complete form #18. If excluded after randomization, complete form #22.

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Adverse Event Administering/Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 5) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

- ID #** Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant’s last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.
- AE Date** Record the date of the adverse event. If it is an ongoing event, record the start date.
- Visit** Check the visit the AE corresponds to. If at a particular visit, check the current visit. If between visits, check the last completed visit.
- Describe** Describe the event in detail. Be sure to include whether it is an ongoing event or if it has been resolved.
- DASH2 related**
 This section should be completed by the clinician at your site. Check “yes” if this event is related to the study.
- Cardiovascular or gastrointestinal event**
 This section should be completed by the clinician at your site. Check “yes” if this is a cardiovascular or gastrointestinal event.
- Outcome** Check “yes” if participant should be excluded from the study due to the adverse event. Check “no” if the participant is okay to continue in the study.

Reviewed by (clinician signature and date)

The clinician at your site must sign and date the AE form after reviewing.

Reviewed by: Record the Staff ID # of the person reviewing the form.

Entered by: Record the Staff ID # of the person entering the data in the computer.

Note: If the participant is excluded prior to randomization, complete form #18. If they are excluded after randomization, complete form #22.

Please FAX or send a copy of each AE form to Reesa Laws at the CC.



during month prior to Run-in

ID# _____

Date ____ / ____ / ____

Eligibility Review

NAME: _____

(First)

(Last)

Please review and answer all of the questions on this form. We are aware that you have answered these questions within the last several months. However, we need updated answers to these questions before you begin run-in feeding.

Thanks very much for your cooperation.

	Yes	No	Unsure	Comments
1. Have you ever had any of the following?				
a. Stroke -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Heart attack -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
c. Heart failure -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
d. Angina -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
e. Coronary bypass surgery or angioplasty -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
f. Prescription for nitroglycerin tablets for heart pain -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
2. Do you have asthma or another chronic obstructive lung disease, such as chronic bronchitis, emphysema or COPD, etc.? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
<i>If yes, within the past 6 months have you:</i>				
a. Changed breathing medications or increased the dosage of your breathing medication? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Been to the emergency room or been hospitalized for breathing problems? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
3. Have you ever had cancer? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
<i>If yes, was it: Active within the past 6 months or treated with radiation or chemotherapy within the past 6 months? -----</i>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____

	Yes	No	Unsure	Comments
4. Have you ever had any of the following stomach or gastrointestinal (GI) conditions?				
a. Chronic GI disorder (such as Inflammatory Bowel Disease, Crohn's Disease, malabsorption)-----	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Colostomy or history of bowel resection (removal) -----	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
5. Have you ever had kidney failure, a kidney transplant, or dialysis? -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
6. Do you have any medical conditions or special dietary requirements that might interfere with your ability to eat study foods or attend the clinic for at least one meal a day five days each week? -----	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
7. Do you regularly take any of the following?				
a. Tums -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
b. Rolaids -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
c. Other non-prescription antacid -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
d. Vitamins -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
e. Calcium, magnesium or potassium supplements -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
f. Salt substitutes -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
g. Over the counter products or medications containing sodium (see attached list)-----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
h. Metamucil -----	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____
8. <i>If you checked yes next to any of the medicines in question 7, would you be willing to stop taking them during the study?</i> -----	<input type="checkbox"/> 1	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 3	_____
9. Have you taken any medications to control your blood pressure in the past 3 months? -----	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	_____

Yes No Unsure Comments

10. Do you regularly take any of the following medications?

- a. Steroid or corticosteroid pills ----- 1 2 3 _____
- b. Cholestyramine or colestipol ----- 1 2 3 _____
- c. Breathing medicines other than inhalers ----- 1 2 3 _____
- d. Dilantin or phenytoin ----- 1 2 3 _____
- e. Digitalis----- 1 2 3 _____
- f. Lithium ----- 1 2 3 _____
- g. Insulin ----- 1 2 3 _____
- h. Diet pills/weight loss medication
(see attached list)----- 1 2 3 _____

11. Do you regularly take medications for psychological or emotional problems?

1 2 3 _____

If yes, have you changed medications or the dosage of the medications you take within the past 6 months?

1 2 3 _____

12. Do you currently use smokeless tobacco products (e.g. chew, snuff)?

1 2 3 _____

13. Are you currently taking any lipid lowering medications? (see attached list)

1 2 3 _____

If yes, have you changed your dosage in the past month?

1 2 3 _____

14. Are you planning to leave the area within the next year?

1 2 3 _____

15. On average, how many drinks of alcohol do you have in a week?

If you don't drink alcohol, enter 0.

(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)

_____ drinks per week

For women only

16. Are you pregnant, planning to become pregnant or breast feeding?

1 2 3 _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Over-the-Counter Drugs and Products Containing Sodium (Question 7, part g)

Baking soda toothpaste
Baking soda for upset stomach
Alka Seltzer
Bisodol powder
Bromo-seltzer

Weight-loss Drugs (Question 10, part h)

This list includes some but not all the over the counter products found in drug stores or health food stores. Please respond yes if you use any product for this purpose.

<u>Generic name</u>	<u>Brand name</u>
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate
	Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex Mazanor
phendimetrazine	Plegine, X-trozone, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Lipid-lowering drugs that are exclusionary only if the dosage has changed(Question 13)

<u>Generic name</u>	<u>Brand name</u>
lovostatin	Mevacor
pravastatin	Pravachol
simvastatin	Zocor
fluvastatin	Lescol
atorvastatin	Lipitor
nicotinic acid	Niacin, Slo-Niacin, Niacor, Nicobid, Niacinamide, Nicotinamide
gemfibrozil	Lopid
clofibrate	Atromid-S
bizafibrate	Bezalip
dextrothyroxine sodium	Choloxin
probucol	Lorelco

Administration and Coding Instructions for Medical Eligibility Review

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered..

Eligibility Review

This review continues the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate. The following information is intended to help you assist applicants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician. This review is mainly intended to catch any new medications that participants may be taking and also follow up on any medications/supplements that participants had agreed to stop taking.

Ultimately, all “Unsure” responses must be resolved and coded either “Yes” or “No”.

This form will be completed by the participant during the month prior to Run-in if more than 1 month has elapsed since the eligibility questionnaire (form #6) was completed_.

Participant and Visit Identifying Data

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be

replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date - Clearly enter the date when this form **is reviewed with the participant**. As appropriate, use leading zeros for numbers less than 10 (08/14/1994 represents the date of August 14, 1994).

Q1a-f. These questions are intended to screen for cardiovascular disease other than hypertension. An individual with only hypertension should answer No to each question.

If any question is answered Yes, participant is ineligible for the study.

Q2. This question is intended to screen for individuals with obstructive airways disease that is unstable and thus could interfere with the study. A person who is currently being treated for asthma or COPD, or who has been treated for one of these conditions as an adult, should answer Yes. If an individual has a history of childhood asthma only, with no recurrences as an adult, they may answer No and skip to question 3. If Yes or uncertain, proceed to second part of question.

The second part of this question refers to the past six months. It is important to find out if there has been a worsening in the individual's asthma or COPD, and that should guide the answers to these questions. Any change in medication, including an increase in dose, should be noted as a Yes for Q2a. A decrease in dose of a regular medication, if no other changes have been made, is not significant and should be answered as No. A refill does not constitute a change in medication.

An asthmatic or COPD episode that resulted in a visit in the last six months to the emergency room, urgent/immediate care clinic, or an admission to the hospital should be noted as a Yes to Q2b.

If Yes to either Q2a or Q2b, participant is ineligible.

Q3. Answer Yes to initial inquiry if a person has ever had a diagnosis of cancer. If there is no history of cancer, answer No and skip to question 4.

Inactive cancers are those which have (1) been in remission for over six months or were removed over six months ago AND (2) have not resulted in any further treatment within the past six months. Active cancers include those that have been present within the past six months OR which have required treatment within the past six months. For instance, a woman with breast cancer who had the tumor removed eight months ago, but who was treated with chemotherapy that ended four months ago, would answer Yes to the question "was (your cancer) active in the past six months?"

If Yes to the second part of question 3, participant is ineligible.

- Q4. This question is intended to ascertain the presence of a chronic GI disorder that could interfere with bowel function (absorption, fluid and mineral balance). Acute infectious disorders are not of significance and need not be noted (answer No if no other problems present).

The “chronic GI disorders” of interest include those listed and any other that could interfere with bowel function. Answer Unsure if a question arises as to the significance of a condition not listed and refer it to a study clinician after the visit.

Surgery that could influence absorption or fluid and mineral balance should be indicated by answering Yes to the question about colostomy or bowel resection. Minor surgery, such as polyp removal, localized removal of a portion of the colon, or hemorrhoidectomy, is not important. An individual with these minor procedures but no other surgery may answer No.

If yes to either Q4a or Q4b, participant is ineligible.

- Q5. This question is for documentation purposes only.
- Q6. If Uncertain, list condition in comment field and refer to a study clinician after the visit.

If Yes, the participant is ineligible.

- Q7-8. If yes to any item in a - h, Q8 should be answered.

If Q8 is answered No, participant is ineligible.

- Q9. If the participant has taken blood pressure medications within the past three months, this question should be answered Yes. If so, the participant is ineligible to continue. Note: participants should be off BP medications for 3 months prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

- Q10. If Yes to any of items a - h, participant is ineligible. If the answer to h (diet pills/weight loss medications), the participant may be screened for a subsequent cohort if they go off the medication. Note: participants should be off weight loss medications 21 days prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

- Q11. This question is intended to identify individuals who are taking unstable doses of psychotropics and/or phenothiazines. If Q11 is answered Yes, ask the second part of the question. Note: participants should have been on a stable dose of psychotropics for 6 months prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

If Yes to the second part of Q11, participant is ineligible.

- Q12. If Yes, participant is ineligible.

Q13. This question is intended to identify individuals who are taking unstable doses of otherwise permissible lipid lowering medications. If Q13 is answered Yes, ask the second part of the question. Note: participants should have been on a stable dose of otherwise permissible lipid lowering medications for one month prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

If Yes to the second part of Q13, participant is ineligible.

Q14. If Yes, participant is ineligible.

Q15. If participant consumes 15 or more drinks per week, he/she is ineligible. Participants who do not drink alcohol should enter zero.

Q16. This is completed only by women. If Yes, participant is ineligible.

Reviewed by - Record the Staff ID # of the person reviewing the form.

Entered by. - Record the Staff ID # of the person entering the data in the computer.

If any of the shaded boxes on this form are checked, the participant is ineligible.



ID # _____

Local Lab Worksheet

	eligible	ineligible
Blood sugar..... <input type="checkbox"/> Repeat	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Hematocrit..... <input type="checkbox"/> Repeat	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Serum Ca..... <input type="checkbox"/> Repeat	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Serum K..... <input type="checkbox"/> Repeat	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Transaminase..... <input type="checkbox"/> Repeat	<input type="checkbox"/> 1	<input type="checkbox"/> 2

Renal insufficiency: Follow the steps below. When you reach an outcome of ELIGIBLE or INELIGIBLE in one of the steps, circle it, and then check the appropriate box below.

Males

1. If serum creatinine \leq 1.5 mg/dl then **ELIGIBLE**, Otherwise go to step 2

2. If clinician chooses to reject participant at this point, then **INELIGIBLE**, Otherwise go to step 3

3. Compute GFR
 Weight in kg = _____ A
 140 - age in years = _____ B
 72 * serum creatinine in mg/dl = _____ C
 GFR = (A * B) / C = _____
 If GFR < 60, then participant is **INELIGIBLE**
 Otherwise participant is **ELIGIBLE**

Females

1. If serum creatinine \leq 1.2 mg/dl then **ELIGIBLE**, Otherwise go to step 2

2. If clinician chooses to reject participant at this point, then **INELIGIBLE**, Otherwise go to step 3

3. Compute GFR
 Weight in kg = _____ A
 140 - age in years = _____ B
 72 * serum creatinine in mg/dl = _____ C
 GFR = ((A * B) / C) * 0.85 = _____
 If GFR < 60, then participant is **INELIGIBLE**
 Otherwise participant is **ELIGIBLE**

	eligible	ineligible
Renal insufficiency eligibility.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2

Lipid eligibility: Follow the steps below. When you reach an outcome of **ELIGIBLE** or **INELIGIBLE** in one of the steps, circle it, and then check the appropriate box below.

1. If total cholesterol \leq 260 mg/dl then **ELIGIBLE**. Otherwise, you have the option of obtaining an LDL and continuing with step 2. Chose not to obtain an LDL. Participant is **INELIGIBLE**.

2. If LDL \leq 160 then **ELIGIBLE**, Otherwise go to step 3

3. LDL $>$ 220 then **INELIGIBLE**, Otherwise go to step 4

Males

4. If age $>$ 35 and LDL $>$ 190 then **INELIGIBLE**, Otherwise go to step 5

5. Calculate risk factors:

- \geq 45 years old
- Family hx of CHD (MI or sudden death in a first-degree male relative $<$ 55 or a female $<$ 65)
- Current smoker
- BP $>$ 140/90 mm Hg
- HDL $<$ 35 mg/dl
- Diabetes mellitus

TOTAL POSITIVE FACTORS: _____

Negative risk factor: If HDL \geq 60 mg/dl then subtract 1 from positive risk factors to get

TOTAL RISK FACTORS: _____

If TOTAL is 2+, then participant is **INELIGIBLE**
Otherwise participant is **ELIGIBLE**

Females

4. If post-menopausal and LDL $>$ 190 then **INELIGIBLE**, Otherwise go to step 5

5. Calculate risk factors:

- \geq 55 years old and no estrogen replacement
- Not menstruating and no estrogen replacement
- Family hx of CHD (MI or sudden death in a first-degree male relative $<$ 55 or a female $<$ 65)
- Current smoker
- BP $>$ 140/90 mm Hg
- HDL $<$ 35 mg/dl
- Diabetes mellitus

TOTAL POSITIVE FACTORS: _____

Negative risk factor: If HDL \geq 60 mg/dl then subtract 1 from positive risk factors to get

TOTAL RISK FACTORS: _____

If TOTAL is 2+, then participant is **INELIGIBLE**
Otherwise participant is **ELIGIBLE**

eligible

ineligible

Lipid eligibility 1

2

Overall local lab eligibility 1

2

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Coding Instructions for Local Lab Worksheet

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Local Lab Worksheet

Participant identification data

ID #: Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Blood Sugar: Enter either eligible or ineligible. If the test is being repeated and remains unresolved, check "repeat". (Repeat will not be entered). If a repeat test was done, the overall eligibility status should be coded before entry.

Hematocrit: Enter either eligible or ineligible. If the test is being repeated and remains unresolved, check "repeat". (Repeat will not be entered). If a repeat test was done, the overall eligibility status should be coded before entry.

Serum Ca: Enter either eligible or ineligible. If the test is being repeated and remains unresolved, check “repeat”. (Repeat will not be entered). If a repeat test was done, the overall eligibility status should be coded before entry.

Serum K: Enter either eligible or ineligible. If the test is being repeated and remains unresolved, check “repeat”. (Repeat will not be entered). If a repeat test was done, the overall eligibility status should be coded before entry.

Transaminase: Enter either eligible or ineligible. If the test is being repeated and remains unresolved, check “repeat”. (Repeat will not be entered). If a repeat test was done, the overall eligibility status should be coded before entry.

Renal Insufficiency: Follow the steps listed on the form to determine whether or not the data indicate renal insufficiency. Be certain to use the appropriate gender (male, female). Enter either eligible or ineligible.

Lipid Eligibility: Follow the steps listed on the form to determine whether or not the data indicate lipid eligibility. Be certain to use the appropriate gender (male, female). Enter either eligible or ineligible.

BP Risk Factor: Use average of screening BPs taken up to this point.

Overall Local Lab Eligibility: If and when **any** individual test indicates ineligibility, enter ineligible for the Overall local lab eligibility field. Once ineligible is entered in the field, no further entries are needed. Enter eligible for this field only when **ALL** tests have been completed and indicate eligibility.



Generic Blood Pressure

ID # _____

BP Date ____ / ____ / _____

Visit (check one):

- RI 5
- IFP/I 6
- IFP/II 7
- IFP/III 8

Generic Blood Pressure Form
 (Not for use at PSV, SV1, SV2, SV3, or initial Run-in BP)

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of Blood Pressure measurements: _____ : _____ AM or PM
(noon = 12:00 pm)

b. Cuff sizeSmall adult (< 24 cm) ____ (1) Adult (24-32 cm) ____ (2)
 Large adult (33-41 cm) ____ (3) Thigh (42-52 cm) ____ (4)

Circle Initial Run-in Cuff Size			
1	2	3	4

Wait five minutes seated

c. Resting 30-second pulse / 30 seconds

d. Pulse obliteration pressure (POP) $\frac{\text{mm Hg}}{+ \quad 6 \quad 0}$

e. Random zero peak inflation level (PIL), minimum 180 mmHg mm Hg

f. Blood Pressure device #

2. FIRST RANDOM ZERO BLOOD PRESSURE

a. Uncorrected value $\frac{\text{SBP / DBP}}{\text{mm Hg}}$

b. Zero Value

c. Corrected value (a - b) / mm Hg

Wait 30 seconds

3. SECOND RANDOM ZERO BLOOD PRESSURE

a. Uncorrected value / mm Hg

b. Zero value

c. Corrected value (a - b) / mm Hg

4. SUM OF 2 SBPs AND 2 DBPs, Items 2c + 3c / mm Hg

If sum of SBP (item #4) is >340 or sum of DBP (item #4) is >210, **complete form #23.** (see Clinical MOP Chapter 18 for further details)

Collected by (staff ID): _____
Entered by (staff ID): _____

Administration and Coding Instructions for Generic Blood Pressure Form

The Generic Blood Pressure Form may be used to record blood pressure measurements taken at any time other than PSV, SV1, SV2, SV3, or initial Run-in BP.

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

BP Date - Clearly enter the date when the blood pressure measurements are obtained, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

Type of Visit - Check in the appropriate box to designate whether Visit is during Run-in, Intervention feeding period 1, Intervention feeding period 2 or Intervention feeding period 3

1. Preparation for Blood Pressure Measurements

Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP, Chapter 11.

- a. This should be the time the person is seated and the process is begun. Noon is 12:00 pm.
- b. Use the same cuff size as used for this participant for the initial Run-in BP.
- c. Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
- d. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
- e. Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level and record the result. If this value is less than 180, enter 180.
- f. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a one digit field.

2. **Blood Pressure Readings**

Obtain two sitting blood pressure measurements using the random-zero device. Wait at least 30 seconds between each reading. Both readings and zero values are recorded to the nearest **even** number. Subtract the zero value from the corresponding reading with a hand calculator **AFTER BOTH MEASUREMENTS ARE OBTAINED**. Record the resulting corrected value for both of the measurements obtained. If DBP goes to 0 mmHg, use the 4th phase DBP for all BP measurements. Be sure to write in leading zeros if less than 100.

Add the two corrected SBP and DBP measurements (2c and 3c) together and record the sum in item #4. The escape BP levels are also shown at the bottom of the page. If these latter thresholds are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#23) should be filled out. Refer to appropriate MOP chapter (Chapter 9 Run-in, Chapter 10 Intervention and/or Chapter 18 Safety Monitoring) for further directions on how to proceed.

3. **DASH Identification Number of Person Taking and Entering BP**

Collected by - record the Staff ID # of the person performing the blood pressure measurements.

Entered by - record the Staff ID # of the person entering the data in the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Coding Instructions for Generic Blood Pressure Form

Visit and participant identification data:

ID #

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

BP Date

Check for leading zeros and four digit year. If a date is missing, illegible, or the time frame is not within the cohort's dates, flag the form and resolve with clinic coordinator before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

Visit

Mark RI if blood pressure is being measured at a visit during Run-in.

Mark IFP/I if blood pressure is being measured at a visit during intervention feeding period 1.

Mark IFP/II if blood pressure is being measured at a visit during intervention feeding period 2.

Mark IFP/III if blood pressure is being measured at a visit during intervention feeding period 3.

1. Preparation for Blood Pressure Measurements

- a. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- b. Check for the correct cuff size. The circumference should correspond to the cuff size. A participant's cuff size may change from SV1 to the initial Run-in Blood Pressure. Use the same cuff size used at the initial Run-in BP throughout the rest of the study. If the cuff size is not marked, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- c. The resting pulse should be a two digit field and cannot be missing. If the resting pulse is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- d. The pulse obliteration pressure is a three digit field and cannot be missing. If the (POP) is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- e. Check for correct addition. The random zero peak inflation level should equal the sum of the (POP) plus 60. If the sum is less than 180, write in 180 for the (PIL). If the (PIL) is missing or is outside the normal range, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- f. This is a one digit field. If the BP device # is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

2. First Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

3. Second Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

4. Sum of 2 SBPs and 2 DBPs. Check for addition accuracy of $2c + 3c$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

5. DASH Identification Number of Persons Taking and Entering BP

Staff ID number of person performing the blood pressure measurements cannot be left blank. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

Staff ID number of person entering the data cannot be left blank. This value should not be on the form until everything else on the form has been entered. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.



Run-In Flow Form

DONE ?

Informed Consent.....

Confirmed not on supplements or other exclusionary medications (day 1) **eligible** 1
ineligible 2

RI-1 weight (exclude if \geq 5% from SV3 weight) **eligible** 1
ineligible 2

Patient History Questionnaire.....

First BP (days 1-7).....

Waist Circumference 1) ____ ____ . ____ **cm**
 2) ____ ____ . ____ **cm**

Symptoms Form (days 8-14)

Medication Questionnaire (days 8-14)

Diet Acceptability Questionnaire (days 8-14)

Second BP (days 8-14)

Case conference (days 8-10)

Randomization (day 11).....

Run-in outcome **okay to continue** 1

***pre randomization exclusion / drop out** 2

**** post randomization study termination** 3

*Complete form #18
 **Complete form #22

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Run-In Flow Form Administration and Coding Instructions

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 5) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

The Run-In Flow Form provides a convenient tool for helping to assure that all of the required clinical measurements occur at the proper time during run-in. Individual items should be checked off as they occur.

ID #:

Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant’s last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Informed Consent:

The need for a consent to be done during run-in will vary by site. If consent is being done, check the “Done?” box when completed.

Supplements/Exclusionary Medications:

Verify (on day 1 of run-in) with participant that they are not taking any supplements or other exclusionary medications. They need to be off these medications by day 1 of run-in. If they are still taking these supplements/medications, they are ineligible. If ineligible is marked, under Run-in outcome, mark pre randomization exclusion (box 2) and complete form #18.

R-I 1 weight:

Participant’s weight is recorded on the Daily Diary. If participant’s weight changes by less than five percent between SV3 and the first full day of run-in (RI-1), mark **eligible** box. If participant’s weight changes by five percent or more between SV3 and the first full day of run-in (RI-1), mark **ineligible** box. If ineligible is marked, under Run-in outcome, mark pre randomization exclusion (box 2) and complete form #18.

Patient History Questionnaire:

Check the “Done?” box after reviewing the completed Patient History Questionnaire.

First BP:

Check the “Done?” box after blood pressure measurement is completed (week 1 of Run-in feeding).

Waist Circumference:

1) Measure participant’s waist following procedure in MOP Chapter 13. Remove the tape from the participant’s waist. Record the measure in centimeters.

2) Following procedure in MOP Chapter 13, measure participant’s waist again. Record the second measurement here.

Symptoms Form:

Complete the Symptoms Form with the participant. If participant answers yes to question 17, the staff person fills out the serious AE form (#12). Check the “Done?” box after reviewing the completed Symptoms Form..

Medication Questionnaire: Check the “Done?” box after medication questionnaire is completed (towards the end of week 2 of Run-in feeding)

Diet Acceptability Questionnaire: Check the “Done?” box after diet acceptability questionnaire is completed (towards the end of week 2 of Run-in feeding)

Second BP:

Check the “Done?” box after blood pressure measurement is completed (week 2 of Run-in feeding)

Case conference:

Check the “Done?” box after the Case Conference Form (#33) has been completed.

If the participant is excluded by the case conference, the Patient Closeout Form (#18) must be completed.

Randomization:

Check the “Done?” box when randomization has been completed.

Run-in outcome:

Check only one response.

If pre randomization exclusion/drop out (box 2) is marked, complete form #18.

If post randomization study termination (box 3) is marked, complete form #22.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.

Administration and Coding Instructions for Medication Questionnaire

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure each question is answered.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 5) The "Entered by" staff ID # should not be written until the form is entered.

This questionnaire is designed to identify individuals who have started taking medications that would exclude them from further participation in the study. It is administered during the last week of Run-in and between days 24 and 30 of each Intervention feeding period. All positive responses should immediately be brought to the attention of a DASH2 clinician, who initiates appropriate action taken in accordance with the protocol, and then signs the form.

ID #:

Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date:

Clearly enter the date when the form is being completed, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

Type of Visit:

Check in the appropriate box to designate whether form is completed during Run-in, Intervention feeding period 1, Intervention feeding period 2, or Intervention feeding period 3.

Item 1. Now regularly taking any medicine or nutritional supplements?

If response is Yes, fill out item 1a. and refer to DASH2 clinician.

Item 2. Now regularly taking (listed items)?

If response is Yes, fill out item 2a. and refer to DASH2 clinician.

Item 3. Changed dosage of any medications in the past month?

This question is for documentation of change only.

Clinician signature:

Must be filled in if responses to Item 1 or Item 2 is Yes.

Date:

Date reviewed by Clinician. Must be filled in if responses to Item 1 or Item 2 is Yes.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.



ID # _____

Date ___/___/_____

Participant Closeout Form

Complete this form for all participants who decline to participate or who are found to be ineligible **prior to randomization**. This form is to be used **between visits**. Use the visit forms for closeouts during a visit.

- Time limit exceeded..... 6
- Diet Compliance. 21
- Other compliance 23
- Investigator discretion for safety. 24
- Refused 88
- Other (specify)_____ *

Notes: _____

Reviewed by (staff ID): _____ Entered by (staff ID): _____

* See code list in coding instructions.

Administration and Coding Instructions for the Participant Closeout Form

Use this form for closeouts **between visits**. For closeouts during visits, use the visit form. Complete this form for all participants who decline to participate or who are found to be ineligible **prior to randomization**.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Coding Closeout Reason

When selecting the reason for closeout, please assign a code to all items checked as "Other compliance" or "Other." A list of codes is on the following page. If you cannot find a code to fit items coded under Other, go ahead and enter it as Other, but fax a copy of the form to the coordinating center for review.

Closeout codes:

6=Time limit exceeded
21=Diet compliance
23=Other compliance
24=Investigator discretion for safety
88=Refused

Other closeout codes:

12=SBP Escape (Run-in)
13=DBP Escape (Run-in)
14=Not willing to stop exclusionary medications (Run-in)
15=Side Effects (Run-in)
16=Missed meals (Run-in)
17=Attendance (Run-in)
18=Missed foods/non-study foods (Run-in)
19=Case Conference (Run-in)
20=Weight Change > 5% (Run-in)
79=Transportation problems
80=Other
81=Started BP Meds
82=Physician's orders
83=Illness
84=Death
85=Moved
86=Schedule/time conflict
87=Objected to saltiness of diet
89=Incomplete



RI
ID # _____

PATIENT HISTORY QUESTIONNAIRE

This form asks you a variety of questions about your background, environment, and habits that may affect or relate to your health. It should take about 10 minutes to complete. Please fill in the information requested, or place a check in the appropriate space. A few questions may be similar to ones you have answered before, but please do not skip any questions. If you are not sure about an answer, please estimate.

If you have questions or would like help filling it out, please call _____ at _____ - _____. Please return this questionnaire by _____. We thank you for your time and your contribution to this research.

PERSONAL INFORMATION AND HABITS

1. How much formal or academic education have you had?
(Check the highest level completed)

- Grade school 1
Some high school 2
Completed high school 3
Some college (including community college) 4
Completed college degree (BA, BS) 5
Postgraduate work 6

2. What is your marital status?

- Single 1
Married 2
Widowed 3
Divorced/Separated 4

3. What is your current employment status? Check the one that applies to the greatest percent of your time.

- Employed full-time 1
Employed part-time 2
Homemaker 3
Retired 4
Disabled, unable to work 5
Unemployed 6
Student 7

4. What is your total household income?
(Please give the best approximation of the total income from all sources within your household in the past year.)

Less than \$14,999 1
 \$15,000 to \$29,999 2
 \$30,000 to \$44,999 3
 \$45,000 to \$59,999 4
 \$60,000 to \$74,999 5
 \$75,000 to \$89,999 6
 \$90,000+ 7

5. Have you smoked at least 100 cigarettes in your entire life? Yes 1
 No 2

IF YES:

Do you smoke cigarettes now? Yes 1
 No 2

IF YES:

On average, about how many cigarettes a day do you now smoke? _____ cigarettes

6. Have you ever smoked a pipe or cigars regularly? Yes 1
 No 2

7. Do you currently smoke a pipe or cigars? Yes 1
 No 2

8. Has a doctor ever told you that you have high blood pressure? Yes 1
 No 2

IF YES:

- a. Have you ever taken medication in order to control your blood pressure? Yes 1
 No 2

- b. Have you ever done any of the following to reduce your blood pressure?

	YES	NO
Reduce sodium (e.g., salt) intake	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Lose weight	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Increase physical activity (or exercise)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Reduce alcohol intake	<input type="checkbox"/> 1	<input type="checkbox"/> 2
Other special diet	<input type="checkbox"/> 1	<input type="checkbox"/> 2

9. Did you participate in the previous DASH study? Yes 1
(By participate, we mean did you eat any meals at the DASH study center?) No 2
10. Please check the appropriate box if any of your **NATURAL relatives** (i.e., related by birth) have had any of the following problems. For example, if your father has/had high blood pressure, place a check in the box under father in the high blood pressure row. If you're unsure about an answer, just leave the box blank.

NOTE: If you do not have any brothers check here
 If you do not have any sisters check here
 If you do not have any children check here

If no relatives have any of these conditions, check here

Condition	Father	Mother	Brothers	Sisters	Children
High blood pressure					
Stroke					
Heart attack or angina					
Kidney failure					
Diabetes					

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Administration and Coding Instructions for the Patient History Questionnaire

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Coding Instructions for the Patient History Questionnaire

Questions 1-4:

Check to make sure only 1 response is marked.

Question 5:

If response is Yes, check to make sure question “smoke cigarettes now” is answered.

If response to “smoke cigarettes now” is Yes, check to make sure “# smoke per day” is answered. “# smoke per day” is a 3 digit field. Be sure to use leading zeros.

Questions 6 & 7:

Check to make sure only 1 response is marked.

Question 8:

If response is Yes, check to make sure both **a.** “ever taken meds to control BP” and **b.** “any of the following to reduce BP” are answered.

Question 9:

Check to make sure only 1 response is marked. Use list of DASH randomized participants provided by the CC to verify the participant's response.

Question #10:

This question consists of three parts.

The first part collects data on the makeup of the participant's family (i.e. whether they have brothers, sisters or children). Check all appropriate boxes. If the participant has ever had one of the listed relatives, the box should not be checked.

The second part "If no relatives have any of these conditions" collects data that confirms whether the boxes in the third part should be blank. If any relative has had any of the conditions listed in the third part, at least one of the boxes in the third part should be checked and the box in the second part should be blank. If the boxes in the third part are blank, the box in the second part should be checked.

The third part collects data on which relative, if any, has had any of the listed conditions. If the participant's relatives have not had any of these conditions, then all boxes should be blank and additionally, the box in the second part should be checked. If any boxes in the third part are checked, the box in the second part must be blank.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by :

Record the Staff ID # of the person entering the data in the computer.



Intervention

ID # _____

Visit (check one) IFP/I 6

IFP/II 7

IFP/III 8

Intervention Flow Form

DONE ?

24-Hour Urine (days 22-30).....

ABPM (days 22-30).....

Fasting Blood (days 22-30).....

Symptoms Form (days 24-30)

Medication Questionnaire (days 24-30).....

Brief Physical Activity Questionnaire (days 24-30).....

Anonymous survey (days 24-30).....

Diet Acceptability (days 7-9).....

(days 27-30)

BLOOD PRESSURE (one set during each of weeks 1-3. Five sets during final 9 days of feeding with at least 2 in the last 4 days)

Week 1

Week 2

Week 3

Last 9 days

Participation Survey (days 24-30 of IFP/III period only)

Exit Interview and Counseling (end of cohort only)

Intervention Outcome:complete 1

*study termination 2

*Complete Premature Study Termination Form (#22)

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Intervention Flow Form Administration & Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 5) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

The Intervention Flow Form provides a convenient tool for helping to assure that all of the required clinical measurements occur at the proper time during intervention. Individual items should be checked off as they occur.

24-hour Urine:

Check the "Done?" box after the 24-hour urine specimen has been collected from the participant.

ABPM:

Check the "Done?" box after the ABPM data has been collected.

Fasting Blood:

Check the "Done?" box after the fasting blood specimen has been collected from the participant.

Symptoms Form:

Complete the Symptoms Form with the participant. If participant answers yes to question 17, the staff person fills out the serious AE form (#12). Check the "Done?" box after reviewing the completed Symptoms Form.

Medication Questionnaire:

Check the "Done?" box after reviewing the completed Medication Questionnaire.

Brief Physical Activity Questionnaire:

Check the “Done?” box after reviewing the Brief Physical Activity Questionnaire.

Anonymous Survey:

Check the “Done?” box after distributing Anonymous survey to participant.

Diet Acceptability Survey: Check the “Done?” box after participant has completed the Diet Acceptability Survey(between days 7-9 and days 27-30 of each intervention feeding period).

Blood Pressure:

Check the “Done?” box after completing the blood pressure forms. During each Intervention feeding period, blood pressure is measured once per week during days 1-21 and five times during the final 9 days including twice during days 27-30.

Participation Survey:

Check the “Done?” box after participant has completed the Participation Survey (during the final week of Intervention feeding period 3).

Exit Interview & Counseling:

Check the “Done?” box after participant has received nutritional counseling and a summary of their data (end of the cohort only).

Intervention Outcome:

Check only one response. If study termination (box 2) is marked, complete form #22.

Reviewed by:- Record the Staff ID # of the person reviewing the form.

Entered by:- Record the Staff ID # of the person entering the data in the computer.



ID # _____
Visit (check one) IFP/I 6
 IFP/II 7
 IFP/III 8

Brief Physical Activity Questionnaire

I would like to ask you some questions about your activities in the past month.

1. For the past month, about how often have you taken part in moderate physical activity (such as bowling, golf, light sports or physical exercise, gardening, taking long walks)?

More than 4 times a week 1
2-4 times a week 2
About once a week 3
2-3 times over the month 4
Rarely or never 5

2. For the past month, about how often have you taken part in vigorous physical activity (such as jogging, running, swimming, aerobics, strenuous sports)?

More than 4 times a week 1
2-4 times a week 2
About once a week 3
2-3 times over the month 4
Rarely or never 5

3. How does the amount of activity you have done for the past month compare with your usual physical activity level?

More active 1
Less active 2
About the same 3

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Administration and Coding Instructions for Brief Physical Activity Questionnaire

Overview: The Brief Physical Activity Questionnaire should be administered during days 24-30 during each of the intervention feeding periods.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 6) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 7) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

ID #:

Place the label for the ID number that has been assigned neatly on the line and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further. .

Type of Visit:

Check in the appropriate box to designate whether form is completed during Intervention feeding period 1, Intervention feeding period 2, or Intervention feeding period 3.

Questions 1-3:

Check to make sure only one response is marked.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.



ID # _____

Premature Study Termination Form

Complete this form for all participants who terminate study participation, post-randomization.

A. Reason For Termination

Started on blood pressure medication 81

Physicians orders 82

Refuses to continue 88

Why _____

Illness 83

Death of participant..... 84

Moved out of area 85

Other (specify) _____ 80

B. If a participant drops out of the study before knowing their treatment status, they will not be included in the analysis. Please answer the following to help us determine analysis eligibility.

Did the participant know of his/her diet assignment before deciding to terminate?

Yes _____
No _____

Notes: _____

PIs signature

Date

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Administration and Coding Instructions for Premature Study Termination Form

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure each question is answered.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (E.g., RL, 7/30/97, incorrect ID)
- 5) The "Entered by" staff ID # should not be written until the form is entered.

Overview

This form should be filled out for all participants who terminate study participation after being randomized. Only the ID#, Date, Section A. Reason For Termination, Section B. Participant learns treatment status, Reviewed by: and Entered by: will be entered into the computer. The rest of Section B will be captured only on the paper form. Once this form is filled out and signed by the PI, please make a copy and send the form to the Coordinating Center by regular mail.

ID

Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Section A:

Check the box that lists the reason for the participant's premature termination. If the appropriate answer is 3 (Refuses to continue), please specify the reason for refusal in the space provided. If the appropriate answer is not included as a termination code given below, code it as "other" and write in the reason in space provided. For forms left coded as "other," please fax a copy to the coordinating center.

Termination Codes:

79=Transportation problems

81=Started on BP meds

82=Physicians orders

88=Refuses to continue

83=Illness

84=Death of participant

85=Moved out of area

86=Schedule/time conflict

87=Objected to saltiness of diet

80=Other

Section B:

Answer “yes” to section B if either (1) the participant shows up for an intervention meal and sees what he/she will be eating or (2) the participant is told, prior to the start of intervention feeding, (a) his/her treatment group (i.e., typical or combination) or (b) whether he/she will be continuing on the run-in diet.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.



ID# _____

Date of Escape: _____

BP Escape Tracking Record

Escape Level: 0 1 2

Status at escape: ^{SV} ^{RI} ^{IV}
 1 2 3

Final outcome for this BP escape event:
 *excluded from study 1
 okay to continue 2

Date of Action	Action Taken (see instructions for codes)	Follow-up Notes (include staff ID#)

*If excluded after randomization, complete form 22.

Reviewed by (staff ID): _____
 Entered by (staff ID):: _____



Administration and Coding Instructions for BP Escape Tracking Record

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure each question is answered.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 5) The “Entered by” staff ID # should not be written until the form is entered.

A separate form will be initiated for **each** BP escape event for **each** participant. Record all actions related to the same BP escape event on the same form.

Date of Escape: Date of the BP that initiates escape level process. Use leading zeros as appropriate. (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

Escape Level: 0 if during SV
1 or 2 if during RI or IV (see Protocol, section 13, Safety Monitoring for details)

Status of Escape: SV = during screening, before run-in
RI = before randomization
IV = after randomization (could include the last couple of days of RI)

Date of Action: Date action taken. There will be a separate, and possibly different, date for each action taken related to a single BP escape event. Use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

Action Taken: Enter appropriate code. If multiple actions taken, start a new line.

1. referred to MD
2. 2nd BP within 3 days
3. 2nd BP within 7 days
4. restart meds
5. follow-up with MD
6. follow-up with participant

7. other (specify)
8. confirmed with participant that they followed up with their provider (physician, nurse, etc)
9. unable to confirm follow up with participant

Follow-up Notes: Note any special follow-up problems. Include Staff ID# of the person who took the action.

Final Outcome:

1. Excluded from study.
If excluded after randomization, complete form 22.
2. Okay to continue

Reviewed by: Record the Staff ID # of the person reviewing the form.

Entered by: Record the Staff ID # of the person entering the data in the computer.

Be sure to file form in participant chart after entry.



Calorie Level: 1600 2100 2600 3100 3600 ID# _____

Diary Date (yesterday): _____

of energy cookies distributed: _____

Weight (today): _____

Daily Diary

Please answer all questions below and fill in any additional information requested.

	yes	no	QUESTION	OFFICE USE ONLY
1.	<input type="checkbox"/>	<input type="checkbox"/>	Did you eat at least one meal at the <u>feeding site</u> yesterday?	Y / N
2.	<input type="checkbox"/>	<input type="checkbox"/>	Did you have any coffee, tea, or soda yesterday? If yes, what kind (give brand name) and how much you consumed: <u>What Kind</u> <u>Caffeinated?</u> <u>Amount (in oz.)</u> (coffee) _____ (tea) _____ (soda) _____	Beverage total ounces Caf Decaf _____ _____
3.	<input type="checkbox"/>	<input type="checkbox"/>	Did you drink any alcoholic beverages yesterday? If yes, what kind and how much? <u>Kind</u> <u>Amount (in oz.)</u> Beer (brand): _____ Wine: _____ Spirits: _____	Alcoholic Beverage ounces _____ _____
4.	<input type="checkbox"/>	<input type="checkbox"/>	Did you eat any of the “energy cookies” yesterday? If yes, how many? <u>Amount</u> _____	# Cookies _____
5.	<input type="checkbox"/>	<input type="checkbox"/>	Was there any food (including broth) left over from what you were served yesterday? If yes, please list the kind and amount, and the reason. <u>What kind</u> <u>Amount</u> <u>Reason (please explain)</u> _____ _____ _____	# Leftover meals _____ # Full servings _____
6.	<input type="checkbox"/>	<input type="checkbox"/>	Did you eat or drink any foods (including salt and other spices) that are not allowed by DASH2 yesterday? If yes, please list the kind and amount, and the reason. <u>What kind</u> <u>Amount</u> <u>Reason (please explain)</u> _____ _____ _____	# Full servings _____
7.	<input type="checkbox"/>	<input type="checkbox"/>	Did you take any vitamins, other dietary supplements or over-the-counter medicines such as Tylenol, cold medications? <u>What kind</u> <u>Amount</u> <u>Reason (please explain)</u> _____ _____	
8.	<input type="checkbox"/>	<input type="checkbox"/>	For women only. Were you menstruating yesterday?	Y / N / NA
9.	<input type="checkbox"/>	<input type="checkbox"/>	Is there anything you would like us to know regarding your participation in this study? _____	

Coded/reviewed by (staff ID): _____

Entered by (staff ID): _____



Calorie Level: 1600 2100 2600 3100 3600

ID# _____

Diary Date (yesterday): _____

of energy cookies distributed: _____

Weight (today): _____

Daily Diary

Administration and Coding Instructions for the Daily Diary

Purpose

The purpose of the daily diary is to collect information related to participant adherence to the protocol in the following broad categories:

- the type and amount of discretionary or “allowed” food items consumed by participants including alcoholic, and non-alcoholic beverages, as well as energy cookies.
- the kind and amount of study foods not eaten and non-study foods eaten, including dietary supplements and over-the-counter medications.
- menstruation information on female participants
- feedback from participants regarding any concerns they may have about participating in the study

The 24-hour time period of the diary covers the day before the visit at which it is given out. For example, if the Daily Diary is given to the participant on Wednesday (“today”), the participant fills it out for Tuesday (“yesterday”).

Distribution and Collection

Distribute at the on-site meal Monday through Friday and with weekend meals. Prepare the form ahead. Diaries are returned at the next on-site meal, or Monday night for weekend meals. If participants forget the Monday diary, distribute a form to complete for the weekend. The dietitian enters the date, participant ID number, circles the calorie level and number of energy cookies in the shaded area before the form is given to the participant.

ID Number

Only record data for one participant per form. Record the participant’s DASH2 identification number. It has five alpha characters and five numerical digits. The alpha characters are replaced by asterisks if there are not enough characters in the participant’s name (e.g. ABCD*12345)

Date Field

Use the following format for the date field: mm/dd/yyyy (i.e. 01/23/1998 for January 23, 1998). This is the date of the day for which meal and snack information is obtained (a calendar day). The day includes breakfast, lunch, dinner, and snacks. Diaries (dated for the previous day) are given at mealtime, completed on-site, and returned before leaving. For example, distribute Monday, January 19 meal diary at Tuesday, January 20 dinner. This diary, 01/19/1998, includes all foods and snacks eaten on 01/19/1998.

Weight

The participant’s weight is measured and recorded to the nearest 0.1 kg. (see Clinical MOP, Chapter 13).

This is a four digit field (e.g., 102.3). The weight is recorded on the previous day's diary (e.g. Wednesday weight goes on Tuesday's diary).

Calorie Level

Circle the participant's assigned calorie level that coordinates with date field.

Number of Energy Cookies Distributed

Record the number of energy cookies distributed to the participant and coordinates with the date field.

Reviewing the Daily Diary

Review the diary as soon as possible. All data should be entered within 24 hours and must be entered within one week.

Make sure the participant has marked either a "Yes" or "No" in the columns asking for this information. Circle the appropriate response in the shaded area on the right for questions 1 and 8. For questions answered "Yes" and requiring additional information from the participant, complete the information before the participant leaves the center. Total amounts of beverages and/or foods and enter in the appropriate section in the shaded area. Leave no fields blank. If appropriate, enter zeros in those fields.

Question 1: Circle the appropriate participant response, "Yes," or "No," in the shaded area. Make sure participants answers are accurate. Verify the participant's answer with your site's attendance records.

Question 2: Record the brand and ounces of non-alcoholic, discretionary beverages the participant consumes. Indicate if the beverage is caffeinated or not. Make sure "Yes" or "No" is marked under the word "Caffeinated?" In the shaded area, note the ounces of both caffeinated and decaffeinated beverages consumed, including coffee, tea, and soda. Crystal Light beverages are recorded in the "Tea" space. See Guidelines for Beverages and Seasonings (Form #106) for a complete list of allowed beverages. **Any coffee, tea, or soda not found on this list is reported in question # 6 and in question #2.**

Examples

Participant drank 4, 12 oz. servings of Diet Pepsi. Record 48 under caffeinated soda.

Participant drank 28 oz. coffee with milk. Clarify if the milk was off the menu and if the coffee was caffeinated. If it was additional milk, record this under question 6. Record 28 under appropriate column in the shaded area. If participant unable to identify if beverage contained caffeine, use caffeinated by default in coding.

Question 3: The participant indicates the ounces of alcoholic discretionary beverages consumed in this question. Make sure the correct brand or type and amount is noted. Record the total ounces of alcohol for each kind of beverage (beer, wine, and spirits) in the shaded area. Record all alcohol consumed, allowed or not allowed here. If a not allowed alcoholic beverage is consumed, such as dark beer, record here and also under Question 6. **If an allowed alcoholic beverage is mixed with a non-allowed beverage, such as whiskey and soda, record the amount of alcohol here, and record the non-allowed beverage in Question 6 and Question 2.** O'Douls is recorded here by participant, but no alcohol is coded in shaded area. If more than allowed amount of O'Douls is consumed, record amount above allowed in Question #6.

Example

Participant drank 2 rum and regular coke drinks. Each had 8 oz of regular coke and 1 oz of rum. Record 2 under spirits in the shaded area. Record the 16 oz of regular coke under question 6.

Question 4: The participant indicates the number of energy cookies consumed. Total the units of energy cookies consumed and record in the shaded area. Round the amount to the nearest 0.5 serving of cookie.

Question 5: The participant indicates the kind and amount of study foods and beverages not eaten and the reason. If the participant has marked the “Yes” column, complete the kind, amount, and reason section. Probe for reasons, if not stated. Calculate the number of leftover meals and/or leftover full servings and record in the shaded area. Use Tables A and B to refer to actual menu portions. An entire meal not eaten is counted as one “leftover meal.” For example the participant was sick and did not eat the study meal.

For any one food not eaten and less than an entire meal, count the individual number of full servings missed. Combine the uneaten servings of items to determine “full servings”. Indicate missed meals in increments of 1,2,3 etc., not partial meals missed. Use 0.5 to record a partial serving. Data is recorded in no less than 0.5 increments. To code, count each food item or serving missed. Total the partial servings in increments of 0.5 to determine the total number of full servings. (For example, participant missed 1/4 of the rice and 1/4 of the milk. Each item is 0.5 serving missed and totals 1.0 full servings).

Guidelines for Counting Servings and Scoring Missed Study Foods

See attached weekly menus (Tables A and B) for clarification. Foods combined into one serving are in **bold**. All other foods listed = 1 serving.

Examples

Participant left 2 T rice and 1 (of 3 as shown on actual Master Production Menu) slice of bread at a meal. All assigned bread (3 slices in this case) at this meal = 1 serving, therefore both items are less than a full serving of two foods. Record 1.0 in the appropriate shaded area.

Participant left all of the baked potato and green beans. This is one full serving each, therefore = 2 servings. Record 2.0 in the shaded area.

Participant left 1/2 serving of Spanish Rice with Chicken. This is one serving on the Food Production from regardless of the calorie level. Record 0.5 in the shaded area.

Participant left all of the turkey/rice/gravy entree served. This entree equals one serving. Record 1.0 in the shaded area.

Food replaced and eaten is not recorded.

Question 6: The participant indicates the kind and amount of non-study foods and beverages consumed and the reasons for the consumption. If the participant has marked the “Yes” column, see that the amount and reason are completed. Probe for reasons if not stated. Calculate the number of full servings and record in the shaded area. See Table C. Combine the number and amount of consumed servings of foods to determine “full servings.” Include any not allowed beverages recorded in Questions 2 and 3. Use Table C to determine the amount of a single serving. For foods not on the list, refer to a similar food on the list to determine serving size. If there are no similar foods, send a message to the CC that includes the food and amount determined to be a single serving. Use 0.5 to record a partial serving. Data is recorded in no

less than 0.5 increments. Total the partial and full servings and record.

Questions 7: The participant indicates the kind and amount of dietary supplements and over-the-counter medications taken and the reason for taking them. If the participant has marked the “Yes” column, complete kind, amount, and reason section. Probe for reasons if not stated. Review “Yes” responses with the dietitian and/or clinician within 24 hours.

Question 8: If the participant is **female**, the “Yes” or “No” column on the left side of the form should be checked. Circle the appropriate response “Yes,” “No,” or “Not Applicable” in the shaded area.

If the participant is a **male**, the “Yes” and “No” column on the left side of the form should be left blank. Circle “Not Applicable” in the shaded area.

Question 9: The question is followed by a narrative if a participant marks the “Yes” column. However, participants may wish to talk to staff rather than make a written comment. Follow-up with participants any “Yes” responses. This information is not recorded in the shaded area. Have the participants use the back of the form if they need more space.

Coder ID#

Record the identification number of the person who reviews and records information in the box at the bottom of the diary.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use black or blue pen on all forms, not pencil.
- 3) Make sure that there is a correct ID # on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. For this form, the person who completes the "Office Use Only" section is the "Reviewer." The "Entered by" staff ID # should not be written until the form is entered into the computer.

Entry of the Daily Diary

The only responses entered from the Daily Diary are in the shaded area on the right hand side of the form. The shaded area is completed by the reviewing dietitian. If a field is blank or unclear the data entry person flags the field and sends it back to the reviewing dietitian. The Data Entry person makes no attempt to correct, recalculate, or interpret the data. At the completion of the entry, the Data Entry person records his/ her staff ID number in the field at the bottom of the form.

TABLE A

	Breakfast	Lunch	Dinner	Snack
Monday	Apple juice Corn Flakes Milk Toast w/ jelly butter	Chicken or ham sandwich w/ lettuce / mayonnaise / mustard Fruit Punch Hard Candy, Jello Chicken Broth	Spaghetti w/meat sauce Parmesan cheese Steamed cauliflower Bread w/butter Frosted Pound Cake Chicken broth	Fruit Punch Butter Cookie
Tuesday	Cranberry juice Bread w/peanut butter and jelly butter	Lean Cuisine Pizza (French Bread) Salad/Italian dressing Chicken breast (roasted) Hard candy Fruit punch and Jello	Hamburger w/roll, ketchup, lettuce, onion Potato salad, chicken broth Peaches Butter	Shortbread cookies Lemonade Drink Applesauce
Wednesday	Apple juice Milk Cinnamon raisin bagel w/jam and butter Cream cheese	Roast Beef sandwich w/ lettuce mayonnaise, mustard Brownie, M&Ms Pretzels Chicken broth	Spanish Rice w/Chicken Green Peas Salad w/cucumbers French dressing Roll w/butter	Sugared orange slices Butter cookie Lemonade
Thursday	Egg bagel Orange marmalade Cream cheese Butter Cranberry-apple juice	Tuna salad sandwich w/tomato Milky Way bar Lemonade drink	Meatloaf w/BBQ sauce Baked potato w/sour cream Bread w/butter Green beans Jello Chicken or beef broth	Cranberry juice Ritz crackers Cheddar cheese
Friday	Cranberry juice Frosted Flakes cereal Milk Toast w/jelly butter	Chicken breast sandwich w/ mayonnaise Mustard Fruit cocktail Chicken broth	Spicy Seafood Scallion Rice Steamed carrots Bread or roll w/butter Pineapple Milk	Cream cheese frosting Butter cookie Fruit Punch
Saturday	Pork Sausage Milk Grits Toast w/butter Apple juice	Tuna Fish salad sandwich w/lettuce Applesauce Butter cookies	Turkey w/rice and gravy Green beans Yellow cake w/choc frosting Bread w/butter Apple juice	Cranberry juice Kit Kat Jello
Sunday	Grits Toast w/jelly butter Cranberry juice Milk	Turkey breast or Turkey Pastrami sandwich w/ bread or Sesame roll, lettuce, mayonnaise, mustard American cheese, cucumber, Applesauce / Peaches & strawberries Lemon cookie Chicken broth	Roast beef round and gravy with Rice Summer squash Bread w/ butter Chocolate chip cookie Fruit Punch Beef broth	Animal crackers Apple juice

TABLE B

	Breakfast	Lunch	Dinner	Snack
Monday	Milk Orange juice Bran chex w/sugar or Shredded Wheat Banana/dried apricots Whole wheat toast w/ margarine & jelly	Chicken breast sandwich w/ lettuce / mayonnaise/ tomato American or Swiss cheese Apple juice Jello	Spaghetti w/veg. Sauce Parmesan cheese Mashed sweet potato Turnip greens Dinner rolls Fruit Punch	Orange juice Apple Mixed nuts
Tuesday	Prune juice Banana Milk Oatmeal Whole wheat toast w/ margarine & jelly	Beef w/ BBQ sauce sandwich on Sesame seed roll w/ lettuce / tomato /pickles Cheddar cheese Potato salad, beef broth Fruit punch	Cod w/lemon Brown rice Cornbread muffins or rolls w/ margarine Spinach Milk	Oranges Mixed dried fruit Graham crackers Milk
Wednesday	Orange juice Milk Oatmeal or Corn Flakes Banana Whole wheat toast w/butter, jelly	Ham sandwich on whole wheat w/ mayonnaise /mustard /lettuce Cheddar cheese Fruit cocktail Chicken broth	Spanish w/chicken Green Peas Milk Roll w/butter Cantaloupe	Dried apricots Nuts Orange juice
Thursday	Orange juice/milk Banana Frosted Mini Wheats Cinnamon-raisin bagel Cream cheese	Tuna salad on whole wheat bread Cantaloupe Cottage cheese with pineapple Lemonade and hard candy	Turkey meatloaf w/BBQ sauce Baked potato w/margarine Sour cream and scallions Collard greens Chicken broth Jello/ fruited yogurt	Orange juice Peanut butter Triscuit crackers
Friday	Orange juice Yogurt Milk Toasted oats granola bar Bananas	Turkey sandwich on ww bread /w mayonnaise, mustard, lettuce Cheddar cheese Oranges Fruit cocktail Chicken broth	Spicy Seafood Scallion Rice, Spanish Spinach Milk Pineapple Bread w/butter or marg Beef broth	Roasted peanuts Apricots Fruit Punch
Saturday	Grape juice/orange juice Kellogg's bran flakes or shredded wheat cereal Milk Whole wheat toast w/marg. Or cinnamon toast Banana / orange	Tuna Salad on whole wheat /pita bread w/lettuce, cucumber & tomato Apple Apricot nectar	Zucchini lasagna w/ Parmesan cheese Spinach, stewed tomatoes Raw carrots Roll w/butter Melon/peaches Milk Beef or chicken broth	Raisins Almonds Fruit yogurt Cranberry juice
Sunday	Bran chex Milk Banana Whole wheat toast w/jelly & margarine Orange juice Yogurt	Chicken salad on ww bread w/mayonnaise cucumber & tomato Fruit cocktail Chicken broth	Roast beef and gravy Baked potato w/ sour cream Bread w/margarine or butter Green beans Milk Peaches Beef broth	Orange juice Nuts Raisins Dried apricots

TABLE C

Guidelines for Counting Servings of Non-Study Foods Eaten

All Food Items = 1 Serving

<u>Food</u>	<u>Amount</u>
Bagel, English muffin, croissant (large)	1 each
Beer	12 ounces
Cake	1/12 of whole
Candy, (hard, sourballs, candy kisses)	2 pieces
Casserole	1 cup
Cereal, cooked (w, w/o milk and/or sugar)	1 cup
Chewing gum, regular	1 stick or piece
Chili	1 cup
Cocoa (hot chocolate)	1 cup
Cookies	2 small, 1 medium, 1 large
Corn on cob, medium	1 ear
Crackers, Saltine or Ritz	6 each
Cream, half & half	1 tablespoon
Doughnut	1
French Fries w/condiments	1/2 cup
French Fries	1/2 cup
Fruit	1
Hamburger or hot dog roll	1 each
High sodium condiments	any amount
Hot dog (bun, condiments)	1 whole
Ice Cream w/toppings	1/2 cup
Ice Cream	1/2 cup
Juice	6 ounces
Lasagna	4" x 4" square
Liquor	1.5
Meat w/sauce	1 piece (4 oz.)
Oil	1 teaspoon
Pancakes, 4 inch diameter	2 each
Peanut butter	2 tablespoons
Peanuts/Nuts	1/4 cup
Pie, fruit (2 crust)	1/6 pie
Pie, pumpkin or custard	1/8 pie
Pizza	1 slice
Popcorn, popped	3 cups
Pot Pie	1
Rice, pasta, beans, cooked	1/2 cup
Salt	any amount
Sandwich (2 bread, filling, condiments)	1 whole
Soda	12 ounces
Sourballs, or any hard candy, candy kisses	2 pieces
Soup	1 cup
Sugar, jam, jelly	1 teaspoon
Syrup or honey	1 tablespoon
Taco	1
Tossed Salad (w, w/o dressing)	1 cup
Vegetables w/sauce	1/2 cup
Vegetables, cooked	1/2 cup
Vegetables, raw	1 cup
Wine	5 ounces

	Example	Serving	Answer
Participant ate/drank:	1 Girl Scout cookie	2 small cookies = 1 serving	0.5 serving
	2 scoops ice cream (1 cup)	1/2 cup = 1 serving	2 servings
	2 tacos	One taco = 1 serving	2 servings
	1 small bowl Corn Chex with milk and sugar	1 cup cold cereal with or without milk and sugar = 1 serving	1 serving
	3 glasses of red wine (5 oz. each)*	5 oz. = 1 serving	3 servings

*Record 15 oz under alcohol in question #3 and code 3 servings under question #6.

Note: Red wine is not allowed.



Stamp #: _____

Visit (check one):

IFP/I 6

IFP/II 7

IFP/III 8

ANONYMOUS SURVEY

Volunteers in studies such as DASH2 sometimes experience difficulties in following all the dietary requirements. In such cases, they either do not eat what is given to them or eat foods other than those provided to them. The following questions will help us determine the accuracy of our results. It will also help us monitor the safety of the diet.

1. Did you always consume all of the foods that were given to you in the past 4 weeks by the DASH2 study?

Yes, always 1

Usually, except 1 to 5 times 2

Usually, except 6-10 times 3

Did not consume all the food more than 10 times 4

2. When you did not eat all the research food, what were the reasons for not doing so? (check all that apply)

Not hungry

Disliked particular food or drink item

Bored with study food

Illness

Forgot

In a hurry

Unusual circumstances / special occasions

Social pressure

Food inedible (spoiled, too ripe)

Food caused physical discomfort

Food poorly prepared

Ate all the research food

3. Did you eat foods or drink beverages (other than the allowed beverages), that were not a part of the research diet provided to you by the DASH2 study?

- No, never 1
- Yes, 1 to 5 times during the study 2
- Yes, 6 to 10 times during the study 3
- Yes, more than 10 times during the study 4

4. If you ate other foods, what were the reasons for doing so?
(check all that apply)

- Hunger
- Bored with study foods
- Craving for a particular food or drink item
- Social pressure
- Illness
- Unusual circumstances / special occasions
- Forgot I was in the study
- In a hurry
- Study food inedible (spoiled, too ripe)
- Study food caused physical discomfort
- Study food poorly prepared
- Didn't eat any non-study foods

5. When you ate foods that were not a part of your research diet, what types of foods were they? (Check all that apply)

- Sweets/desserts
- Meats/fish
- Fruits/vegetables
- Salty foods
- Starchy foods (potatoes, corn)
- Alcoholic beverages
- Dairy products (milk, cheese, yogurt)
- Juices and soft drinks (including punch)
- Didn't eat any non-study foods

Since this is an anonymous survey, we have no way to link your responses to what we know about you through your other contacts with DASH2. Your answers to the following questions will provide information that we need to analyze the data.

6. Your sex:

- Male 1
Female 2

7. Your age:

- 18-30 years 1
31-55 years 2
56-70 years 3
71 years and over 4

8. Was coming to the clinic on a daily basis difficult?

- Yes 1
No 2

9. Household income:

- Less than \$14,999 1
\$15,000 to \$29,999 2
\$30,000 to \$44,999 3
\$45,000 to \$59,999 4
\$60,000 to \$74,999 5
\$75,000 to \$89,999 6
\$90,000+ 7

10. What flower name were you assigned?

- Rose 01
Daisy 02
Sunflower 03
Tiger-Lily 04
Lilac 05
Carnation 06
Iris 07
Violet 08
Snapdragon 09
Marigold 10
Tulip 11
Poppy 12

11. Education (check the highest level completed):

- Grade school 1
- Some high school 2
- Completed high school 3
- Some college (including community college) 4
- Completed college degree (BA, BS) 5
- Postgraduate work 6

12. What is your primary race?
(check one answer only)

- American Indian or Alaskan Native 1
- Asian/Pacific Islander 2
- Black/African American 3
- White 4
- Other (specify) _____ 5

13. Do you consider yourself to be Hispanic?

- Yes 1
- No 2

Thank you for taking the time to complete the survey!

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Anonymous Survey Administration and Coding Instructions

This form is designed to help determine accuracy of results, help monitor safety of the study diets, and to evaluate compliance with the study diets. Have each participant complete this form at the end (days 24-30) of each of the 3 Intervention feeding periods. Mark the appropriate box in the upper right corner of the form. A stamp number should be recorded on the top of the form **before** administering the survey. (see coding instructions below for appropriate stamp numbers). A clinic staff member should review the form for completeness and write their ID number after "Reviewed by Staff ID." The Staff ID # of the person entering the data should be added to the form at the time the data is entered in the computer.

Each site will have their own site specific protocol for administering the anonymous survey. Appropriate steps should be taken to assure the participants' anonymity.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Anonymous Survey Coding Instructions

Participant identification data:

Do not place participant identifier on this form. Since this is an anonymous survey, responses will not be linked to participant identifiers.

Stamp Number:

Each survey should have a stamp number recorded before administering the survey. This stamp number is a five digit field. The first digit is the cohort number. The second digit is the site number. The last three digits are an assigned sequential (unique) number. This unique number is not used to identify participants. It is used in order to have a unique number for each survey. The staff person administering the survey needs to track the numbers used. (Do **not** track what number is assigned to each participant). For example, cohort 1, site 2, person 1, should be coded as "12001". Note: use leading zeros when relevant for the last three digits.

Site codes:

1=Baltimore

2=Baton Rouge

3=Boston

4=Durham

Visit:

Check whether the appropriate box has been checked to designate when form was completed (Intervention feeding period 1, Intervention feeding period 2, or Intervention feeding period 3). Only one box should be marked.

Question 1. Did you always:

Only one response should be checked.

Question 2. When you did not eat all:

More than one response may be checked. If any items between item 1 (not hungry) and item 11 (food poorly prepared) are checked, item 12 (ate all research food) should not be checked. If items 1 through items 11 are blank, item 12 should be checked.

Question 3. Did you eat foods or drink:

Only one response should be checked.

Question 4. If you ate other foods:

More than one response may be checked. If any items between item 1 (hunger) and item 11 (study foods poorly prepared) are checked, item 12 (did not eat any non-study foods) should not be checked. If items 1 through items 11 are blank, item 12 should be checked.

Question 5. When you ate foods:

More than one response may be checked. If any items between item 1 (sweets/desserts) and item 8 (juices and soft drinks) are checked, item 9 (did not eat any non-study foods) should not be checked. If items 1 through items 8 are blank, item 9 should be checked.

Question 6. Your sex:

Code the appropriate gender (male, female).

Questions 7-11

Only one response should be checked.

Question 12. What is your primary race:

This question is intended for demographic purposes. Record the primary race. This should be the one the participant identifies with the most. Check only one answer. If the respondent asks for clarification, please note the following: If the respondent enters “Hispanic” under “other”, code Q13 as “yes”, ask participant if they consider themselves to be white Hispanic, black Hispanic, or other Hispanic. Code Q12 as appropriate based on the answer. The “other” category should not be checked simply because the participant lists Hispanic.

1=American Indian, Alaskan Native

2=Asian/Pacific Islander

3=Black/African American, Ethiopian, Maloto

4=White, Spanish, Capeverdian, Lebanese, Spanish, Persian, Jewish,
Brazilian, Portuguese, Milano, Russian, German-Arab, Arab

5=Other, (anything coded as “other” will not be classified as a minority by NIH. Contact the CC for “other” races that you are unable to recode into the above categories.)

Question 13. Do you consider yourself Hispanic:

Although often used as a racial category, “Hispanic” actually relates more closely to ethnicity and is thus complementary to Q12. If the respondent asks for clarification, note the following: If Hispanic is written in above or Q13 is “yes”, probe for primary race code.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.



ID# _____

Participation Survey

This survey is about your experience in the DASH2 study. Your answers will help us improve the way we conduct DASH2 and similar studies in the future.

1. Overall, how would you describe your experience with the study?
(check all that apply)

- Beneficial to me
Informative
Interesting
Pleasant
Difficult but worthwhile
I regret that I agreed to participate

2. Based on your experience in the DASH2 study, would you participate in another similar research study?

- Yes 1
No 2

3. Would you encourage your friends to participate in the DASH2 study or other feeding research studies?

- Yes 1
No 2

4. Have you been influenced by this study to eat differently after the study is over?

- Yes 1
- No 2

If yes, check the boxes below that describe the changes you will be making in the way you eat.

Increase fruits and/or vegetables	<input type="checkbox"/>
Decrease food consumption (includes decreasing snacks)	<input type="checkbox"/>
Become more aware of food (read labels, prepare food differently, etc.)	<input type="checkbox"/>
Reduce weight	<input type="checkbox"/>
Don't skip meals	<input type="checkbox"/>
Decrease foods high in salt	<input type="checkbox"/>

5. On a scale of 1 - 5, how helpful were the following DASH2 staff in answering your questions or addressing your concerns?

- | | Not
Helpful | | Somewhat
Helpful | | Very
Helpful |
|------------------------------|----------------|---|---------------------|---|-----------------|
| a) Dietitians | 1 | 2 | 3 | 4 | 5 |
| b) Clinical staff..... | 1 | 2 | 3 | 4 | 5 |
| c) Other research staff..... | 1 | 2 | 3 | 4 | 5 |

6. On a scale from 1-5, how clear were the instructions you received about the following:

- | | Not
Clear | | Somewhat
Clear | | Very
Clear |
|--|--------------|---|-------------------|---|---------------|
| a) scheduling of meals..... | 1 | 2 | 3 | 4 | 5 |
| b) types of food to be eaten | 1 | 2 | 3 | 4 | 5 |
| c) restrictions of foods/beverages | 1 | 2 | 3 | 4 | 5 |
| d) restrictions on over the counter
medications | 1 | 2 | 3 | 4 | 5 |
| e) completing all forms (including
daily diary) | 1 | 2 | 3 | 4 | 5 |

**Not
Clear**

**Somewhat
Clear**

**Very
Clear**

f) collection of blood and urine
samples.....1.....2.....3.....4.....5

g) blood pressure measurements1.....2.....3.....4.....5

7. Before becoming involved in the DASH2 study, how often did you prepare your own meals at home? (This includes breakfast, lunch, or dinner.)

- Less than 7 meals/week 1
- 7-12 meals/week 2
- 13-18 meals/week 3
- 19-21 meals/week 4

8. During the time the DASH2 study was providing your meals, how often did you prepare meals for other family or household members? (This includes breakfast, lunch, or dinner.)

- Less than 7 meals/week 1
- 7-12 meals/week 2
- 13-18 meals/week 3
- 19-21 meals/week 4

9. Prior to the study, how many meals did you usually eat outside of the home?
(This includes breakfast, lunch, or dinner.)

- Less than 7 meals/week 1
- 7 - 12 meals/week 2
- 13 - 18 meals/week 3
- 19 - 21 meals/week 4

10. On a scale of 1 to 5, which of the following were helpful for you to keep up with the daily demands of the DASH2 study (circle one number for each item).

- | | Not at all
Helpful | | Somewhat
Helpful | | Very
Helpful |
|---|-------------------------------|-------|-----------------------------|-------|-------------------------|
| a) Not having to shop for and cook food for myself and family members | 1 | | 2 | | 3.....4.....5 |
| b) Free food | 1 | | 2 | | 3.....4.....5 |
| c) Attention of the DASH2 staff | 1 | | 2 | | 3.....4.....5 |
| d) Daily diary | 1 | | 2 | | 3.....4.....5 |
| e) Free choice beverages | 1 | | 2 | | 3.....4.....5 |
| f) Raffles, gifts, and other incentives | 1 | | 2 | | 3.....4.....5 |
| g) Family/friends | 1 | | 2 | | 3.....4.....5 |
| h) Knowing I will learn more about my blood pressure | 1 | | 2 | | 3.....4.....5 |
| i) Knowing I will receive information about my lab tests..... | 1 | | 2 | | 3.....4.....5 |
| j) Knowing I will learning more about food, nutrition, and health..... | 1 | | 2 | | 3.....4.....5 |
| k) Monetary compensation..... | 1 | | 2 | | 3.....4.....5 |
| l) Increase discipline..... | 1 | | 2 | | 3.....4.....5 |
| m) Breaks between feed periods (if applicable) | 1 | | 2 | | 3.....4.....5 |

11. On a scale of 1 to 5, did any of the following make it difficult for you to meet the daily demands of the DASH2 study? (Circle one number for each item.)

- | | Not a
Problem | Somewhat
Difficult | Very
Difficult | | |
|--|--------------------------|-------------------------------|---------------------------|---|---|
| a) Length of study..... | 1 | 2 | 3 | 4 | 5 |
| b) Family/Friends | 1 | 2 | 3 | 4 | 5 |
| c) Other social pressures | 1 | 2 | 3 | 4 | 5 |
| d) Employment/work
schedule..... | 1 | 2 | 3 | 4 | 5 |
| e) Time involved with
coming in to eat my meals | 1 | 2 | 3 | 4 | 5 |
| f) Time involved for blood
pressure measurement..... | 1 | 2 | 3 | 4 | 5 |
| g) Commuting and parking
arrangements..... | 1 | 2 | 3 | 4 | 5 |
| h) Special occasions
(birthdays, holidays, etc.)..... | 1 | 2 | 3 | 4 | 5 |
| i) Blood sampling | 1 | 2 | 3 | 4 | 5 |
| j) Urine collections | 1 | 2 | 3 | 4 | 5 |
| k) Lack of freedom to choose
what, and when to eat..... | 1 | 2 | 3 | 4 | 5 |
| l) Repetition of menus | 1 | 2 | 3 | 4 | 5 |
| m) Breaks between feeding periods
(if applicable) | 1 | 2 | 3 | 4 | 5 |

12. On a scale of 1 to 5, which of the following made it difficult for you to eat all of the DASH2 food and to not eat any non-study food? (Circle one number for each item.)

- | | Not a
Problem | Somewhat
Difficult | Very
Difficult |
|--|--------------------------|-------------------------------|---------------------------|
| a) Too much food..... | 1 | 2 | 3 4.....5 |
| b) Too little food | 1 | 2 | 3 4.....5 |
| c) Too much or too little
food at specific meals..... | 1 | 2 | 3 4.....5 |
| d) Unappetizing or foods
lacking taste | 1 | 2 | 3 4.....5 |
| e) Bad taste of the food | 1 | 2 | 3 4.....5 |
| f) Lack of variety or boredom
with the food | 1 | 2 | 3 4.....5 |
| g) Foods I am not used
to eating..... | 1 | 2 | 3 4.....5 |
| h) Craving for sweets or salty
snacks..... | 1 | 2 | 3 4.....5 |
| i) Craving for salty foods..... | 1 | 2 | 3 4.....5 |

13. On a scale of 1 - 5, did any of the following (other than the food itself) make it difficult for you to eat all of the food provided to you during the study? (Circle one number for each item.)

- | | Not a
Problem | Somewhat
Difficult | Very
Difficult |
|---|--------------------------|-------------------------------|---------------------------|
| a) Cooking food for
other family members | 1 | 2 | 3.....4..... 5 |
| b) Side effects of the diet
(belching, diarrhea,
constipation, etc.)..... | 1 | 2 | 3.....4..... 5 |
| c) Desire to eat foods other
than the study foods | 1 | 2 | 3.....4..... 5 |

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Participation Survey Administration and Coding Instructions

This form is designed to assess participant satisfaction with the study. Have each participant complete this form at the end (days 24-30) of the 3rd Intervention feeding period. A clinic staff member should review the form for completeness write their ID number after "Reviewed by Staff ID." The Staff ID # of the person entering the data should be added to the form at the time the data is entered in the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Participation Survey Coding Instructions

Participant identification data

ID #: ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Question 1. Overall, how would you describe:

More than one response can be checked.

Questions 2-3. :

Check to make sure only one response was marked.

Question 4. Have you been influenced by this study:

If the participant checked “yes”, at least one of the following 6 boxes should be checked. If the participant checked “no”, skip to question 5.

Question 4. If yes...

More than one response can be checked.

Questions 5-6. :

Only one number can be circled for each line.

Questions 7-9. :

Only one response can be checked.

Questions 10-13:

Only one number can be circled for each line.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the form.



ID _____

Visit (check one): IFP/I 6

IFP/II 7

IFP/III 8

ABPM PLACEMENT FORM

1. Did the participant agree to wear an ABPM? agree 1
refuse 2
other 3

2. Was this a repeat recording after an unsuccessful attempt? yes 1
no 2

3. ABPM placement

(a) Tech ID _____

(b) Monitor ID _____

(c) Date of placement _____/_____/_____
month day year

(d) Time of placement (noon=12:00 PM) ____ : ____ am
pm

(e) Arm used for cuff placement left 1
right 2

(f) 1st RZ BP (SBP/DBP) _____/_____
random zero level _____

(g) 2nd RZ BP (SBP/DBP) _____/_____
random zero level _____

(h) 1st BP by ABPM (SBP/DBP) _____/_____

(i) 2nd BP ABPM (SBP/DBP) _____/_____

4. Next three readings manually aborted?

5. Instructions to participant provided and reviewed?

6. ABPM Cuff Size Used (17-26 cm) Sm adult 1
(24-32 cm) Adult 2
Arm circumference from 1st Run-in BP _____ cm (32-42 cm) Lg adult 3
(38-50 cm) XL adult 4

Reviewed by (staff ID): _____
Entered by (staff ID): _____

ABPM PLACEMENT FORM

Used For: Placement of ABP Monitor on participant during the last nine days of each intervention period. Additional information on completion of form on page 6 of chapter 20.

ADMINISTERING INSTRUCTIONS

Placement of the monitor should follow the instructions on page 5 and 6 of ABP Monitor Chapter 20.

Complete questions 1 and 2.

3. a. The ID of the staff person placing the monitor.
 - b. Each monitor should have a 3 digit ID, the first digit being your site (1,2,3 or 4).
 - c. Date of placement Format is MM-DD-YYYY.
 - d. Time of placement, be sure to use correct AM or PM.
 - e. Arm used for cuff placement should be non-dominant arm unless no arm exist or for medical reason.
 - f. Record the first RZ reading and zero value.
 - g. Record the second RZ reading and zero value
 - h. Record the first ABP Monitor reading
 - i. Record the second ABP Monitor reading
4. Manually abort the next three readings only if there were no errors with the first two readings.
5. Review instructions with participant.
6. Record the Cuff size. Follow the guideline for cuff size on page 3 of chapter 20.

If participants arm circumference is larger then 50cm, do not conduct ABPM on this participant and check other in question # 1.

GENERAL CODING INSTRUCTIONS

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure each question is answered.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 5) The “Entered by” staff ID # should not be written until the form is entered.

ID #: Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant’s name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

VISIT: Check the appropriate box to indicate which intervention feeding period the participant is now in.

Q1. Check to make sure only one response is marked.

Q2. Check to make sure only one response is marked.

Q3 a. Record your staff ID number. This is a 3 digit number that starts with your site ID# (1,2,3 or 4).

b. Record the 3 digit number that appears on the monitor.

c. Check for leading zeroes and four digit year. If a date is missing, illegible, or the date is not within the cohort’s time frame, flag the form and resolve with clinic coordinator before entering the form.

d. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator.

e. Only one box should be checked.

f. The RZ BP should be an even number. This cannot be left blank. This field is a 3 digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator.

g. Same as 3f.

h. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator.

i. Same as 3h..

Q4. This information will not be entered. This is just a process check.

Q5. This information will not be entered. This is just a process check.

Q6: Check for the correct cuff size. The circumference should correspond to the cuff size. The cuff size and arm circumference should match what is on the initial Run-In Blood Pressure Form (#37). If cuff size is not marked, flag the form and resolve the clinic coordinator.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Record the Staff ID # of the person entering the data in the computer.

ABPM Participant Questionnaire

Overview

Have the participant complete questionnaire on return of monitor. Additional information on completion of form on page 6 of chapter 20.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure each question is answered.
- 4) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
- 5) The "Entered by" staff ID # should not be written until the form is entered.

ID #: Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

VISIT: Mark in one of the 3 boxes provided to indicate which intervention feeding period the participant is now in.

Q1: Check to make sure only one response is marked.

Q2: Check to make sure only one response is marked. If answer is "yes", then answer is needed for question 2a (interfere with work activities) needs to be answered also. If answer is "no" then skip to question 3.

Q2a: If "yes" to question 2, check one response.

Q3-5: Check to make sure only one response is marked.

Q6: Verify AM/PM, noon = 12:00pm

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer



ID # _____

Participant Information Sheet (Page 1 of 2)

The information included in this information sheet is very important to help us keep in contact with you during the course of the study. Please complete each item, printing in block capital letters. If there are parts that you cannot fill out, we will go over them with you later in the visit.

1. Name: _____
(first) (middle) (last)

2. Address: _____
(number) (street) (apt. number)

(city) (state) (zip code)

3. Home phone number: (_____) _____ - _____

4. Social Security number: _____ - _____ - _____ None _____

5. Name of employer:* _____

Address: _____
(number) (street)

(city) (state) (zip code)

Work phone number: (_____) _____ - _____

If necessary, is it all right to call you at work? Yes _____ No _____

6. What is the best time to call you? _____ Is this at HOME or at WORK (circle one)?

7. Who is your usual doctor or health care provider?*

Name: _____

Address: _____
(number) (street)

(city) (state) (zip code)

Phone number: (_____) _____ - _____

* We will not contact your employer or doctor without your permission.

Participant Information Sheet (Page 2 of 2)

Since it will be very important for us to stay in touch with you throughout the study period, it would be a great help if you could provide us with the names of two relatives or friends who do not live with you and whom we could contact if we were unable to reach you directly.

8. Name: _____
(first) (middle) (last)

Address: _____
(number) (street) (apt. number)

(city) (state) (zip code)

Daytime phone #: (_____) _____ - _____ Evening phone #: (_____) _____ - _____

Relationship to you: _____

9. Name: _____
(first) (middle) (last)

Address: _____
(number) (street) (apt. number)

(city) (state) (zip code)

Daytime phone #: (_____) _____ - _____ Evening phone #: (_____) _____ - _____

Relationship to you: _____

THANK YOU VERY MUCH



ID# _____

Visit (check one):

Screening 4

IFP/I 6

IFP/II 7

IFP/III 8

Central Lab Collection Form - 24-hour urine

Data from worksheet (best of initial sample or repeat)

Collect Start Date _____ / _____ / _____

Start Time _____ : _____ AM or PM

Collect Stop Date _____ / _____ / _____

Stop Time _____ : _____ AM or PM

Time Sufficient (22-26 hours)..... Yes 1
No 2

Total Volume _____ cc

Volume Sufficient (500 cc) Yes 1
No 2

Sample obtained correctly Yes 1
 discarded initial void ≤1 voiding missed not menstruating No 2

Sample Collection Outcome Ready to ship to lab* 1
Failed 2

Duplicate Collection Outcome Ready to ship to storage* 1
Failed 2

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

Collected by (staff ID): _____
Entered by (staff ID): _____

Instructions for Central Lab Collection Form - 24-hour Urine and Central Lab Collection Form - 24-hour Urine - Worksheet

This form will be used to track the collection and shipping of 24-hour urine specimens. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a 24-hour urine specimen. Be sure to attach a label printed with the participant's DASH2 ID# to the upper right corner of each page of the form. Complete the worksheet first. Then fill in the form that will be sent to the lab with the specimen. The specimen should be collected during Screening or prior to the first full day of run-in (RI-1) and during days 22-30 of each Intervention feeding period.

Central Lab Collection Form - 24-hour Urine

Visit:

Mark Screening if specimen collected **prior to** the first full day of run in (RI-1).

Mark IFP/I if specimen collected **during** days 22-30 of intervention feeding period 1.

Mark IFP/II if specimen collected **during** days 22-30 of intervention feeding period 2.

Mark IFP/III if specimen collected **during** days 22-30 of intervention feeding period 3.

Data from worksheet (best of initial sample or repeat):

If the initial sample is adequate, copy all the data from the worksheet to this form. If it was necessary to repeat the sample, choose the better of the two to send to the lab and copy the data for the chosen sample from the worksheet to this form.

Sample Collection Outcome:

Mark ready to ship to lab when specimen has been collected and processed. It is possible that both samples will be inadequate. In this case the better of the two will be shipped to the lab.

Mark Failed if neither sample can be sent to the lab.

Duplicate Collection Outcome:

Mark Ready to ship to storage when an additional aliquot is available to be sent to the lab for storage. Mark Failed when no aliquot is available to be sent to the lab for storage.

Collected by and Entered by Staff ID:

Record the staff ID of the staff person collecting the sample. Record the staff ID of the staff person entering the data into the DASH2 Data Entry system after the form is entered.

Central Lab Collection Form - 24-hour Urine - Worksheet

Initial Sample

1. Collect Start Date and Start Time:

Record the start date and start time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 pm.

2. Collect Stop Date and Stop Time:

Record the stop date and stop time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 pm.

3. Number of Hours:

Subtract stop time from start time. Round answer, in hours, to nearest whole number. This is a two digit field. Use leading zeros as appropriate.

4. Time Sufficient:

Mark Yes if Number of Hours is at least 22 but not more than 26 hours.
Mark No if Number of Hours is fewer than 22 or more than 26 hours.

5. Total Volume:

Record total volume in cubic centimeters of urine as measured using a graduated cylinder. Use leading zeros if necessary. This is a 4 digit field.

6. Volume Sufficient:

Mark Yes if Total Volume is at least 500 cc.
Mark No if Total Volume is less than 500 cc.

7. Sample obtained correctly:

Mark Yes only if all three boxes below are checked.

Mark No if any of the three boxes below are not checked.

discarded initial void. Mark box if participant has discarded the first urine of the day and recorded the time of that first voiding as the start time.

≤ voiding missed. Mark box if participant has missed collecting no more than 1 sample during the 24 hour collection period

not menstruating. Mark box if participant is not menstruating.

8. Initial Sample Collection Outcome:

Mark Adequate if answers are YES to #4, #6 and #7.

If **any** of the #4, #6 or #7 are answered NO, mark Inadequate.

Repeat Sample

9. Collect Start Date and Start Time:

Record the start date and start time as recorded on the label attached to the urine collection jug, For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 pm.

10. Collect Stop Date and Stop Time:

Record the stop date and stop time as recorded on the label attached to the urine collection jug, For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 pm.

11. Number of Hours:

Subtract stop time from start time. Round answer, in hours, to nearest whole number.

12. Time Sufficient:

Mark Yes if Number of Hours is at least 22 but not more than 26 hours.

Mark No if Number of Hours is fewer than 22 or more than 26 hours.

13. Total Volume:

Record total volume in cubic centimeters of urine as measured using a graduated cylinder. Use leading zeros if necessary. This is a 4 digit field.

14. Volume Sufficient:

Mark Yes if Total Volume is at least 500 cc.

Mark No if Total Volume is less than 500 cc.

15. Sample obtained correctly:

Mark Yes only if all three boxes below are checked.

Mark No if any of the three boxes below are not checked.

discarded initial void. Mark box if participant has discarded the first urine of the day and recorded the time of that first voiding as the start time.

≤ voiding missed. Mark box if participant has missed collecting no more than 1 sample during the 24 hour collection period

not menstruating. Mark box if participant is not menstruating.

16. Repeat Sample Collection Outcome:

Mark Adequate if answer is YES to #12, #14 **and** #15.

If answer is NO to **any** of #12, #14 or #15, mark Inadequate.

Overall Collection Outcome:

Mark whether the Initial sample was adequate or the better of the two, the Repeat sample was adequate or the better of the two, or Both collection attempts failed and neither sample can be sent to the lab. Copy the data from the chosen sample onto page 1 of form 30.



ID# _____

Visit (check one):

- SV3 4
- IFP/I 6
- IFP/II 7
- IFP/III 8

Central Lab Collection Form - Fasting Blood

Data from worksheet (best of initial draw or repeat)

Collect Date / /

Collect Time : AM or PM

Fasting time hours

Fasting time sufficient (8+ hours) Yes 1
No 2

Upright time (for renins) minutes

Upright time sufficient (90+ minutes, include seated time) Yes 1
No 2

Lipid Vial Collection Outcome (red) Ready to ship to lab* 1
Failed 2

Renin Vial Collection Outcome (purple) Ready to ship to lab* 1
Failed 2

Buffy Vial Collection Outcome (purple) Ready to ship to storage* 1
Failed 2

Extra Serum Vials Collection Outcome (red) Ready to ship to storage* 1 # vials: _____
Failed 2

Extra Plasma Vials Collection Outcome (clear) Ready to ship to storage* 1 # vials: _____
Failed 2

*Includes adequate draws, and also inadequate draws where obtaining an adequate draw was not possible.

Collected by (staff ID): _____ Entered by (staff ID): _____
--



ID# _____

Central Lab Collection Form - Fasting Bloods - Worksheet

Initial Draw

1. Collect Date ___/___/____ Collect Time ___:___ AM or PM
2. Fasting time _____ hours
3. Fasting time sufficient (8+ hours) Yes No
4. Upright time (for renins) _____ minutes
5. Upright time sufficient (90+ minutes, include seated time) Yes No
6. Lipid Vial Collected (red)..... Yes No Hemolyzed
7. Renin Vial Collected (purple)..... Yes No Hemolyzed
8. Buffy Vial Collected (purple)..... Yes No Hemolyzed
9. Extra Serum Vials Collected (red)..... Yes No Hemolyzed # vials: _____
10. Extra Plasma Vials Collected (clear)..... Yes No Hemolyzed # vials: _____
11. Initial Draw Outcome..... Adequate (answer is YES to #3, #5-#10)
Inadequate, repeat the draw (optional)

Repeat Draw

12. Collect Date ___/___/____ Collect Time ___:___ AM or PM
13. Fasting time _____ hours
14. Fasting time sufficient (8+ hours) Yes No
15. Upright time (for renins) _____ minutes
16. Upright time sufficient (90+ minutes, include seated time) Yes No
17. Lipid Vial Collected (red)..... Yes No Hemolyzed
18. Renin Vial Collected (purple)..... Yes No Hemolyzed
19. Buffy Coat Vial Collected (purple)..... Yes No Hemolyzed
20. Extra Serum Vials Collected (red)..... Yes No Hemolyzed # vials: _____
21. Extra Plasma Vials Collected (clear)..... Yes No Hemolyzed # vials: _____
22. Initial Draw Outcome..... Adequate (answer is YES to #14, #16-#21)
Inadequate

Overall Collection Outcome

- Initial draw was adequate, or initial draw was the best of the two
- Repeat draw was adequate, or repeat draw was the best of the two
- Failed (neither draw can be sent to the lab)

Instructions for Central Lab Collection Form - Fasting Bloods and Central Lab Collection Form - Fasting Bloods - Worksheet

This form will be used to track the collection and shipping of fasting blood specimens. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to draw a fasting blood specimen. Be sure to attach a label printed with the participant's DASH2 ID# to the upper right corner of each page of the form. Complete the worksheet first. Then fill in the form that will be sent to the lab with the specimen. The specimen should be drawn during Screening or prior to the first full day of run-in (RI-1) and during days 22-30 of each Intervention feeding period.

Central Lab Collection Form - Fasting Bloods

Visit:

Mark Screening if specimen collected **prior to** the first full day of run in (RI-1).
Mark INT1 if specimen collected **during** days 22-30 of intervention feeding period 1.
Mark INT2 if specimen collected **during** days 22-30 of intervention feeding period 2.
Mark INT3 if specimen collected **during** days 22-30 of intervention feeding period 3.

Data from worksheet (best of initial sample or repeat):

If the initial sample is adequate, copy all the data from the worksheet to this form. If it was necessary to repeat the sample, choose the better of the two to send to the lab and copy the data for the chosen sample from the worksheet to this form.

Lipid Vial Collection Outcome:

Mark Ready to ship to lab when specimen has been collected and processed. It is possible that both samples will be inadequate. In this case the better of the two will be shipped to the lab.
Mark Failed if neither sample can be sent to the lab.

Renin Vial Collection Outcome:

Mark Ready to ship to lab when specimen has been collected and processed. It is possible that both samples will be inadequate. In this case the better of the two will be shipped to the lab.
Mark Failed if neither sample can be sent to the lab. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

Buffy Coat Vial Collection Outcome:

Mark Ready to ship to storage when specimen has been collected and processed. It is possible that both samples will be inadequate. In this case the better of the two will be shipped to the storage. Mark Failed if neither sample can be sent to the storage. Note: Because Buffy coats are not collected during the intervention periods, draw a slash through the answer field at IFP/I, IFP/II and IFP/III. The data entry program will skip this field.

Extra Serum Vials Collection Outcome:

Mark Ready to ship to storage when additional aliquots are available to be sent to the lab for storage. Mark Failed when the aliquots will not be sent to the lab for storage.

Extra Plasma Vials Collection Outcome:

Mark Ready to ship to storage when the additional aliquots are available to be sent to the lab for storage. Mark Failed when the aliquots will not to be sent to the lab for storage.

Collected by and Entered by Staff ID:

Record the staff ID of the staff person collecting the sample. Record the staff ID of the staff person entering the data into the DASH2 Data Entry system after the form is entered.

Central Lab Collection Form - Fasting Bloods - Worksheet

Initial Draw

1. Collect Date and Collect Time:

Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 PM.

2. Fasting Time:

Round answer, in hours, to nearest whole number. This is a two digit field. Use leading zeros as appropriate.

3. Fasting Time Sufficient:

Mark Yes if Number of Hours is at least 8 hours. Mark No if Number of Hours is less than 8 hours.

4. Upright Time (for renins):

Mark the number of minutes in upright position. This a three digit field. Use leading zeros as appropriate. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

5. Upright Time Sufficient:

Mark Yes if Upright Time is at least 90 minutes. Mark No if Upright Time is less than 90 minutes. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

6. Lipid Vial Collected (red):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed.

7. Renin Vial Collected (purple):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

8. Buffy Coat Vial Collected (purple):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Note: Because Buffy coats are not collected during the intervention periods, draw a slash through the answer field at IFP/I, IFP/II and IFP/III. The data entry program will skip this field.

9. Extra Serum Vials Collected (red):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Record the number of vials collected.

10. Extra Plasma Vials Collected (clear):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Record the number of vials collected.

11. Initial Draw Outcome:

Mark Adequate if **all** of the following answers are YES: #3, #5, #6, #7, #8, #9, **and** #10.

Mark Inadequate if **any** of the following answers are NO or Hemolyzed: #3, #5, #6, #7, #8, #9, or #10. A repeat draw is optional.

Repeat Draw

12. Collect Date and Collect Time:

Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Noon = 12:00 PM.

13. Fasting Time:

Round answer, in hours, to nearest whole number. This is a two digit field. Use leading zeros as appropriate.

14. Fasting Time Sufficient:

Mark Yes if Number of Hours is at least 8 hours. Mark No if Number of Hours is less than 8 hours.

15. Upright Time (for renins):

Mark the number of minutes in upright position. This a three digit field. Use leading zeros as appropriate. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

16. Upright Time Sufficient:

Mark Yes if Upright Time is at least 90 minutes. Mark No if Upright Time is less than 90 minutes. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

17. Lipid Vial Collected (red):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed.

18. Renin Vial Collected (purple):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Note: Because renins are not collected at SV3, draw a slash through the answer field at SV3. The data entry program will skip this field.

19. Buffy Coat Vial Collected (purple):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Note: Because Buffy coats are not collected during the intervention periods, draw a slash through the answer field at IFP/I, IFP/II and IFP/III. The data entry program will skip this field.

20. Extra Serum Vials Collected (red):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Record the number of vials collected.

21. Extra Plasma Vials Collected (clear):

Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed. Record the number of vials collected.

22. Repeat Draw Outcome:

Mark Adequate if **all** of the following answers are YES: #14, #16, #17, #18, #19, #20, **and** #21. Mark Inadequate if **any** of the following answers are NO or Hemolyzed: #14, #16, #17, #18, #19, #20, or #21.

Overall Collection Outcome:

Mark whether the Initial sample was adequate or the better of the two, the Repeat sample was adequate or the better of the two, or Both collection attempts failed and neither sample can be sent to the lab. Copy the data from the chosen sample from the worksheet to the first page of form 31.



Site: _____

Cohort: _____

Week of: _____

Recruitment Activities Log

Description of Activity	Type of Activity	Quantity of Activity

Codes for Type of Activity:

- 01 = Mailed letter/brochure/flier
- 02 = Non-paid radio story
- 03 = Screening events/health fair
- 05 = Non-paid print story
- 06 = Non-paid TV story
- 07 = Presentations
- 08 = Valpack
- 09 = Brochure/flier distributed other than mailing
- 10 = Paid print advertisement
- 11 = Paid radio advertisement
- 12 = Paid TV advertisement
- 13 = Email distribution list

Units of Quantity of Activity:

- # brochures, rounded to nearest 100
- # stories
- # events (not persons)
- # stories
- # stories
- # presentations (not persons)
- # brochures, rounded to nearest 100
- # brochures distributed, rounded to nearest 100
- # spots printed
- # spots aired
- # spots aired
- # email messages sent

Entered by (staff ID): _____

Instructions for Recruitment Activities Log

The purpose of this form is to collect information about the various activities performed to recruit participants for DASH2. Part of the data will be entered and used in generation of recruitment reports. Data is to be entered weekly.

Site:

Baltimore	=	1
Baton Rouge	=	2
Boston	=	3
Durham	=	4

Cohort #: Use numbers 1, 2, 3, etcetera

Week of: Use Monday's date. Use leading zeros as appropriate. (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

Description of Activity (this information will not be entered.) These descriptions will be used to help the sites keep track of exactly what was done, what population was involved and any other pertinent information about the activity.

Codes for Type of Activity (this information will be entered.) The codes (defined below) are the same as codes used on the PSV form to collect information about how a participant learned about the study. This is a two-digit field.

01=Mailed letter/brochure/flier: any mass mailing of DASH2 information that requests a mail or phone response. This does not include calls or cards returned as a result of distributing brochures by other means (e.g. hand distribution at stores, malls). Those should be coded as **(09)**.

02=Non-paid radio story: any free radio announcement, ad, interview or program that gives information about DASH2.

03=Screening events/health fair: any gathering or event that occurs outside a DASH2 clinic. It may last one or more days. Screening could include , churches, shopping malls, special events, etc.

05=Non-paid print story: any free local or national newspaper or magazine article or public service announcement or newsletter (church, worksite, hospital, HMO, MCO, and professional organization) that gives information about DASH2. This would also include payroll stuffers that are placed without a fee.

06=Non-paid TV story: any free TV announcement, ad, interview, or program that gives information about DASH2.

07=Presentations: any presentations other than screening done outside a DASH2 center.

Additional codes:

08=Valpack: any mass mailing through companies which include DASH2 brochure or special coupons with other coupons.

09=Brochure/flier distributed other than mailing: this includes brochures left on display at sites, libraries, grocery stores, and pharmacies. These should be coded to distinguish them from other brochures. Be sure staff answering phones are aware of posting of information or distribution of fliers and brochures

10=Paid print advertisement: any print (newspaper, circular, magazine, etc.) ad that is paid for by a DASH2 site. This could include inserts in newspapers or utility bills (if it was paid to be inserted).

11=Paid radio advertisement: any radio ad or announcement that is paid for by a DASH2 site.

12=Paid TV advertisement: any TV ad or announcement that is paid for by a DASH2 site.

13=E-mail distribution list: any information distributed through e-mail.

Units of Quantity of Activity (This information will be entered. # of digits in field to be decided later) These numbers are crucial to building accurate recruitment reports.

Activity Code # 01 Mailed letter/brochure/flier

Activity Code # 08 Valpack

Activity Code # 09 Brochure/flier distributed other than mailing

= **number of brochures/fliers, rounded to the nearest 100.**

Activity Code # 02 Non-paid radio story

Activity Code # 05 Non-paid print story

Activity Code # 06 Non-paid TV story

= **number of stories/articles.** For this activity, it is important to count total number of stories. For example, if your newspaper ran a series of articles that talked about DASH2, each day it appeared would count as one story.

Activity Code # 10 Paid print advertisement

Activity Code # 11 Paid radio advertisement

Activity Code # 12 Paid TV advertisement

= **number of spots aired/printed.** For this activity, it is important to count total spots. For example if you had a radio spot that aired 3 times daily for 1 week, you would enter 21 total spots.

Activity Code # 03 Screening events, health fairs

Activity Code # 07 Presentations

= **number of events or presentations (not # of persons attending).**

Activity Code # 13 E-mail

= **number of email messages sent.**



Run-in (days 8-10)

ID # _____

Case Conference Form

The Case Conference occurs after day 8 of run-in. The purpose is to determine eligibility for randomization. The dietary staff use the compliance data collected during run-in to make the determination. The following materials are recommended to be used:

- Compliance Report (days 2-8 of run-in)
- Weight Tracking Report
- Daily Diaries (days 2-8 of run-in)
- Participant chart

Date of Conference _ _ / _ _ / _ _ _ _

Notes: _____

Case Conference Outcome..... **eligible** 1
ineligible 2

Once the case conference has been completed, check the appropriate box on the Run-In Flow Form (#16). If the participant is determined not to be eligible, check “pre randomization exclusion/dropout” for run-in outcome and complete the Participant Closeout Form (#18). On the closeout form, check “diet compliance”, for the reason of exclusion.

Reviewed by (staff ID): _____ Entered by (staff ID): _____

Case Conference Form Instructions

The Case Conference Form is used to determine eligibility for randomization. The following materials are recommended to use when conducting the conference.

- Compliance Report (days 2-8 of Run-in)
- Weight Tracking Report
- Daily Diaries (days 2-8 of Run-in)
- Participant chart

GENERAL CODING INSTRUCTIONS

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns. .
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Case Conference Form Coding Instructions

ID #: Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

DATE OF CONFERENCE:

Clearly enter the date, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use four digit year. If date is missing, illegible, or the time frame is not within the cohort's dates, flag the form and resolve question before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

NOTES:

Not to be entered. Use for any notes about participant.

OUTCOME:

Code the final outcome by checking the appropriate box. Once the case conference has been completed, check the appropriate box on the Run-In Flow Form (#16). If the participant is determined not to be eligible, check "pre randomization exclusion/dropout" for run-in outcome and complete the Participant Closeout Form (#18). On the closeout form, check "diet compliance" for the reason of exclusion.

Reviewed by:

Record the Staff ID # of the person reviewing the form.

Entered by:

Record the Staff ID # of the person entering the data in the computer.



Name _____

ID # _____

REASON FOR NON-ENROLLMENT

Date of Non-enrollment _ _ / _ _ / _ _ _ _

A. Fill this section out for participants INELIGIBLE prior to PSV who have no study forms completed:

Please mark the primary reason for ineligibility:

1. blood pressure medication
2. medical history exclusion
3. other exclusion: _____

B. Fill this section out for participants who decide NOT TO ENROLL or to DISCONTINUE PARTICIPATION at any time for reasons other than eligibility.

Please mark the primary reason.

1. DASH2 not a weight loss program
2. unwilling/ unable to change diet
3. not enough time or scheduling problem
4. transportation problem
5. doesn't want to participate in research
6. too much effort involved
7. too many lab tests required
8. persistent no show
9. other reason for lack of interest: _____

C. Fill this section out for EVERYBODY who does not enroll or discontinues. At what point did the participant either lose interest or become ineligible?

1. Prior to PSV(no other study forms completed)
2. At a screening visit (complete Visit Flow form)
3. Between visits prior to randomization (complete Participant Closeout form 18)
4. After randomization (complete Premature Study Termination form 22)

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Administrative and Coding Instructions for Reason for Non-Enrollment Form

Beginning at PSV, DASH2 staff should identify the primary reason why participants did not enroll in the trial. These data will be collected and analyzed locally at each DASH2 clinical center, primarily for the purpose of identifying why individuals did not enter the trial. These data will be collected during cohort 1 on the Reason for Non-Enrollment form. The recruitment coordinator at each site will track the completion of this form.

Section A is completed only for participants who are ineligible prior to PSV who have no other study forms completed. Reasons for ineligibility at any other time are recorded on other study forms.

Section B is completed for participants who decide not to enroll or to discontinue participation at any time for reasons other than eligibility.

Section C is completed for everyone on whom this form is completed.

Because the purpose of the form is to capture primary reason, either section A or B is completed for a participant but not both.

If the form is completed prior to PSV, it will have no ID number but will have the participant's name. The form will not be attached to anything.

If the form is completed during PSV, the site will have a choice about whether to complete the regular PSV form to have identifying information. The form will be attached to the completed PSV form. The site may enter that PSV information for participants who are either not interested or not eligible for SV1 but an ID # is not generated.

If the form is completed after PSV, it will have a specific ID # associated with it. It is intended to be used at any point in the process up through intervention and is intended to pick up a level of detail about the reasons that is not captured in the standard process. **This form does not replace the standard process for closing out participants.** Official closeout can be done at a visit and recorded on the visit flow form. Participant Closeout Form (# 18) must still be completed for anyone closed out prior to randomization and between visits. If the participant has been randomized, the Premature Study Termination Form (#22) is used to close out the participant. The current form (#34) does not alter the standard process at all.

Using your best judgement, the recruitment tech should check the one category that best describes why the participant did not enroll. For persons who are uninterested, ask the individual for the reason. For persons who are ineligible, a DASH2 staff member should indicate the exclusion criterion (if the reason for ineligibility has not previously been recorded on a PSV or other study form). There may be times when two categories apply, in which case the person completing the form should select the primary reason.

Initially, the data from this form will not be entered. Until further notice, ignore the field "Entered by (staff ID)."

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns. .
- 10) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Reason for Non-Enrollment Form

Name: When completing form, enter participant’s name if ID# has not yet been assigned..

ID #: When completing form, enter participant’s DASH ID# if one has been assigned at PSV.

Section A: Fill out this section only for participants who are **ineligible prior to PSV**. Mark only one answer.

Section B: Fill out this section only for participants who **decide** not to enroll or to discontinue participation **at any time for reasons other than eligibility**. Mark only one answer.

Section C: Fill out this section for everyone who does not enroll or discontinues. Mark only one answer.

If C. 1. marked, complete no other study forms.

If C. 2. marked, complete Visit Flow form.

If C. 3. marked, complete Participant Closeout form (#18).

If C. 4. marked, complete Premature Study Termination form (#22).

Reviewed by: Record the staff ID of the person reviewing the form for completeness.

Entered by: Initially, the data from this form will not be entered. Until further notice, ignore the field “Entered by (staff ID).”



ID#: _____

Date: ____/____/____

Visit (check one):

Visit:

RI 5

IFP/I 6

IFP/II 7

IFP/III 8

Days (IFP only):

7-9 1

27-30 2

Diet Acceptability Questionnaire

Please answer the following questions concerning the food you have been given to eat **for the past week**. Please **circle one number only** for each question.

1. Please rate how much you **liked this diet** overall:

Disliked Extremely				Neither Liked nor Disliked				Liked Extremely
1	2	3	4	5	6	7	8	9

2. Please rate how **salty** you thought the diet was:

Not at all Salty				Moderately Salty				Extremely Salty
1	2	3	4	5	6	7	8	9

3. Please rate whether you liked **the overall saltiness** of this diet:

Dislike Extremely				Neither Like nor Dislike				Liked Extremely
1	2	3	4	5	6	7	8	9

4. How willing would you be to **continue eating this level of saltiness** after this study:

Not at all Willing				Unsure				Extremely Willing
1	2	3	4	5	6	7	8	9

5. Please rate how much you liked eating the **amount of fruits and vegetables** in this diet:

Dislike Extremely				Neither Like nor Dislike				Like Extremely
1	2	3	4	5	6	7	8	9

6. How willing would you be to **continue eating this amount of fruits and vegetables** after this study:

Not at all Willing				Unsure				Extremely Willing
1	2	3	4	5	6	7	8	9

7. Please rate how much you liked eating the **amount of milk and dairy products** in this diet:

Dislike Extremely				Neither Like nor Dislike				Like Extremely
1	2	3	4	5	6	7	8	9

8. How willing would you be to **continue eating this amount of milk and dairy products** after this study:

Not at all Willing				Unsure				Extremely Willing
1	2	3	4	5	6	7	8	9

9. How willing would you be to **continue eating this type of diet** after this study:

Not at all Willing				Unsure				Extremely Willing
1	2	3	4	5	6	7	8	9

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Administration and Coding Instructions for Diet Acceptability Questionnaire

Administering Instructions

The Diet Acceptability Questionnaire is administered by the dietary staff, preferably prior to eating on the day it is administered. The staff should be available to answer questions about the form the first time that the participant completes it.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black, or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made, by first making a slash through the incorrect entry, and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Diet Acceptability Questionnaire Coding Instructions

ID #: ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant’s name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date: Enter the date when the form was completed, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four-digit year.

Type of Visit: Check whether the appropriate box has been checked to designate when form was completed (during Run-in or in one of the 3 Intervention feeding periods. Only one box should be marked.)

Days: For each Intervention feeding period, this questionnaire is collected twice, once between days 7 and 9 and again between days 27 and 30. Check to make sure one box is checked and that it is the appropriate box.

Questions 1 - 9: Check to be sure only one response (numbers 1 through 9) was circled for each question.



SHIPPING LOG

Mail to: Reesa Laws
 DASH2 Coordinating Center
 Kaiser Permanente Center for Health Research
 3800 N Interstate Avenue
 Portland, OR 97227-1098

Phone: (503) 499 - 5780
 FAX: (503) 499 - 5680

From: Study Center (circle one):

1 - Baltimore

2 - Baton Rouge

3 - Boston

4 - Durham

Quantity Sent	Description	Coordinating Center Use Quantity Received	Staff ID
_____	Diskettes _____	_____	_____
_____	Form #9-Food Frequency Questionnaire (original)	_____	_____
_____	Certification Forms	_____	_____
_____	Forms for Validation (copy)	_____	_____
_____	Database Corrections	_____	_____
_____	Other, describe _____	_____	_____

Shipped: __/__/__

Shipped by (Staff ID): _____

Via: Regular Mail _____
 UPS/Fed. Ex. 2-day _____
 UPS/Fed. Ex. Overnight _____
 Hand-Delivery _____

Comments:

Coordinating Center Received: __/__/__ Received by (Staff ID): _____

Comments:

Coding Instructions for Shipping Log

This form is used for shipping to the Coordinating Center; diskettes, Food Frequency forms, Certification forms and forms that the Coordinating Center requests for validation.

Study Center: Select and circle your site.

Quantity Sent: Record the number of forms/diskettes that you are sending to the CC.

Description:

Diskettes: Describe what files are on the diskette(s).

Food Frequency Questionnaires: Record the ID numbers of the FFQ's sent on the back of the shipping log. Make copies and send the originals to the CC.

Certification Forms: Record the form type(s) and staff IDs of those forms on the back of the shipping log.

Forms for Validation: Record the form type(s) and IDs on the back of the shipping log. Make copies and send copies to the CC.

Database Corrections: Record correction type(s) and ID's on the back of the shipping log.

Other: Describe

Quantity Received/Staff ID: To be filled out by CC.

Shipped: Record the ship date (MM/DD/YY) and Staff ID of person preparing shipment.

Via: Check which mail option you are using.

Comments: Record any comments about this shipment.

Coordinating Center Received: To be filled out by CC (date received and staff ID)

Comments: To be filled out by CC.



Initial Run-In
 ID # _____
 BP Date ____ / ____ / ____

Initial Run-In Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of Blood Pressure measurements: _____ : _____ AM or PM
 (noon = 12:00 pm)

b. Cuff size Small adult (< 24 cm) _____ (1) Adult (24-32 cm) _____ (2) Arm circumference _____ cm
 Large adult (33-41cm) _____ (3) Thigh (42-52 cm) _____ (4)

c. Able to obtain valid reading (see instructions) _____ yes (1) _____ no (2)

Wait five minutes seated

d. Resting 30-second pulse _____ / 30 seconds

e. Pulse obliteration pressure (POP) _____ mm Hg
 + 6 0

f. Random zero peak inflation level (PIL), minimum 180 mmHg _____ mm Hg

g. Blood Pressure device # _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value _____ / _____ mm Hg

b. Zero Value _____

c. Corrected value (a - b) _____ / _____ mm Hg

Wait 30 seconds

3. SECOND RANDOM ZERO BLOOD PRESSURE

a. Uncorrected value _____ / _____ mm Hg

b. Zero value _____

c. Corrected value (a - b) _____ / _____ mm Hg

4. SUM OF 2 SBPs AND 2 DBPs, Items 2c + 3c _____ / _____ mm Hg

If sum SBP (item #4) >340 or sum DBP (item #4) >210, **complete Form #23.**
 (see Clinical MOP Chapter 18 for further details)

Collected by (staff ID): _____ Entered by (staff ID): _____
--

Administration and Coding Instructions for Initial Run-in Blood Pressure Form

USE FOR: Blood pressure data collection for potential participants during run-in.

PURPOSE: Collect Blood Pressure data and remeasure arm circumference.

The Initial Run-in Blood Pressure Form must be filled out during the first week of run-in. ID # labels should be printed and placed on the Initial Run-in BP form.

Some data may require that participants be referred to site medical staff for consultation and the BP escape tracking form (#23) be completed.

Type of Visit - Verify that the correct blood pressure form is being used for this visit by checking the visit code in the upper right corner. It should say "Initial Run-in". This is form #37.

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. Assure that the ID # contains the first three letters of the participant's last name and the first two letters of the first name. If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

BP Date - Clearly enter the date when the blood pressure measurements are obtained, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four digit year.

1. Preparation for Blood Pressure Measurements

Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 11.

- a. This should be the time the person is seated and the process is begun. Noon is 12:00 pm.
- b. Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement.
- c. Indicate here whether you were able to obtain a valid blood pressure reading. If the brachial artery is occluded by the cuff, the participant is excluded from participating in DASH2 (see MOP Chapter 11. If this is so or if you were unable to obtain a valid blood pressure reading for any reason, Check No, note the reason, and check Ineligible on the Run-in Flow Form (#16). If you were able to obtain the reading, check Yes.

- d. Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
- e. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
- f. Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level and record the result. If this value is less than 180, enter 180.
- g. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a one digit field.

2. **Blood Pressure Readings**

Obtain two sitting blood pressure measurements using the random-zero device. Wait at least 30 seconds between each reading. Both readings and zero values are recorded to the nearest **even** number. Subtract the zero value from the corresponding reading with a hand calculator AFTER BOTH MEASUREMENTS ARE OBTAINED. Record the resulting corrected value for both of the measurements obtained. If DBP goes to 0 mmHg, use the 4th phase DBP for all BP measurements. Be sure to write in leading zeros if less than 100.

Add the two corrected SBP and DBP measurements (2c and 3c) together and record the sum in item #4. The escape BP levels are also shown at the bottom of the page. If these latter thresholds are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#23) should be filled out. Refer to MOP Chapter 6 for details and complete form #23.

3. **DASH Identification Number of Person Taking and Entering BP**

Collected by: record the Staff ID # of the person performing the blood pressure measurements.

Entered by: record the Staff ID # of the person entering the data into the computer.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns. .
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Coding Instructions for Initial Run-in Blood Pressure Form

Visit and participant identification data:

ID

ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

BP Date

Check for leading zeros and four digit year. If a date is missing, illegible, or the time frame is not within the cohort's dates, flag the form and resolve with clinic coordinator before entering the form. An audit will be created if data entered are outside the normal range or if data are missing.

1. Preparation for Blood Pressure Measurements

- a. Check for the correct time. The time should correspond to the DASH2 clinic operating hours. If the time is outside the operating hours, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- b. Check for the correct cuff size. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Code the rounded arm circumference. The circumference should correspond to the cuff size. If the cuff size is not marked, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

- c. Check whether valid blood pressure was obtained. If No is checked, the fields that follow (1.d. through 4.) will be blank and no audit will be created. If Yes is checked, all the following fields must be filled in. Any missing data in these fields will generate an audit.
- d. The resting pulse is a two digit field and, if item 1.c. is marked yes, cannot be missing. If the resting pulse is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- e. The pulse obliteration pressure is a three digit field and, if item 1.c. is marked yes, cannot be missing. If the (POP) is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- f. Check for correct addition. The random zero peak inflation level should equal the sum of the (POP) plus 60. If the sum is less than 180, write in 180 for the (PIL). If the (PIL) is missing or is outside the normal range, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.
- g. This is a one digit field. If the BP device # is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

2. First Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
- c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing

3 Second Random Zero Blood Pressure

- a. The uncorrected value should be an even number, this cannot be left blank. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic

coordinator. An audit will be created if data entered are outside the normal range or if data are missing

- b. The zero value should be an even number and cannot be left blank. This field is a two digit field, a leading zero should be used if the value is less than two digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
 - c. The corrected value should be an even number and should not be left blank. Check subtraction of zero value from uncorrected value. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing
4. Sum of 2 SBPs and 2 DBPs. Check for addition accuracy of $2c + 3c$. This field is a three digit field and a leading zero should be used if the value is less than three digits. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

5. DASH Identification Number of Persons Taking and Entering BP

Staff ID number of person performing the blood pressure measurements cannot be left blank. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.

Staff ID number of person entering the data cannot be left blank. This value should not be on the form until everything else on the form has been entered. This is a three digit field and the first digit should always start with the site ID #. If the value is missing, flag the form and resolve with the clinic coordinator. An audit will be created if data entered are outside the normal range or if data are missing.



Central Lab Shipping Log - Urine

Ship to: Lab 1
Storage 2
Box Number: _____
Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

Ship to: Lab 1

Storage 2

Box Number: _____

Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					
41					
42					
43					
44					
45					
46					
47					
48					
49					

Reviewed by (staff ID): _____

This form is for internal use only. It will not be entered into the DASH2 data entry system. Below are suggestions for how you may want to use/code this form.

Coding Instructions for Central Lab Shipping log - Urine

Samples should be logged while placing them in the shipping box.

Ship to

Check if samples are going to Cole's Lab or to Storage.

Box number

Record the unique box number

Clinical Site

1=Baltimore
2=Baton Rouge
3=Boston
4=Durham

Slot Number

The box slot number corresponds to the place in the shipping box where the urine sample is placed. See box mapping at the end of the coding instructions.

Participant ID

The ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

Visit

Record the visit when the samples were taken.

4=SV3
6=IFP/I
7= IFP/II
8= IFP/III

Collect Date

Record the date when the sample was collected (mm/dd/yyyy).

Sample Type

1=With HCL
2=No HCL

Comments

Record any comments/problems with the samples.

Reviewed by:

Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank.

Box Mapping:

Do not place any samples in the shaded area. See map below. Shaded portion of form should be left blank.

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7



Central Lab Shipping Log - Blood

Ship to: Lab 1
Storage 2
Box Number: _____
Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

Ship to: Lab 1

Storage 2

Box Number: _____

Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					
41					
42					
43					
44					
45					
46					
47					
48					
49					
50					

Ship to: Lab 1
Storage 2
Box Number: _____
Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
51					
52					
53					
54					
55					
56					
57					
58					
59					
60					
61					
62					
63					
64					
65					
66					
67					
68					
69					
70					
71					
72					
73					
74					
75					

Ship to: Lab 1
 Storage 2
 Box Number: _____
 Clinical Site: _____

Slot Number	Participant ID	Visit #	Collect Date	Sample Type	Comment
76					
77					
78					
79					
80					
81					
82					
83					
84					
85					
86					
87					
88					
89					
90					
91					
92					
93					
94					
95					
96					
97					
98					
99					
100					

Reviewed by (staff ID): _____

This form is for internal use only. It will not be entered into the DASH2 data entry system. Below are suggestions for how you may want to use/code this form.

Coding Instructions for Central Lab Shipping log - Blood

Samples should be logged while placing them in the shipping box.

Ship to

Check if samples are going to Cole's Lab or to Storage.

Box Number

Record the unique box number

Clinical Site

1=Baltimore

2=Baton Rouge

3=Boston

4=Durham

Slot Number

The box slot number corresponds to the place in the shipping box where the urine sample is placed. See box mapping at the end of the coding instructions.

Participant ID

The ID # should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345)

Visit

Record the visit when the samples were taken.

4=SV3

6=INT1

7=INT2

8=INT3

Collect Date

Record the date when the sample was collected (mm/dd/yyyy).

Sample Type

1=Serum

2=Plasma

Comments

Record any comments/problems with the samples.

Reviewed by:

Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank.



Quarterly Checklist for Monitoring DASH2 Blood Pressure Observers
(To be kept on file at the Clinical Center)

Performing DASH2 Technician Certification Code # _____

Observer DASH2 Technician Certification Code # _____

Date Observed ___/___/___ (Month/Day/Year)

Instructions: Check if procedure step is carried out correctly.

<u>Procedure</u>	<u>Comments</u>
1. ___ Check equipment	_____
2. ___ Give participant explanation of procedures	_____
3. ___ Measure arm for correct cuff size	_____
4. ___ Palpate brachial artery	_____
5. ___ Mark brachial artery point	_____
6. ___ Check center of bladder and wrap cuff correctly	_____
7. ___ Wrap cuff center of bladder over brachial pulse	_____
8. ___ Leave subject for 5 min. rest, instruct on posture, smoking, talking	_____
9. ___ Take radial pulse	_____
10. ___ Determine pulse obliteration using standard manometer	_____
10a. ___ Calculate peak inflation level	_____
11. ___ Open bellows valve, wait for mercury to settle	_____
12. ___ Turn thumb wheel gently	_____
13. ___ Place stethoscope in ears	_____
14. ___ Palpate brachial artery, position bell of stethoscope on brachial artery	_____
15. ___ Inflate rapidly to peak inflation level (PIL)	_____
16. ___ Count full 5 seconds with pressure steady	_____
17. ___ Close bellows knob	_____
18. ___ Deflate cuff 2 mmHg per second	_____
19. ___ Deflate cuff 10 mmHg after last audible sound heard	_____
20. ___ Instruct participant to raise arm for 5 seconds	_____
21. ___ Record readings	_____
22. ___ Read zero value	_____
23. ___ Begin steps for next readings	_____



Name (trainee) _____
Staff ID # _____
Date _____ / _____ / _____

BLOOD PRESSURE WRITTEN EXAMINATION

1. Whenever the pulse is measured, it must be counted for ____ seconds.
2. Whenever the blood pressure is to be measured, the participant must first be in the _____ position for _____ minutes without _____.
3. a. To find the pulse obliteration pressure by use of a standard sphygmomanometer, first inflate the cuff while palpating the radial pulse until the pressure reaches ____ mmHg, and then slowly inflate ____ mmHg at a time until the radial pulse can no longer be felt.
b. It is not permitted to use this inflation of the cuff for carrying out an actual DASH2 reading:
True False
4. a. To find the peak inflation level to be used for Random-Zero (R-Z) readings, a number must be added to the correct pulse obliteration pressure.
True False
b. This number is _____.
5. The deflation rate of the cuff must be carefully controlled, at a rate of _____ mmHg per second.
6. The interval between readings must be at least ____ seconds.
7. Use of regular adult cuff when a larger one is required would (check which applies):
____ (1) give a falsely high blood pressure reading
____ (2) likely cause difficulty in securely wrapping the cuff
____ (3) be preventable by checking the DASH2 range markings before wrapping the cuff, and being properly equipped
____ (4) all of the above
____ (5) none of the above

8. The major cause of digit preference is dropping the mercury too quickly.

True

False

9. One arm is used to measure the blood pressure. In DASH2 the preferred arm is:
(circle one)

Right

Left

10. All blood pressure technicians are to be blinded to diet assignment, and participants are blinded to their study blood pressure data.

True

False

11. The major advantage of the random-zero device is that it: Explain:

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Name (trainee) _____
 Staff ID # _____
 Date _____/_____/_____

Trainer
 Technician

Set: 1
 2
 3

BLOOD PRESSURE (Y-TUBING) CERTIFICATION FORM

Blood Pressure Measurement
 ** Wait 5 minutes seated **

Resting 30-second pulse _____/30 sec. Arm Circumference _____/ cm.

Cuff Size Small adult (<24 cm) _____ Adult (24-32) _____
 Large adult (>32-41cm) _____ Thigh (>41 cm) _____

Pulse obliteration pressure (POP) _____ mmHg
 + 6 0

Peak inflation level (PIP) for RZM _____ mmHg

1. First random zero blood pressure SBP/DBP
 Uncorrected _____/_____ mmHg
 Zero value _____
 Corrected _____/_____ mmHg

** Wait 30 Seconds**

2. Second random zero blood pressure SBP/DBP
 Uncorrected _____/_____ mmHg
 Zero value _____
 Corrected _____/_____ mmHg

Total of two measurements SBP/DBP _____/_____ mmHg
 Average of two measurements _____/_____ mmHg

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

BLOOD PRESSURE OBSERVATION CHECKLIST

A. Equipment and Supplies

The technician should indicate that all equipment and supplies needed for blood pressure measurements are present. Check each item as identified:

- ___ (1) Random-Zero Sphygmomanometer
- ___ (2) Standard Sphygmomanometer
- ___ (3) Cuffs - full set of 4 ("small adult", "adult", or "regular", "large adult", and "thigh") with DASH2 range markings added.
- ___ (4) Inflation Bulb
- ___ (5) Bell Stethoscope
- ___ (6) Watch with second hand or stop watch
- ___ (7) BP Assessment Form

B. Arm Measurement

- ___ (1) Arm bare from elbow to shoulder
- ___ (2) Determination of correct cuff size using the DASH2 range markings or using the cm tape measure

C. Preparation for BP Reading

- ___ (1) Description of what participant should be told (no talking, feet flat on floor, legs uncrossed)
- ___ (2) Brachial artery palpated
- ___ (3) Midpoint of bladder within the cuff located
- ___ (4) Cuff applied with midpoint of bladder over brachial artery (don't extend beyond proper markings on cuff)
- ___ (5) Correct cuff size used
- ___ (6) Arm positioned with midpoint of cuff width at "heart level", lower edge
2- 3 cm (1 inch) above crease
- ___ (7) Sphygmomanometer connected to cuff
- ___ (8) Sphygmomanometer scale (midpoint) is at sitting eye level
- ___ (9) Radial pulse located

D. Measurement of Pulse

- ___ (1) Five-minute period at rest (leave room to avoid talking)
- ___ (2) Radial artery palpated
- ___ (3) Counting with watch, full 30 seconds
- ___ (4) Recording of 30-second count
- ___ (5) Pulse obliteration pressure (POP) determined
- ___ (6) 60 mmHg added to POP to yield peak inflation level (PIL)

E. Measurement of Blood Pressure

- ___ (1) Brachial artery palpated, if cuff is to be reapplied
- ___ (2) Wheel of the RZ is spun downward several strokes (valve OPEN)
- ___ (3) Stethoscope in ears facing down and forward
- ___ (4) Bell over artery, without cuff or tubing contact
- ___ (5) Cuff inflated quickly, smoothly to 180 mmHg or to the peak inflation pressure, whichever is greater
- ___ (6) This pressure is maintained for 5 seconds
- ___ (7) Valve is turned to CLOSE
- ___ (8) Deflation at 2 mmHg/second to 10 mmHg below K5
- ___ (9) Cuff quickly and completely deflated
- ___ (10) Cuff disconnected
- ___ (11) Recording of SBP, DBP and "zero"
- ___ (12) Math not done until after third reading is completed

F. Between Readings

- ___ (1) Arm raised passively overhead for 5 seconds. Total 30 second rest
- ___ (2) Arm lowered and tubing reconnected

G. Second Blood Pressure Readings

- ___ (1) Conform with procedures as described in E above
- ___ (2) "Zero" values for all three readings subtracted using calculator

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID#	_____



BLOOD PRESSURE OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for BP observer certification, recertification and checks. It is to be completed by the BP certifier by observing the BP observer make a BP measurement. The measurement should be done on a non-study individual using a regular stethoscope. Do not complete this form for measurements made using the Y-stethoscope.

The certifier should be out of the immediate work area of the BP observer and should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.



**STANDARD, RZ AND CUFFS
INSPECTION AND MAINTENANCE LOG**
(to be completed every 6 months)

DATE	MANOMETER #	STAFF ID	SCREW CAPS	RECORD ZERO LEVELS (MIN & MAX)	MACHINE LEVEL?	BELLOWS VALVE (RZ)	GLASS COLUMN CLEAN?	MERCURY LEAKS?	CUFF(S)* FITTINGS & VALVES	**COMMENTS

*Check Cuff(s) with the machine. Techs should observe cuffs used in visits during use and repair/replace as needed.

**Minimum and Maximum zero level should be checked if readings >0 mmHg above posted.

Name _____
Staff ID _____
Date _____
Tape # _____



DASH2 Videotape Test Sheet

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____



ID# _____

Date of Placement ____/____/____

ABPM INITIALIZATION CHECKLIST

____ Tech ID: _____ Date: ____/____/____*

____ New batteries

____ Monitor ID: _____

____ Initialized with

(a) dummy code (9999)

(b) numeric portion of DASH ID _____

____ Monitor power off

ABPM DOWNLOADING CHECKLIST

____ Tech ID: _____ Date: ____/____/____

____ Download to computer

____ Full DASH ID entered

____ Numeric portion of DASH ID correctly entered

____ File name: _____**

____ Review of raw data for 14 satisfactory BP

____ Reschedule participant if repeat session needed

TRANSFER CHECKLIST

____ Create file for data to be transferred Date: ____/____/____

____ Transfer file ID: _____**

____ Place transfer file in SITEWORK/ABPM directory on DASH2 file server

* Monitor should be placed within one week of initialization.

**File name = Transfer file ID = numeric portion of DASH ID, then "A" or "B" or "C," then "1" or "2"

(See MOP chapter for detailed explanation.)

ABPM Initialization Checklist, ABPM Downloading Checklist, and Transfer Checklist

Used for: Initializing, Downloading the ABP Monitor and Transferring data to the file server.

Enter participant ID

Enter date of placement

ABPM Initialization Checklist

Enter the ID# of person initializing the monitor.

Change AA batteries before initializing the monitor and check New batteries.

Record the monitor ID#. The 3 digit number starting with your site ID# (1,2,3, or 4)

Follow the instruction for Initializing the ABP Monitor on page 4-5 of the ABP Monitor chapter 20.

- a. enter 9999 if that was used to initialize the Monitor
- b. enter the numeric portion of the DASH2 ID if that was used to initialize the Monitor

Turn the monitor off and check the form

ABPM Downloading Checklist

Enter the ID# of person reading the monitor.

Enter date monitor is downloaded.

Follow the instructions for "To Read the Monitor" on page 6-7 of the ABP Monitor Chapter 20.

Check to see if the numeric portion of the DASH2 ID is correct or changed if initialize with 9999.

Enter the file name followed by the appropriate letter for the intervention period and the number 1 or 2.

Review the raw data for the 14 satisfactory BP following the instructions on page 6-7 of the ABP Monitor Chapter 20.

If fewer than 14 readings, reschedule the participant.

Transfer Checklist

Copy your ABPM data to floppy disk following the MOP instructions on page 7 of ABP Monitor Chapter 20.

Enter the date this file was created for transfer.

Record the file ID assigned in Initialization and Downloading.

Place the files on your floppy in SITEWORK/ABPM directory on the file server. Follow the direction in your data management manual for coping from A: drive to Sitework.



AMBULATORY BLOOD PRESSURE MONITORING

INSTRUCTIONS TO PARTICIPANTS

- Wear a shirt/blouse with a loose fitting sleeve on the day that the monitor is placed. The cuff will be placed directly on the arm, not over clothing.
- The monitor will take a reading every 30 minutes. It will beep to alert you when it is about to take a reading, count-down 5 seconds, and the measurement will take place. (Note: there will be no beep between midnight and 6 a.m.)
- When the cuff inflates, keep your arm relaxed, straight, and still.
- If possible, stop your activity and remain motionless during the reading. For example, if you are walking, stop temporarily.
- You can remove the monitor and cuff in order to shower. To do this, remove the monitor immediately after a measurement, shower, and be sure to put the monitor and cuff back on before the next reading (in 30 minutes).
- If you have any questions or problems, call _____ at _____ during the day or _____ at _____ after clinic hours.
- At night, place the monitor box to the side of your bed. If the noise of the monitor bothers you, place the monitor under a pillow.
- Please do not touch the buttons, remove the monitor box from its case, or turn it off, unless directed to do so.
- If the monitor is unable to take a reading, you will hear several short beeps. Check to be sure that:
 - 1) The arrow is placed directly over brachial artery (indicated by the ^ mark on your arm).
 - 2) The cuff is not too loose or too tight.
 - 3) The tubing is not kinked or disconnected.
 - 4) The cuff is at least one inch above the bend in your elbow

The monitor will try to take another reading in 2 minutes.



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

ABPM CERTIFICATION WRITTEN TEST

1. On which arm should the ABPM be placed? R L Non-dominant

2. As part of DASH2 criteria, you should record two ABPM readings on the Placement form. How many readings should you then abort before the patient leaves the office?
 - A. 3
 - B. 5
 - C. 2
 - D. You don't need to abort readings

Why would you need to abort any readings? _____

3. How often will the monitor take a reading?
 - A. Every 20 minutes
 - B. Every 30 minutes
 - C. Every 60 minutes
 - D. Depends on time of day

4. Please explain why it is important for a patient to have his/her arm relaxed, straight, and motionless during an ABP reading.

5. If a patient calls and says there is an error reading, what would you advise them to check?
- _____

6. For a reading to be successful for the DASH2 study, how many blood pressure measurements must be recorded?

- A. 12
- B. 14
- C. 16
- D. 24

During which hours should there be this many readings?

- A. 6 AM to 6 AM
- B. Midnight to Midnight
- C. Midnight to 6 AM
- D. 6 AM to Midnight

7. What size cuff should be placed on patients for ABPM?

- A. Follow the SpaceLabs guidelines
- B. The same size used for that patient for manual readings (exception: 'XL' for thigh cuff users)
- C. Whatever fits around the arm best

8. How often do I need to replace the 4 AAA batteries in the monitor?

- A. Batteries can be re-used once (every two patients)
- B. Batteries must be replaced for each 24-hour reading
- C. The batteries last indefinitely

9. After subject smija12345 has repeated his second feeding period ABPM (the first one was inadequate), and you are storing his ABP data in the computer, what file name do you use?

- A. 12345F2
- B. 12345B1
- C. 12345D2
- D. 12345B2

10. After having worn the monitor yourself, what point do you find most helpful to tell study participants?

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Name (trainee) _____
 Staff ID # _____
 Date _____/_____/_____

CERTIFICATION FORM

ABPM Placement

I. WEAR ABPM FOR 24 HOURS _____ (check if done)

II. CHECK EXISTING ABP FILES FOR COMPLETENESS

Indicate next to the file names below if the ABPM reading was successful:

<u>YOLANDA1</u>	Yes	No	Explain: _____
<u>MARJIT1</u>	Yes	No	Explain: _____
<u>YOCHUM1</u>	Yes	No	Explain: _____
<u>LAURAI</u>	Yes	No	Explain: _____
<u>MARILYN1</u>	Yes	No	Explain: _____
<u>JONES1</u>	Yes	No	Explain: _____
<u>SALES1</u>	Yes	No	Explain: _____
<u>YOLANDT2</u>	Yes	No	Explain: _____

III. Place devices on two participants. Initialize, place, and download. Complete the required forms and attach to this form.

Names of files for ABP Monitors placed:

_____ Reviewer Comments: _____
 _____ Reviewer Comments: _____

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Name (trainee) _____

Staff ID # _____

Date _____/_____/_____

WEIGHT OBSERVATION CHECKLIST

Weight Certification (Kgs)

- ____ (1) Scale zeroed correctly
- ____ (2) Participant in light, indoor clothing only, without shoes
- ____ (3) Participant standing in center of platform
- ____ (4) Measured to the nearest 0.1 kg

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



WEIGHT OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for weight technician certification, recertification and checks. It is to be completed by the weight trainer by observing the technician make a weight measurement.

The trainer should be out of the immediate work area of the technician and should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.



Name (trainee) _____

Staff ID # _____

Date _____ / _____ / _____

Trainer
Technician

WEIGHT CERTIFICATION FORM

Person 1:

Weight (kg) 1) _____ . _____

2) _____ . _____

Average _____ . _____

Repeat test if the two values are not within .2 kg of each other

Weight (kg) 3) _____ . _____

4) _____ . _____

Average _____ . _____

Person 2:

Weight (kg) 1) _____ . _____

2) _____ . _____

Average _____ . _____

Repeat test if the two values are not within .2 kg of each other

Weight (kg) 3) _____ . _____

4) _____ . _____

Average _____ . _____

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Check one:
 Kilograms
 Pounds

**Weight Scale (s): Accuracy check and yearly certification log
 (to be completed every other month)**

Date	Scale #	Tech Initials	Tech ID	Person Wt	Weight of mass added (20-30)	Person Wt + mass	Scale Reading*	Weight of mass added (40-50)	Person Wt + mass	Scale Reading*	Yearly Certification**	Comments

mass = amount of weight added to scale (either in Kgs or lbs)

- * Please describe measures taken to correct discrepancies between Person Wt and mass added, under Comments.
- ** Place date in this column to indicate when yearly certification by the Bureau of Weights and Measures or equivalent body was completed. Documentation should be on file at the clinic.



Name (trainee) _____

Staff ID # _____

Date _____ / _____ / _____

HEIGHT OBSERVATION CHECKLIST

Height Certification (cms)

- ____(1) Shoes and headgear removed, heels together, feet flat on the floor
- ____(2) Participant looking straight ahead with his/her head in the Frankfort horizontal plane
- ____(3) Head of the person taking the measurement in the same horizontal plane as the participant
- ____(4) Height board brought down snugly (as opposed to tightly) on top of participant's head
- ____(5) Measured to the nearest .1 cm

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



HEIGHT OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for height technician certification, recertification and checks. It is to be completed by the height trainer by observing the height observer make a height measurement.

The trainer should be out of the immediate work area of the height technician and should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.



Name (trainee) _____

Staff ID # _____

Date _____ / _____ / _____

Trainer
Technician

HEIGHT CERTIFICATION FORM

Person 1:

Height (cm) 1) _____ . ____

2) _____ . ____

Average _____ . ____

Repeat test if the two values are not within 1 cm of each other

Height (cm) 3) _____ . ____

4) _____ . ____

Average _____ . ____

Person 2:

Height (cm) 1) _____ . ____

2) _____ . ____

Average _____ . ____

Repeat test if the two values are not within 1 cm of each other

Height (cm) 3) _____ . ____

4) _____ . ____

Average _____ . ____

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



Name (trainee) _____

Staff ID # _____

Date _____/_____/_____

WAIST CIRCUMFERENCE OBSERVATION CHECKLIST

Waist circumference Certification (Kgs)

- ____(1) Landmark of 1 cm above the top of the navel was measured and marked
- ____(2) Tape remained horizontal during measurement
- ____(3) Technician gave instructions to participant regarding breathing and tightening of abdomen during measurement
- ____(4) Measurement was done at the end of normal expiration of air
- ____(5) Technician took two measurements
- ____(6) Technician removed tape between two measurements

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



WAIST CIRCUMFERENCE OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for waist circumference technician certification, recertification and checks. It is to be completed by the waist circumference trainer by observing the waist circumference technician make a waist circumference measurement.

The trainer should be out of the immediate work area of the waist circumference technician and should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Ambulatory Blood Pressure Observation Checklist

This form is for use in certifying site personnel responsible for placement of ABP Monitors. The steps outlined should be done in the order indicated.

A. ABPM Initialization

The trainee should indicate that all equipment needed for initialization are present. Check each item as identified.

- _____ (1) ABPM Monitor
- _____ (2) Four AA batteries
- _____ (3) Spacelabs Computer program with key and cable
- _____ (4) ABPM Initialization/Downloading Checklist (form #59)

The trainee should do each of the following:

- _____ (1) Insert fresh batteries into monitor
- _____ (2) Log into computer to call up ABPM Program
- _____ (3) Turn on monitor
- _____ (4) Attach ABPM Monitor to cable
- _____ (5) Check default settings
- _____ (6) Enter pt. ID or "9999" under "patient name" field
- _____ (7) Enter monitor ID under "comments"
- _____ (8) Choose "Communications" from the main menu bar and "Init Monitor" from the drop down menu
- _____ (9) Disconnect monitor from cable, turn off monitor and place in case
- _____ (10) Complete ABPM Initialization Checklist

B. ABPM Placement

The trainee should indicate that all equipment needed for ABPM placement are present. Check each item as identified.

- _____ (1) ABPM Monitor
- _____ (2) Shoulder strap/belt
- _____ (3) Blood pressure cuff
- _____ (4) Velcro clip
- _____ (5) ABPM Placement Form (#27)
- _____ (6) ABPM Instructions to Participants (form #60)

The trainee should do each of the following:

- _____ (1) Record patient ID on ABPM Placement form
- _____ (2) Record first two ABPM readings on Placement form
- _____ (3) Manually abort next three readings
- _____ (4) Verbally review procedures with participant:
 - *review frequency of readings and times tones are heard
 - *keep arm relaxed and still during readings
 - *try not to sleep on arm with cuff
 - *explain aborted reading beeps
 - *do not touch buttons
 - *in emergency, remove cuff and monitor and return to center
 - *proper cuff placement (arrow position, not too tight, etc.)
- _____ (5) Give patient "Instructions to Participants" form
- _____ (6) Make sure patient knows how to remove and put on cuff (for showering)
- _____ (7) Put piece of paper with patient name in case

C. Downloading

The trainee should do each of the following:

- _____ (1) Check that patient has worn the monitor for 24 hours
- _____ (2) Have patient fill out ABPM Participant Questionnaire (form #28)
- _____ (3) Log into computer; connect monitor and turn on
- _____ (4) Under "file name," type the 5 digits of DASH ID plus "A" for period 1, "B" for period 2 or "C" for period 3, followed by "1" or "2" for first or second attempt
- _____ (5) Review BP readings. If there are 14 acceptable readings between 6:00 am and 12:00 midnight, the monitoring is acceptable.
- _____ (6) Complete DASH ABPM Downloading Checklist

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID#	_____



Proposal for a DASH2 Paper

Submit to PASC Chair (Laura Svetkey, FAX: 919-419-5841)
and to CC (PASC Coordinator FAX: 503-528-2494)

TO BE COMPLETED BY THE PROPOSER:

Date Submitted: _____ Phone: _____

Proposer's Name*: _____ Clinical Center: _____

Title of Proposal: _____

Short title (3-10 words): _____

Research question:

Primary variables to be used in the analysis:

Do you plan to submit an abstract based on these results? Y___ N___

If yes, when is the abstract due? _____

Other authors who you know will be working on the analysis?

Analysis/Data Release Plans

Note: *This information for CC planning purposes only. You may request analyses or data releases later even if not noted on this form.*

At this time are you planning to have any analyses performed at the coordinating center? Yes No
Do you plan to request a data release? Yes No

**If approved, the proposer will serve as convener of the writing committee. The committee will select the chair after it has convened.*



PASC Review Form for a DASH2 Publication Proposal

Return completed form to the CC
(PASC Coordinator, Fax: 503-528-2494)

Attached is a Form 72 (Proposal for a DASH2 Paper) for a new DASH2 publication project. Please complete the items below and FAX your response as soon as possible, including the names of other potential authors from your site. *Nonresponse will be considered approval after the approval deadline below.*

Approval deadline _____

Project Title: _____

Reviewer's name _____ Reviewer's Site: _____

_____ Approve _____ Disapprove _____ Need to discuss further

Comments (include any stipulations that might allow you to approve a project you feel needs more discussion, or reasons for disapproval as well as suggestions for improvement):

Other interested authors from your site:

FOR CC USE ONLY:

Date Received: _____

Instructions for DASH2 Form 73

The DASH2 Coordinating Center uses Form 73 (PASC Review form) to help facilitate timely PASC approval of DASH2 paper proposals, which are submitted on Form 72 (Proposal for a DASH2 paper).

When the Coordinating Center receives a Form 72, the CC completes Form 73 and sends it, along with the Form 72 and any attachments, to the members of the PASC. The approval deadline is 14 days after the form is distributed.

PASC members are responsible for notifying potential authors at their sites and informing the CC on Form 73. PASC members who are not DASH PIs also notify their PI. The members of the PASC return Form 73 to the CC Project Administrator within 14 days, or their nonresponse is considered to be approval of the project. If no negative votes or concerns are raised, the project is considered approved. The CC contacts the PASC chair and the convener with the results.

If negative votes or concerns have been raised, the PASC chair notifies the CC and the convener once the project is approved or disapproved.



DASH2 Ancillary Study Request Form

Submit to PASC Chair (Laura Svetkey, Fax: 919-419-5841)
and to CC (PASC Coordinator, Fax: 503-528-2494)

TO BE COMPLETED BY INVESTIGATOR

Date Submitted: _____

Investigator's Name: _____

Clinical Center: _____

Project Title: _____

Brief Description of Project (attached, 3 to 4 pages):

Please provide the following information:

1. Reason for doing study and questions to be asked.
2. Procedures to be employed and which patients will qualify.
3. Potential risks and procedures to be used to minimize these risks.
4. How much time will be required by each subject.
5. How will the study affect participant flow.
6. Will study require resources from the current grant? ___Yes ___No
If so, what are the resources?

Note: the following information is for CC planning purposes only. Analyses or data releases may be requested later even if not noted on this form.

At this time, are you planning to have any analyses performed at the CC? ___Yes ___No
Do you plan to request a data release? ___Yes ___No

NOTE: If a proposal is subsequently submitted to your IRB, you must send a copy of the IRB letter of approval and the consent form to the CC.

TO BE COMPLETED BY CC:

Deadline for receiving comments: _____ (2 weeks)

Return form to CC (PASC Coordinator, FAX: 503-528-2494)

TO BE COMPLETED BY PASC MEMBERS:

Reviewers Name: _____

___ Approve

___ Disapprove

___ Need more information

Comments: _____

Other interested collaborators from your site:

Instructions for DASH2 Form 74

The DASH2 Coordinating Center uses Form 74 (Ancillary Study Request Form) to help facilitate timely PASC approval of proposed DASH2 ancillary studies.

When the Coordinating Center receives a Form 74, the CC copies the completed Form 74 for each PASC member and sends it, along with any attachments, to the members of the PASC. The approval deadline is 14 days after the form is distributed.

PASC members are responsible for notifying potential collaborators at their sites and informing the CC using Form 74. PASC members who are not DASH2 PIs also notify their PI. The members of the PASC return Form 74 to the CC Project Administrator within 14 days, or their nonresponse is considered to be approval of the ancillary. If no negative votes or concerns are raised, the project is considered approved by the PASC. The CC contacts the PASC chair and the convenor with the results.

If negative votes or concerns have been raised, the PASC chair notifies the CC and the convenor once the project is approved or disapproved.

Once approved by the PASC, ancillary studies are reviewed by the Steering Committee.



DASH2 Data Analysis Request Form
Submit to CC (Lead Analyst, FAX: 503-528-2494)

This form is to be used for analysis proposals that have been approved by the Publications and Ancillary Studies Committee.

Paper #: _____ (required)
Short title: _____
Request Date: _____
Requester: _____ Staff ID: _____
Continuation of another request: Y N Previous Req. #: _____

Is this request for an abstract submission? Y N
If yes, what is the abstract due date? _____

Summary of Request: (include objective, outcome measures, statistical methods)

Population:

Please use the Coordinating Center Analysis Guide to complete the following.

Datasets Needed: (list across top row of table)

Variables Needed: (list under each dataset)

New variables/calculations: _____

Tables, figures, and graph mock ups must be created before the work begins on this request. Have you included these with your request? _____ yes
 _____ no

Instructions for completing the Data Analysis Request Form

The step by step instructions are given below for filling out a data analysis request form (#75). This form has to be filled out before any analysis will take place. Following these instructions is a sample data analysis request that has been completed to help you in this process.

Paper #:	Required
Request Date:	Self explanatory
Requester:	Self explanatory
Staff ID:	Fill in your staff ID. These are the same IDs that have been assigned previously. See your clinic coordinator if you do not know your staff ID number.
Continuation:	Circle Y if you are requesting additional analyses from an analysis request that has already gone through the request system. Circle N if this is an original request.
Previous Req. #:	Answer this only if you answered yes to continuation. Write in the number that was assigned to the previous analyses. Leave blank if this is an original request.
Abstract	Circle Y if this is for an abstract submission and if so, write abstract due date. If this is not an abstract submission, circle N.
Summary of Req:	Write a summary of the data analysis request in this section. This should include the objective, the outcome measures and statistical methods. Attach any additional information if more space is needed.
Population:	Write in the population for this request. (e.g., participants entering run-in, randomized participants, etc.)
Datasets Needed:	Using the analysis guide, list the datasets needed for this analysis request. List the dataset names across the top row of the blank table. Check the demographics and outcomes datasets first!
Variables Needed:	Using the analysis guide, list the variables under the appropriate dataset that you need in your analysis. Check the demographics and outcomes datasets first!
New variables:	Describe any new variables or calculations that you need to have for this request. List the variables needed to create these variables and how you want them created/defined.
Tables, figures:	In order for us to begin this request, we need to have a clear picture of your vision of the endpoint. We need mock-ups of any tables, figures and/or graphs that you want created for this request. Check yes, if they are attached.

Instructions for completing the Data Release Form

The step by step instructions are given below for filling out a data release form. (An example of a completed form is provided.)

Paper #:	Required
Request Date:	Self explanatory
Requester:	Self explanatory
Approval:	All data release requests must be approved by the Steering Committee.
Staff ID:	Fill in your staff ID. These are the same IDs that have been assigned previously. See your clinic coordinator if you do not know your staff ID number.
Summary of Req:	Write a brief summary of the research questions you are trying to answer. This will help us assess your data needs.
Population:	Write in the population from this request. (e.g., participants entering run-in)
Datasets Needed:	Using the analysis guide, list the datasets needed for this analysis request. List the dataset names across the top row of the blank table. Check the demographics and outcomes dataset first!
Variables Needed:	Using the analysis guide, list the variables under the appropriate dataset that you need in your analysis. Check the demographics and outcomes dataset first!
Format:	Choose a DBF or ASCII file format.



DASH2 Abstract Review Form

Submit directly to PASC members
(Svetkey, Sacks, Appel, Vollmer, Windhauser,
Moore, Obarzanek, copy to Souvanlasy @ CC)

TO BE COMPLETED BY THE AUTHOR:

Date Submitted: _____

Title of Abstract: _____

Authors: _____

Date of abstract deadline (if applicable): _____
(form must be submitted at least 5 working days prior to the abstract deadline)

Deadline for receiving comments: _____ (3 working days)

TO BE COMPLETED BY PASC MEMBERS (or designated alternates, if unavailable)
and returned to the PASC Chair and CC.

Rating: _____ Approval
 _____ Approval with suggestions for revision (do not wish to re-review)
 _____ Approval only after appropriate revision (request re-review)
 _____ Disapproval

Comments for Author:

CC member only: Have these
numbers been verified?



Manuscript Review Form

Submit to PASC Chair (Laura Svetkey, FAX: 919-419-5841)
and to CC (PASC Coordinator FAX: 503-528-2494)

TO BE COMPLETED BY THE CC:

Date Submitted: _____

Title of Manuscript _____

Authors: _____

Date of abstract deadline (if applicable): _____

TO BE COMPLETED BY THE PASC CHAIR:

Deadline for receiving comments: _____ (30 working days)

Return form to PASC Chair

TO BE COMPLETED BY PASC MEMBERS: Reviewers Name: _____

- Rating:
- _____ Approval
 - _____ Approval with suggestions for revision (do not wish to re-review)
 - _____ Approval only after appropriate revision (request re-review)
 - _____ Disapproval

Comments for Author:

CC member only: Have these numbers been verified?



Name (trainee) _____

Staff ID # _____

Date _____

Dietary Screening Certification

1. Review the following materials:

DASH2 Manual of Operations

Read the following sections:

- DASH2 Clinical MOP Chapter 5 - Prescreening Visit 1
- DASH2 Clinical MOP Chapter 6 - Screening Visit 1
- DASH2 Clinical MOP Chapter 7 - Screening Visit 2
- DASH2 Clinical MOP Chapter 8 - Screening Visit 3
- DASH2 Diet MOP Chapter 31 - Dietary Screening

DASH 2 Forms and Procedures

Read and review the following dietary assessment forms and procedures in the DASH2 Forms Manual and discuss with the Dietary Assessment trainer:

- General Dietary Information Questionnaire (Form #100)* and accompanying instructions
- Study Food Checklist (Form #101)* and accompanying instructions
- Food Questionnaire (Form #09)* and instructions
- Participant instructions of How to Fill Out the Food Questionnaire (Form # 103)* and accompanying instructions
- Study Menus (Form #102)*

2. Complete

- Food Questionnaire (Form #09)*
- General Dietary Information Questionnaire (Form #100)*
- Study Food Checklist (Form #101)*
- Food Questionnaire Test (Form #131)*
 - Pre-mailing edit test, exercise 1*
 - Pre-mailing edit test, exercise 2*
 - Post-mailing edit test*

3. Be observed and evaluated by the Dietary Assessment trainer or Coordinating Center Quality Assurance staff administering, reviewing, and editing the following forms. The trainer should complete the Dietary Screening Observation Checklist (Form #81) on the trainee.

- General Dietary Information Questionnaire (Form #100)*
- Study Food Checklist (Form #101)*
- Study Menus (Form #102)*
- Food Questionnaire (FFQ, Form #09)*

4. Complete this form and send a copy to the DASH2 Coordinating Center

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Trainer Staff ID#	_____

Instructions for Completing the Dietary Screening Certification Form

The purpose of this form is to ensure that all staff conducting dietary screening activities are appropriately trained. The form is completed and mailed to the coordinating center for every new employee.

Once a new staff member has completed all training and is appropriately evaluated, complete the form as follows:

Name (trainee): His/her name go in this field.

Staff ID #: ID number of trainee

Date: Date the certification is completed.

For each of the observations, please indicate whether the trainee has acquired the indicated skill by marking yes, no, or n/a.

Passed: Trainer indicates if the trainee passed the certification or not.

Trainer Staff ID#: ID number of trainer

Mail a copy of the form to the coordinating center.



Name (trainee) _____
 Staff ID # _____
 Date _____/_____/_____

Dietary Screening Observation Checklist

Observation	Yes	No	N/A	Comments
Form #100: Follows procedures specified in the DASH2 Diet Manual of Operations to administer and evaluate appropriateness of participant for study				
Form # 101: Follows procedures specified in the DASH2 Diet Manual of Operations to administer and explain the purpose of the form				
Form #102: Understands how the study menus are organized and how to explain them to participants.				

Dietary Screening Observation Checklist

Observation	Yes	No	N/A	Comments
Food Questionnaire Administration:				
Follows procedures specified in the DASH2 Diet Manual of Operations to introduce the Food Questionnaire to the participant.				
Does not present inappropriate nutrition information.				
Answers participant questions in a non-leading manner.				
Premailing Editing of Food Questionnaire: (includes cursory review)				
Follows procedures specified in the DASH2 Manual.				
Reviews the front page for accuracy and completion of data as specified.				
Reviews for skipped pages or entire sections.				
See that all Yes/No questions are answered				
Reviews line items on pages 3 to 7.				
Checks for large blocks of missing data (e.g., frequency columns and portion sizes).				
Checks for multiple marks.				
Checks for predominance of a single response (e.g., same frequency or portion size marked for a substantial number of foods).				
Reviews summary questions on pages 8.				
Frequency column completed for each question.				

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Trainer Staff ID# _____	

Instructions for Completing Dietary Screening Observation Checklist

The Dietary Screening Observation Checklist is used to conduct quality assurance on the dietary screening process. It is also used during the certification of staff to ensure that a trainee has acquired the skills required to successfully screen participants.

Once the checklist is complete, or a trainee has completed all the training activities and has been appropriately evaluated, complete Form #81 as follows:

Name (trainee): His/her name go in this field.

Staff ID #: ID number of trainee

Date: Date the certification is completed.

For each of the observations, please indicate whether the trainee has acquired the indicated skill by marking yes, no, or n/a.

Passed: Trainer indicates if the trainee passed the certification or not.

Trainer Staff ID#: ID number of trainer

Mail a copy of the form to the coordinating center.



Orientation Quality Assurance Checklist

Clinical Site		_ _	
Person being observed		_ _ _	
Person documenting observation		_ _ _	
Date of observation		_ _ - _ _ - _ _	(M/D/Y)
Type of observation	<input type="checkbox"/>	Site QA	
	<input type="checkbox"/>	CC QA	

DATE:	Yes	No	N/A	Comments
Intro. (5 min)				
-Remind re: blinding				
Video (10 min) - Optional				
Coordinator:				
Location/Time of meals/schedule				
Daily routine (BP, wt, meal)				
Other tests: blood, urine, ABPM				
Medications/Vitamins				
Remind re: activity level				
Dietitian:				
Weight maintenance & energy cookies				
Food packaging and menu checks				
Meal guidelines, inc. finish all food and no additional foods				
Allowed beverages, etc				
Daily Diary				
Food safety				
Emergency meals				
Perks/Prizes				
Communication with staff				
Provide written materials: #?, #?, #? and any site-specific forms				
Sample meal or foods (recommended)				
Remind pts: don't overeat day before study!				
OTHER OPTIONAL:				
Tour of facility				
Report from prior DASH participant/s				

Instructions for Completing Orientation Quality Assurance Checklist

The purpose of the Orientation Quality Assurance Checklist is to ensure that all appropriate staff members acquire the competency to conduct the orientation.

The lead trainer should observe the trainee conducting the orientation and determine whether they have covered all the points outlined in the checklist.

After completion of the training, complete the form as follows:

Clinical site: Fill out your clinical site number and name.

Person being observed: Refers to the trainee. Their name and staff ID # go in this field.

Person documenting observation: Refers to the lead trainer at each site. Their name and staff ID go in this field.

Date of observation: Date the training is completed.

Type of observation: Indicate whether the training/certification was done at your site or by the cc staff. For each of the observations, please indicate whether the trainee has acquired the indicated skill by marking yes, no, or n/a.

Store the form with other QA forms at your site for each staff member for audit purposes. Mail a copy of this form to the coordinating center for each newly trained or certified staff member.



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Food Preparation Certification

I. Read the following materials:

DASH 2 Diet Manual of Operations

- Chapter 40, Food Procurement, Safety, and Preparation

DASH2 Forms and Procedures

- Food Production Form A-Blue Diet (Form #112)
- Food Production Form A-Red Diet (Form #112)
- Food Production Form A-Yellow Diet (Form #112)
- Food Production Form B-Blue Diet (Form #112)
- Food Production Form B-Red Diet (Form #112)
- Food Production Form B-Yellow Diet (Form #112)
- DASH2 recipes (Form #108)
- Tray Assembly Form (Form #113)
- Food Service Sanitation Inspection Checklist (Form #91)
- Checking Recipes, Meals, and Food Items (Form #87)
- Kitchen Quality Control Schedule (Form, #93)
- Kitchen Scale (s): Weekly Accuracy Check (Form #90)

- II. **Complete the tasks on the Food Preparation Checklist (Form #128)**
- III. **Complete the Food Production Training**
- IV. **Complete the DASH2 Food Preparation and Distribution Test (Form #92)**

Passed:	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
Lead Trainer Staff ID #	_____

Instructions for Completing the Food Preparation Certification

The Food Preparation Certification (Form #84) is used to ensure that a trainee has acquired the skills to prepare food according to the DASH2 Diet MOP, Chapter 40, Food Procurement, Safety and Preparation.

All persons who prepare and distribute food are trained and certified yearly.

The lead trainer sees that the trainee has been shown, demonstrates, and/or completes each item on the list. After completion of the training, complete the form as follows:

Check the box when the trainee completes each activity satisfactorily.

Name (trainee): Record the name of the person being trained.

Staff ID #: Record the DASH2 identification number of the person being trained.

Date: Record the date certification is complete.

Passed (Yes or No): Mark Yes or No depending on the outcome of the certification process.

Lead Trainer Staff ID#: Record the Lead Trainer identification number.

Store the form with other quality assurance forms for your site for audit purposes. Mail a copy of the form to the coordinating center for each newly trained staff member.



Site _____
 Cohort _____
 Staff ID # _____
 Date _____/_____/_____

EXIT INTERVIEW QUALITY ASSURANCE CHECKLIST

Observation	Yes	No	N/A	Comments
Health Risk Assessments on each participant were reviewed				
The Health Risk Assessment was introduced following the script (either in group or individual)				
The Exit Interview was conducted according to the Exit Interview Flow (either in group or individual)				
MD or clinician remained blinded to treatment assignments				
Participants were not told of their intervention treatment assignments				
Appropriate educational materials were offered and available				
Participants were encouraged to make an action plan and the Action Planning Worksheets were available				
Participant Action Plans were reviewed and details discussed with the participants to ensure reasonable and attainable goals				
Participant Attendance sheet was completed				
Health Risk Assessments sent to participants who were not present for the Exit Interview				

Instructions for Completing Exit Interview Quality Assurance Checklist

The Exit Interview Quality Assurance Checklist is to be used to ensure that the Exit Interview process was successfully conducted. The form is completed once for each cohort as a way of tracking the components of the process.

Clinical site: Fill out your clinical site number and name.

Cohort: Fill out the cohort that the information refers to.

Staff ID #: Refers to the staff member completing the form.

Date of observation: Date the form is completed.

For each of the observations, please indicate whether the activity was successfully conducted by marking yes, no, or n/a. Add any comments which may include dates, people not present, presenters, etc.



Name (trainee) _____

Staff ID # _____

Date _____ / _____ / _____

EXIT INTERVIEW CERTIFICATION

I. Review the following materials

DASH2 Diet Manual of Operations

- Chapter 37 - Participant closeout and counseling

DASH2 Forms and Procedures

- DASH2 Health Risk Assessment (obtained from the CC for each participant)
- Form #123, the Exit Interview Flow
- Form #124, the Exit Interview Height/Weight Table
- Form #122, the Action Planning Worksheet
- Form #126, the Health Risk Assessment Cover Letter

Educational Materials

- Healthy Snacking with Fresh Fruits
- Fruits and Vegetables: It's Easy to Take the "5 A Day Challenge"
- Facts About Sodium and Healthy Blood Pressure
- The Lean'n Easy Way to Enjoy Meat
- Milk Gets a Makeover: New Labels Help Make Shopping a Snap
- The ABCs of Fats, Oils, and Cholesterol
- Health and Fitness Come In All Sizes
- Healthy Weight – It's About Balance
- Cholesterol and Your Heart
- About High Blood Pressure

- Just Move
- Clearing the Air
- Sensible Drinking

II. Discuss with the lead trainer the blood pressure and blinding requirements of staff and participants.

III. Be observed and evaluated by the master trainer staff for:

- Introducing the Health Risk Assessment
- Conducting the Exit Interview according to the Exit Interview Flow
- Offering and giving advice appropriately
- Developing and reviewing action plans appropriately

Passed: Yes
 No

Master Trainer Staff ID # _____

Instructions for Completing Exit Interview Certification Form

The purpose of this form is to ensure that all staff conducting exit interviews have been appropriately trained. The form is to be completed and mailed to the coordinating center for every new employee. Additionally, it is to be completed after the yearly training for purposes of recertifying existing staff.

Once a new staff member has completed all training and has been appropriately evaluated, complete Form #86 as follows:

Clinical site: Fill out your clinical site number and name.

Person being certified: Refers to the trainee. His/her name and staff ID # go in this field.

Person documenting certification: Refers to the lead trainer at each site. His/her name and staff ID go in this field.

Date of certification: Date the training is completed.

Mail a copy of the form to the coordinating center.



Checking Recipes, Meals, and Food Items

Cohort: _____

Date	Circle diet/color/ meal calories/day/ Write item/recipe	Check if complete/ accurate or describe problem	Staff ID	Plan of action for correction of problem	Date action completed or Follow up	Staff ID
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					
	<u>Diet:</u> A B <u>Color:</u> Y R B <u>Calories:</u> 16 21 26 31 36 <u>Day:</u> M T W Th F St Su <u>Meal:</u> B L D S <u>Item or Recipe:</u>					

Instructions for Completing Spot Checking of Recipes, Meals, and Food Items

The purpose of the Spot Checking Form is to monitor the accuracy and safety of meals distributed to participants. It is to be used to monitor four of the areas identified in the section of Diet MOP Chapter 35 called "Food Preparation and Safety: Quality Control Activities." The frequency of monitoring these activities is also indicated in the MOP and on the Kitchen Quality Control Schedule (Form # 93).

Make a copy of Form #87 for each of the four quality control areas identified in Diet MOP Chapter 17 section entitled "Food Preparation and Safety: Quality Control Activities."

Complete the form as follows:

Date is date that spot checking is done.

Circle diet/color/day/meal/ and Write item/recipe refers to one of the six areas identified in the "Food Preparation and Safety: Quality Control Activities" section of Diet MOP Chapter 35, Training Module 5. All meals or food items must be described by circling letter (A or B), color (yellow, red or blue), calorie level (1600, 2100, 2600, 3100, 3600), day (M, T, W, Th, F, St, Su) and meal (B, L, D, S). When applicable write in the food item or recipe.

Accuracy and completeness or description of the problem. If the given item being checked is complete and accurate, place a check mark here. If not, describe the problem

Plan of action for correction of problem. Explain the action that was taken to correct the problem identified under "accuracy and completeness or description of the problem" field.

Action completed or follow-up. If the action plan for correcting identified problems has been taken, place a check mark here. Otherwise, indicate that follow-up is required by writing "follow-up" here.

Follow-up dates and comments. This is the date that the identified problems were resolved.

Staff ID This is the ID of the person conducting the spot checking.

Keep this form together with your other diet quality control forms.



REQUEST FOR ADDITIONAL LAB SUPPLIES

Send this form to:
Thomas Cole, PhD
Washington University School Of Medicine
660 S. Euclid Ave. Box 8046
St. Louis MO 63110
or FAX to (314) 362-4782
or telephone (314) 362-7465

Clinical Site: _____ *Date of order: _____

# needed	Lab Supplies
_____	Visit kits
_____	2 mL Plastic Freezing Vials
_____	8 mL Plastic Freezing Vials
_____	13 mL Plastic Pooling Vials
_____	Disposable Transfer Pipets
_____	Needles
_____	Colored Caps (Color)
_____	Colored Caps (Color)

OTHER SUPPLIES _____

* Please allow seven days for delivery



Kitchen Scale (s): Weekly Accuracy Check

Date	Scale #	Tech Initials	Tech ID	Scale Check										Service Required Y/N	Comments**
				1g Range 1.0		10g Range 10.0		50g Range 50.0*		100g Range 99.9-100.1		1 Kg Range 998-1002g			
				1	2	1	2	1	2	1	2	1	2		

* Scales that read out of range must be recalibrated.
 ** Please describe measures taken to correct discrepancies under Comments.



Cohort: _____

Food Service Sanitary Inspection Check List and Action Plan

A. Personnel

1. Hands clean, fingernails short, no chipped nail polish
2. Frequent hand washing stressed
3. Wearing of hair nets or caps
4. Proper handling of food and utensils
5. Free of infections or illnesses
6. Clean work clothes and appropriate footwear
7. No smoking/eating in food preparation areas
8. No dangling and excessive jewelry

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					

B. Food Handling

1. Food kept at proper temperatures
 Cold below 40°F
 Hot above 150°F
2. Food preparation area clean and free of debris
3. Frozen food thawed properly
4. Food covered or protected from contamination
5. Leftovers properly disposed or/stored
6. Food handlers disposable gloves worn
7. Raw and cooked/ready to serve foods prepared in different work areas
8. Sanitation/food handling employee training

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					

C. Equipment

1. Utensils clean and free of corrosion
2. China and glasses free of cracks and chips
3. Equipment in good repair and working order
4. Equipment surfaces and parts readily accessible for cleaning
5. Cutting boards clean/sanitize after each use
6. Stoves and ovens properly vented or hooded
7. Hoods/filters free of grease/condensation
8. All equipment cleaned after each use
9. Self-service equipment and silverware (flatware) dispensed so only handles are touched
10. Dishwasher clean thoroughly after each use
11. Mops/mop pails cleaned and stored properly
12. Ice machines cleaned and used only for food services

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					

D. Storage Practice

1. Refrigerators kept at 40°F or below
2. Freezers kept at 10°F or below
3. Food stored off floor
4. Storage areas clean and in order
5. Non-food items stored in separate areas
6. Thermometers and thermostats operating
7. Shelves above floor for proper cleaning
8. Food properly identified, dated, and logged
9. No dented and corroded cans
10. Cleaning materials stored outside food areas
11. Shelves and cupboards clean and free of dust

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					

D. Dishwashing

1. Dishes washed at 140°F or higher and rinsed at 180°F for 15 seconds
2. Dishes allowed to air dry
3. Clean utensils and dishes stored protected from contamination
4. Dishwasher water changed frequently
5. Proper amount of detergent used
6. Dishwasher clean and working properly
7. No overloading or improper loading
8. Wash hands between soiled and washed ware handling

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					

F. Department Area

1. Floors easily cleaned and in good repair
2. Walls, ceilings cleaned and in good repair
3. Doors and windows screened
4. Well lighted food preparation areas
5. Hand washing sinks available
6. Toilet facilities adequate
7. Trash cans cleaned and covered
8. Wiping cloths sanitized daily and restricted to specific uses
9. Garbage disposals clean and operation
10. Pest control program in effect

Week	ID #	Y/N	Problem	Action Plan	Follow-up
0					
2					
4					
6					
8					
10					
12					



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Food Preparation and Distribution Test

1. The person to whom I should report in case of a question or concern about DASH2 food preparation is _____.
2. Breads, juices, and vegetables are to be weighed to the \pm _____ grams.
3. Milk, dried fruits, and meats are to be weighed to the \pm _____ grams.
4. Spices and salt (all the time), and fats (when equal to or less than a total amount of 10 grams is needed) are to be weighed to the \pm _____ grams.
5. Fats (when greater than a total amount of 10 grams is needed), rice and vegetables are to be weighed to the \pm _____ grams.
6. During food preparation, the time that perishable foods remain out of the refrigerator is not to exceed _____ minutes.
7. For sanitary purposes, food preparation staff should always wear _____

8. Find Production menu for the low sodium, combination Monday menu. How many grams of Swiss cheese does the 2100-calorie level receive? _____
9. Using the same production form, how many units of mayonnaise does the 3100-calorie level receive at lunch? _____
10. Using the same production form name the products listed that are without salt or unsalted.

11. The DASH2 Diet MOP, Chapter 40 procedures for cooking, and DASH2 recipes can be altered as the food preparation staff determines necessary to ease production and/or make the food tastier. **TRUE or FALSE**

Passed:	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
Lead Trainer Staff ID #	_____

Instructions for Completing the Food Preparation and Distribution Test

This test checks to see that the dietary staff person understands the DASH2 food preparation and safety procedures. Each question is worth 9 points. To pass, a score of 90 is necessary.

The test is administered after the lead trainer has trained the staff person according to the process in the DASH2 Diet MOP, Chapter 35, Diet Training.

Complete the header as follows:

Name (trainee): Record the name of the person being trained.

Staff ID #: Record the DASH2 identification number of the person being trained.

Date: Record the date certification is complete.

Complete the lower box as follows:

Passed (Yes or No): Mark Yes or No depending on the outcome of the certification process.

Lead Trainer Staff ID#: Record the Lead Trainer identification number.

Store the form with other quality assurance forms at the site for audit purposes. Mail a copy of the test to the coordinating center for each newly trained staff member and staff being re-certified.



Kitchen Quality Control Schedule

Item to be Monitored	Method of Monitoring	Documentation	Frequency of Monitoring
1. Recipes.	Observation of staff preparing recipes.	Form #87 - Spot Checking of Recipes, Meals, and Food Items	Each recipe checked at least once/cohort or during pre-preparation.
2. Weighed Foods.	Check of brands and weights of food items. Weigh 2 different food items in triplicate.	Form #87	Twice per week (Run-in and intervention)
3. Meals.	Inspection of all on-site and packed meals with exception of Saturday and Sunday.	Site specific for all meals. Form #87 For each meal, document check of one on-site/packed meal per diet per sodium level (6 total).	Daily Daily
4. Meal Delivery.	The delivery of all meals to the participants are checked according to site specific procedures.	Site specific.	Daily
5. Kitchen Sanitation and Safety.	Inspection of DASH2 research kitchens, equipment, and employees.	Form #91, Food Service Sanitary Inspection Checklist	Every two weeks
6. Food Storage.	Inspection of refrigerator and freezer temperatures.	Site specific Refrigerator/ Freezer Temperature Forms	Daily
7. Electronic Balances.	Check of weights and calibration of balances.	Form #90, Kitchen Scales: Weekly Accuracy Check	Once per week



Cohort # _____
 # of Participants _____
 Date ____/____/____

Participant Orientation Checklist

	Yes	No	N/A	Comments
Prepare participant packets according to MOP				
Introduce key staff				
Protocol				
Blinding issues				
DASH2 Video (10 minutes) – Optional				
Participant expectations				
Location/time of meals/schedule				
Daily routine: BP, wt, meal				
Clinical measurements: blood, urine, ABPM				
Medications/vitamins				
Activity level				
Weight maintenance				
Finishing all foods/no additional foods				
Importance of salt/sodium				
Energy foods/emergency energy foods				
Allowed beverages and seasonings				
Food safety				
Completeness of meals/checks				
Meal passes				
Emergency meals				
Daily Diary				
Communication with staff				
Optional site-specific items to cover:				
Provide site specific written materials				
Serve a sample meal or foods				
Perks/Prizes				
Tour of the facility				
Report from DASH participants				

Please attach a list of participant ID numbers for those attending this orientation session.

Please list Staff IDs for those staff present at the orientation session:

Instructions for Completing Participant Orientation Checklist

The purpose of the Participant Orientation Checklist is to document appropriate orientation procedures with all participants. It is completed once for each orientation session. The staff person will review with the participant, pertinent items on the checklist while doing an orientation.

Cohort: Record the cohort number for the orientation session.

of Participants: Record the number of participants attending the session.

Date: Record the date the checklist is complete.

Attach a list of participant IDs that attended the session, to the form.

List all DASH2 staff ID numbers, for staff present at the orientation session.

Store the form and the attached list of IDs with other quality assurance forms for audit purposes.



Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Ambulatory Blood Pressure Observation Checklist (ABPM Placement ONLY)

This form is for use in certifying site personnel responsible for placement of ABP Monitors. The steps outlined should be done in the order indicated.

ABPM Placement:

The trainee should indicate that all equipment needed for ABPM placement are present. Check each item as identified.

- _____ (1) ABPM Monitor
- _____ (2) Shoulder strap/belt
- _____ (3) Blood pressure cuff
- _____ (4) Velcro clip
- _____ (5) ABPM Placement Form (#27)
- _____ (6) ABPM Instructions to Participants (form #60)

The trainee should do each of the following:

- _____ (1) Record patient ID on ABPM Placement form
- _____ (2) Record first two ABPM readings on Placement form
- _____ (3) Manually abort next three readings
- _____ (4) Verbally review procedures with participant:
 - *review frequency of readings and times tones are heard
 - *keep arm relaxed and still during readings
 - *try not to sleep on arm with cuff
 - *explain aborted reading beeps
 - *do not touch buttons
 - *in emergency, remove cuff and monitor and return to center
 - *proper cuff placement (arrow position, not too tight, etc.)
- _____ (5) Give patient "Instructions to Participants" form
- _____ (6) Make sure patient knows how to remove and put on cuff (for showering)
- _____ (7) Put piece of paper with patient name in case

Passed:	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Master Trainer Staff ID# _____	



SV1

ID # _____

Name _____

General Dietary Information Questionnaire

1. Do you have access to a refrigerator a) at home? Yes No

b) at work? Yes No

2. Do you have access to a microwave or regular oven a) at home? Yes No

b) at work? Yes No

3. Please circle any of the foods below that you cannot or will not eat for religious reasons or because of allergies or severe physical discomfort (e.g., vomiting, diarrhea, severe stomach cramps):

Dairy Products

Milk

Butter

Yogurt

Cottage cheese

Cream cheese

Cheddar cheese

Swiss cheese

American cheese

Sour cream

Margarine

Meat and poultry

Fish

Pork sausage

Ham

Roast beef

Ground beef

Turkey

Turkey pastrami

Tuna fish

Chicken

Legumes and nuts

Mixed nuts

Peanuts

Almonds

Fruits and juices

Prune juice

Apricot nectar

Orange juice

Cranberry juice

Cranapple juice

Grape juice

Apple juice

Bananas

Apples

Cantaloupe

Strawberries

Pineapple

Dried apricots

Raisins

Dried apples

Oranges

Canned peaches

Fruit Cocktail

Please circle any of the foods below that you cannot or will not eat for religious reasons or because of allergies or severe physical discomfort (e.g., vomiting, diarrhea, severe stomach cramps):

Breads and Grains

Whole wheat bread
White bread
White rice
Brown rice
Dinner rolls
Bagels
Pita bread
Bran Chex
Shredded Wheat
Oatmeal
Grits
Corn Flakes

Vegetables

Collards
Turnip greens
Spinach
Cauliflower
English peas
Squash
Green beans
Carrots
Potatoes
Sweet potatoes
Tomato/Tomato products
zucchini

Condiments

Mustard
Ketchup
Mayonnaise
Beef gravy
Turkey gravy
Chicken broth
Beef broth
Barbeque sauce

4. Are there any other foods not listed above that you cannot or will not eat for religious reasons or because of allergies or severe physical discomfort (e.g., vomiting, diarrhea, severe stomach cramps)?

Yes No

If yes, please specify

Reviewed by (staff ID): _____ Staff ID _____

Instructions for the General Dietary Information Questionnaire

The purpose of this form is to identify, at an early stage in the screening process, participants who are not likely to be able to comply with the dietary requirements of the study. Specifically the form is designed to identify participants who cannot tolerate common study foods due to serious allergies or other types of physical discomfort. The form also gathers preliminary information about whether a given participant can safely store and prepare food away from the clinical site.

The form is intended to be brief and is deliberately not comprehensive in its review of study foods and food preparation/storage facilities. A detailed review of the study menus and logistical considerations will take place as part of SV3.

Instructions

This form is to be completed during the SV1 visit. Place a label with the participant's study ID number in the upper right hand corner of the form. If an ID has not yet been assigned and no label is available, leave this field blank and complete it later. Record the participant's name on the next line.

The form may either be completed, by the participant, while they are waiting in the clinic or it may be administered directly. If the form is completed by the participant, it must be reviewed by a DASH2 staff person prior to the end of the visit.

Participants who answer "no" to either question 1a or question 2a do not have adequate facilities in their homes to store and prepare study foods and are thus ineligible to participate in the study. Indicate ineligible on the SV1 Visit Form (form # 3).

Participants who answer "no" to questions 1b or 2b are eligible for the study. However, their forms should be reviewed by the dietary staff, after the visit so that they can plan to provide thermos bottles, flasks, and coolers to those participants.

Participants who indicate that they are allergic to or experience serious physical discomfort when they eat any of the foods listed in question 3 should probably also be excluded. However, individual clinics should review this list with their dietitian in order to determine if the exclusion is absolute or if provisions can be made to work around it. For example, participants who have a lactose intolerance may be able to consume dairy products if they are willing to use Lactaid.

Participants who list any foods in question 4 should be evaluated by the dietary staff. This evaluation need not occur as part of the SV1 visit.

The staff member reviewing the form should enter their DASH2 Staff ID # at the bottom of the form.



SV3
ID # _____

STUDY FOOD CHECKLIST

All the foods listed below are a part of the DASH2 menus. It is possible you will be asked to eat any of these foods either daily or weekly. A few foods may not be part of the diet you are assigned to. Please circle all the foods you cannot or will not eat.

1. Vegetables

Carrots	Green beans	Parsley	Tomatoes
Cauliflower	Green peas	Potatoes	Tomato products, e.g., tomato sauce
Celery	Green peppers	Spinach	Turnip greens
Collard Greens	Lettuce	Sweet potatoes	Yellow squash
Cucumber	Onions (green and yellow, raw cooked)		Zucchini squash
Garlic			

2. Eggs and milk products

Eggs	<i>Cheese:</i>		
Milk (all kinds of cow milk)	American	Parmesan	Cottage
Yogurt	Cheddar	Swiss	Cream cheese

3. Fruits and fruit juices

Apple juice	Grape juice	Apples	Peaches
Apricot nectar	Lemonade	Apples, dried	Pineapple
Cranapple juice	Orange juice	Apple sauce	Raisins
Cranberry juice	Prune juice	Apricots, dried	Strawberries
Fruit punch		Bananas	Fruit cocktail
		Cantaloupe	
		Oranges	

4. Meat, poultry, and fish

Roast beef	Chicken	Ham	Turkey
Ground beef	Cod	Pork sausage	Tuna
			Turkey Pastrami



SV3

ID # _____

5. Breads, cereals, and grains

Breads:

Cinnamon-raisin bagel
Corn bread
Egg bagel
Pita bread
Whole wheat bread
White bread

Cookies and Desserts:

Animal crackers
Brownies
Butter cookies
Choc. chip cookies
Jell-O
Oatmeal raisin cookies
Peanut butter cookies
Yellow cake

Breakfast cereals:

Bran Chex
Bran flakes
Corn flakes
Cream of Wheat
Grits
Oats
Frosted flakes
Granola bar
Shredded wheat

Grains:

Pasta
Rice

Crackers:

Graham crackers
Ritz
Saltines
Triscuits

Snack foods:

Pretzels

6. Oils, spreads, sauces, and spices

Spreads and condiments:

Butter\Margarine
Ketchup
Jelly
Mustard
Mayonnaise
Peanut butter

Oils:

Canola oil
Corn oil
Olive oil
Safflower oil

Salad dressings:

Creamy Italian
French
Creamy French

Herbs and Spices:

Basil
Cinnamon
Dill
Garlic Powder
Onion Powder
Paprika
Black/red/white
pepper
Thyme

Sauces and

gravies:

Barbecue
Turkey gravy
Beef gravy

Soups:

Chicken broth
Beef broth

7. Nuts and seeds

Almonds
Mixed nuts
Peanuts

8. Candy

Candied orange slices
Hard candy
Kit Kat
Milky Way

9. Mixed dishes

Pizza
Lasagna

The following questions ask you a variety of questions related to your overall eating environment. Your answers will help DASH2 staff determine ways they can make your participation in the study more enjoyable.

- | | Yes | No | |
|--|--------------------------|--------------------------|--------------------------------|
| 1. Do you foresee any problems transporting, storing, refrigerating, and warming your DASH2 study foods when you are away from our center? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2. Do you participate in activities where food is served, such as sporting events, religious gatherings, business meetings, etc.? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3. Will any holidays, birthdays, family reunions, vacations, etc., occur during the period you are on the study? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4. If you are responsible for preparing meals in your household, will this make it difficult for you to meet study requirements? | <input type="checkbox"/> | <input type="checkbox"/> | NA
<input type="checkbox"/> |
| 5. Will anyone in your household be affected or inconvenienced by your participation in this study? | <input type="checkbox"/> | <input type="checkbox"/> | |
| If yes, who are they and how will they be affected? | | | |
| 6. Will your employment status (e.g., job transfer) or work hours (e.g., moving to a night shift) change during the study? | <input type="checkbox"/> | <input type="checkbox"/> | NA
<input type="checkbox"/> |
| 7. Do you, or anyone in your household, work in the food service industry (cafeteria, bakery, restaurant, etc.)? | <input type="checkbox"/> | <input type="checkbox"/> | |
| If yes, do you eat any meals or snacks at work, either as a requirement of your job or as a matter of convenience? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 8. If you have any concerns about the study, please write them in the space provided below (use the back of this page if you need additional space). | | | |

Reviewed by (staff ID): _____



SV3
ID # _____

INSTRUCTIONS FOR THE STUDY FOOD CHECKLIST

The purpose of the Study Food Checklist (form #101) is to review the study menus and foods with the participant to make sure he is fully aware of the foods and menus of the study. In addition, the form identifies persons who are not likely to comply to the dietary requirements of the study because they cannot, or do not, eat the study foods due to dislikes or allergies, or cannot comply due to environmental, family or work situations.

Instructions

This form is completed at the SV3 visit. Place a label with the participant's study ID number in the upper right hand corner of the form..

The form can be completed by the participant while he is waiting to be seen or it can be administered directly. If the form is completed by the participant, it must be reviewed by a DASH2 staff person, preferably a nutritionist, prior to the end of the visit.

Ask the participant, to circle all foods listed on the first two pages that he cannot, or will not, eat. Make sure the participant understands the foods listed will be included in the DASH2 diet and he will be expected to eat them during the intervention period.

Ask the participant to answer the questions on page 3 by marking the appropriate box. If the response to any question is "Yes," have the dietitian review the questionnaire with the participant to evaluate the situation and assess the ability of the participant to comply with the study protocol.

Reviewing and Editing the Form

Review the form for completeness. The staff member reviewing the form should enter their DASH2 staff ID number at the bottom of the form.

Exclusion Criteria

If the participant is unable or unwilling to eat the study foods, he is not eligible to participate in the study.



Study Menus

	Diet A			
	Breakfast	Lunch	Dinner	Snack
Monday	Apple juice Corn Flakes w/milk Toast w/butter and Jelly	Chicken or ham sandwich w/ lett / mayo / mustard Fruit Punch Hard Candy Jello	Spaghetti w/meat sauce Parm. cheese Steamed cauliflower Bread w/butter Frosted Pound Cake	Fruit Punch Butter Cookie
Tuesday	Cranberry juice Bread w/peanut butter, jelly and butter	Lean Cuisine Pizza (French bread) Salad / Italian dressing Chicken Breast (roasted) Hard candy Fruit Punch and Jello	Hamburger w/roll, ketchup, lettuce, onion Potato Salad Peaches Butter	Shortbread cookies Lemonade drink Applesauce
Wednesday	Apple juice Milk Cinnamon raisin bagel w/jam and butter Cream cheese	Roast Beef sandwich w / lettuce mayo, mustard Brownie Pretzels M&M's	Spanish rice with chicken Green Peas Salad w/cucumbers French dressing Roll w/butter	Sugared orange slices Butter cookie Lemonade
Thursday	Egg bagel Orange marmalade Cream cheese Butter Cranberry-Apple juice	Tuna salad sandwich w/tomato Milky way bar Lemonade drink	Meatloaf w/BBQ sauce Baked potato Sour cream Bread w/butter Green beans Jello	Cranberry juice Ritz crackers Cheddar cheese
Friday	Cranberry juice Frosted Flakes cereal Milk Toast w/jelly and butter	Chicken breast sandwich w/ mayo, Mustard Fruit cocktail	Spicy Seafood Scallion Rice Steamed carrots Bread or roll w/butter Pineapple Milk	Cream cheese frosting Butter cookie Fruit Punch
Saturday	Pork Sausage Milk Grits Toast w/butter Apple juice	Tuna Fish salad sandwich w/lettuce Applesauce Butter cookies	Turkey w/rice and gravy Green beans Yellow cake w/choc frosting Bread w/butter Apple juice	Cranberry juice Kit Kat Jello
Sunday	Grits Toast w/butter, jelly Cranberry juice Milk	Turkey breast or Turkey Pastrami sandwich w/ bread or Sesame roll, lett, mayo, mustard American cheese, cucumber, Applesauce / Peaches & strawberries Lemon cookie	Roast beef round and gravy with rice Summer squash Bread w/ butter Chocolate chip cookie Fruit Punch	Animal crackers Apple juice

Study Menus

	Diet B			
	Breakfast	Lunch	Dinner	Snack
Monday	Milk Orange juice Bran chex w/sugar or Shredded Wheat Banana/dried apricots Whole wheat toast w/ margarine & jelly	Chicken breast sandwich w/ lettuce / mayonnaise/ tomato American or Swiss cheese Apple juice Jello	Spaghetti w/veg. Sauce Parmesan cheese Mashed sweet potato Turnip greens Dinner rolls Fruit Punch	Orange juice Apple Mixed nuts
Tuesday	Prune juice Banana Milk Oatmeal Whole wheat toast w/ margarine & jelly	Beef w/ BBQ sauce sandwich on Sesame seed roll w/ lettuce / tomato /pickles Cheddar cheese Potato salad Fruit punch	Cod w/lemon Brown rice Cornbread muffins or rolls w/ marg. Spinach Milk Chicken broth	Oranges Mixed dried fruit Graham crackers Milk
Wednesday	Orange juice Milk Oatmeal or Corn Flakes Banana Whole wheat toast w/butter, jelly	Ham sandwich on whole wheat w/ mayonnaise /mustard /lettuce Cheddar cheese Fruit cocktail	Spanish rice with chicken Green Peas Milk Roll w/butter Cantaloupe	Dried apricots Nuts Orange juice
Thursday	Orange juice/Milk Banana Frosted Mini Wheats Cinnamon-raisin bagel Cream cheese	Tuna salad on whole wheat bread Cottage cheese Pineapple, cantaloupe Lemonade and hard candy	Turkey meatloaf w/ BBQ sauce Baked potato w/margarine Sour cream & scallions Collard greens Jello/Fruited yogurt	Orange juice Peanut butter Triscuit crackers
Friday	Orange juice Yogurt Milk Toasted oats granola bar Bananas	Turkey sandwich on ww bread /w mayonnaise, mustard, lettuce Cheddar cheese Oranges Fruit cocktail	Spicy Seafood Scallion Rice Spinach Milk, Pineapple Bread w/butter of marg Beef broth	Roasted peanuts Apricots Fruit Punch
Saturday	Grape juice / orange juice Kellogg's bran flakes or Shredded wheat cereal Milk Whole wheat toast w/ marg or Cinnamon toast Banana/orange	Tuna salad on whole wheat / pita bread Lettuce, cucumber & tomato Apple Apricot nectar	Zucchini Lasagna Spinach, stewed tomatoes Raw carrots Parmesan Cheese Roll w/ butter Melon/peaches Milk	Raisins Almonds Fruit yogurt cranberry juice
Sunday	Bran Chex Milk Banana Whole wheat toast w/jelly & marg Orange juice Yogurt	Chicken Salad on ww bread w/ mayonnaise & tomato Cucumbers Fruit cocktail	Roast beef and gravy Baked potato w/ sour cream Bread w/margarine or butter Green beans Milk Peaches Chicken broth	Orange juice Nuts Raisins Dried apricots



How to Fill Out the Food Questionnaire

The questions on the Food Questionnaire ask about the foods you ate over the past year (12 months).

Please fill out the form **YOURSELF**. Use an ordinary (#2) pencil.

Remember to think about:

- The foods **YOU** ate,
- **NOT** what your **FAMILY** ate,
- **NOT** what you **THINK** you should eat.

Don't be afraid to mark "large" servings. Almost everyone eats large servings of their favorite foods!

Remember to include the foods that you eat at home, at the office, at restaurants, and from fast food places.



Diet Orientation Form

While you are participating in the DASH study, it is important that you follow these guidelines carefully. If you have any questions or problems related to your diet during the study, please call _____ at _____.

1. Please **FINISH ALL FOODS AND BEVERAGES** that are fed to you at the center and that we give you to take home. Some examples:
 - You should eat skins from fruit and vegetables, unless they are inedible.
 - Sop up leftover gravies and sauces with bread or rubber spatula.
 - Squeeze packages of mayonnaise, salad dressing, mustard, etc., until they are emptied completely.
 - Scrape all margarine, butter, yogurt, etc., from containers.
2. All of your “to go” food has been cooked; however, your meals may be heated in a microwave or a conventional oven. Please remove all plastic lids and wraps prior to placing food in oven. Please remove food from any metal or tin containers before placing them in the microwave.
3. Use a rubber spatula when transferring foods from one container to another, so that no food is lost.
4. Do not eat or drink anything other than what we give you, except for beverages listed on the “Guidelines for Beverages and Seasonings.” This includes vitamins and dietary supplements. Please check with study staff before using any over-the-counter medications.
5. Bring study foods to social functions so you have something to eat in case you get hungry.
6. Refrigerate “to go” items as soon as possible to prevent spoilage.
7. We will give you copies of your menus during the study. Please compare all “to go” foods to these menus to be sure that all items are there. Refer to these menus when assembling your meals. If something is missing, or there is a problem with your meals, please call the study staff. Do not make substitutions unless directed to do so.
8. Complete your **DAILY DIARY** every day. The diary reflects what happened during the preceding day. On this diary, record allowed additional items consumed, any problems with the diet, any foods you did not completely eat, and whether you would like to meet with us in private about any aspect of the study.

THANK YOU



Diet Orientation Form

During your participation in the DASH2 study, you will be asked to follow these guidelines carefully. If you have any questions or problems related to your diet during the study, please call _____ at _____.

Diet Instructions:

1. Maintain normal activity/exercise patterns throughout the study.

If a change occurs, record on Daily Diary immediately.

2. Let us know if you are hungry or too full.

Especially during the first week of the study, let us know if you are too full or hungry so calories can be adjusted. *Please do not try even a bite of other foods or sip of fluids not provided by DASH2, with the exception of the “allowed beverages and seasonings.”*

3. Finish everything:

Please finish ALL FOODS AND BEVERAGES that we provide at the center and that we give you to take home. Some examples:

- Eat skins from fruit and vegetables, unless they are inedible.
- Sop up leftover gravies and sauces with bread or rubber spatula.
- Squeeze packages of mayonnaise, salad dressing, mustard, etc., until they are emptied completely.
- Scrape all margarine, butter, yogurt, etc., from containers.
- Use a rubber spatula when transferring foods from one container to another, so that no food is lost.

4. IT'S ALL YOURS:

Study foods cannot be shared with other study participants, friends, family members, or others. Everything edible must be consumed. If you are not sure if something is edible, ask DASH2 staff. For example: potato and apple skins are EDIBLE, apple core/seeds, orange skin, and gristle from meat are NOT edible.

5. Meals at the sites

We will be looking for you every day at your scheduled time! If you don't expect to arrive on time, call us as soon as possible so that we can make other arrangements. Please eat only DASH2 foods during the study, except for beverages listed on the handout.

6. DASH2 meals may be heated.

All of the “to go” food has been cooked; however, DASH meals may be heated in a microwave or a conventional oven. Please remove all plastic lids and wraps before placing food in oven, and remove food from any metal or tin containers before placing them in the microwave.

7. Eat study food when away from home.

Bring study foods to social functions so you have something to eat in case you get hungry.

8. Compare menus and “to go” food.

We will give you copies of your menus during the study. Please compare all “to go” foods to these menus to be sure all items are there. Refer to these menus when assembling your meals. If something is missing, or there is a problem with your meals, please call the study staff. It is important not to make substitutions unless directed to do so. Snacks are sometimes packed with the breakfast or lunch “to go” meals.

9. Refrigerate “to go” food.

Refrigerate “to go” items as soon as possible to prevent spoilage.

10. Emergency meals

You will be given one day’s worth of meals that **should be frozen and saved for an emergency**. If you eat your emergency meal, let us know, and record on the daily diary.

11. Energy cookies

Energy cookies for DASH2 are used to help maintain your weight. They are wrapped individually and distributed with your “to go” meals. Also, you will be given 2 energy cookies to put in your freezer. *Eat these if you become unusually hungry.* When you eat these, record the number eaten on the Daily Diary in addition to any that were included with your daily meal. Request replacements for these when eaten.

12. Beverages

Lactose Intolerant? Let us know if you are lactose intolerant, or have trouble digesting dairy products and need Lactaid. We will provide this for you.

Caffeine: Review list of allowed beverages, amount of beverages that makes one serving, and the number of servings allowed. Caffeinated beverages are allowed in the amounts given on list. Beverages listed here are not necessarily provided by the study, but may be purchased and consumed according to the guidelines. *Servings:* a standard can of soda is 12 ounces, a cup is 8 ounces, and ½ cup is 4 ounces.

Water: is allowed in unlimited amounts and does not need to be recorded.

Alcohol: Review the list of allowed alcoholic beverages, amounts, and serving sizes.

Note: a standard can of beer is 12 ounces.

13. Complete your DAILY DIARY every day.

The Daily Diary reflects what happened during the preceding day. On this diary, record allowed additional items consumed, any problems with the diet, any foods you did not completely eat, and whether you would like to meet with us in private about any aspect of the study.

We hope you enjoy participating in DASH2. You are a valuable part of the study and we want to make it a pleasant experience for you.

THANK YOU



Guidelines for Beverages and Seasonings

BEVERAGES - Limit to Three Servings Per Day Total

Please remember to record your intake daily on your Daily Diary. This includes beverages served at your on-site meal.

Brewed or instant coffee(regular or decaffeinated) 8 ounces (1 cup)
(May be sweetened with artificial sweetener; no milk, cream, or coffee lightener added unless it is a part of your daily menu)

Brewed or instant tea (black or herbal tea; no green or loose leaf tea) 8 ounces (1 cup)
(May be sweetened with artificial sweetener; no milk, cream, coffee lightener, or lemon juice added unless it is a part of your daily menu)

Crystal Light* 8 ounces (1 cup)
(Iced Tea Flavor (decaf & caf), citrus blend, fruit punch, lemon lime, pink grapefruit, Lemonade)

*only caffeinated tea contains caffeine

Diet Sodas and Beverages

Diet Pepsi 12 ounces (1 can)
(with or without caffeine)

Diet Coke 12 ounces (1 can)
(with or without caffeine)

Diet Seven-up 12 ounces (1 can)

Diet Ginger Ale (no Schweppes) 12 ounces (1 can)

Fresca 12 ounces (1 can)

ALCOHOL - Limit to Two Servings/Day

Please remember to record your intake daily on your Daily Diary.

White wine (no White Zinfandel, blush, or rose) 5 ounces (1/2 cup + 2 Tablespoons)

Light Beer (ex. Bud Light, Coors Light, Miller Lite) 12 ounces (1 can)

Beer, Regular (ex. Bud, Coors)- no amber or dark beers 12 ounces (1 can)

Non-alcoholic beer (ex. O'Doul's) 12 ounces (1 can)

Gin, Vodka, Whiskey, Rum (can be mixed only with an allowed beverage) 1.5 ounces (1 small jigger, about 3 Tbls)

SEASONINGS AND FLAVORINGS - Unlimited

You may consume as much as you want of the following seasonings, beverages, sugar substitutes, mints, and gum. These do not need to be recorded on your Daily Diary.

SEASONINGS

Curry Powder

Onion Powder

Garlic Powder

Pepper, Black

Pepper, Cayenne (Red)

McCormick Lemon Pepper Seasoning packet

McCormick All Purpose Seasoning packet

BEVERAGES THAT ARE UNLIMITED

May be consumed at any time and with unlimited quantity by participant. Beverages listed do not need to be recorded on diary.

Water

Poland Springs - Carbonated Water (e.g., cherry, lemon-lime)

Polar Seltzers

Crystal Light- strawberry-kiwi, raspberry ice, pineapple orange

SUGAR SUBSTITUTES

Equal

Nutrasweet

Sweet 'n' low

MINTS AND GUM

Breathsavers, sugarfree

Certs, sugarfree

Dentyne Gum, sugarfree

Carefree Sugarless Gum

Bubblicious Sugarfree gum

Trident Sugarless

Extra, sugarfree



Safe Foods TO GO

1. What are TO GO Foods?

TO GO foods are the meals that you pick up from your feeding study site and eat at home, work, or away. You are to eat all of the food provided.

2. What are emergency meals and energy cookies?

Emergency meals are meals that we will provide to you so that you will have a replacement meal. An emergency meal may be needed in the event that inclement weather occurs or one of your meals mistakenly spoils. You are to use emergency meals only when the DASH staff instructs you to do so.

Energy cookies are foods that are similar in nutritional value to your study diet. They are used to adjust your calories for you to maintain your weight. At the beginning of the study, you will be given the option to eat these, should you get hungry. Later in the study you may be required to eat them as a daily part of your TO GO meals. The DASH staff will let you know.

3. How do I know my TO GO foods are safe to eat?

We have prepared carefully your TO GO foods using the freshest ingredients. We follow the state's health department food sanitation requirements and guidelines for food preparation. It is important that you, too, handle the TO GO foods safely.

4. How should I store my TO GO foods to keep them safe?

In hot weather, do not store TO GO foods in the trunk of your car. Instead, you should place the foods inside your car with air conditioning.

TO GO foods may contain perishable foods that require immediate refrigeration (for example: meats, fish, tuna, poultry, sausage, milk, cheese, cottage cheese, cream cheese, sour cream, yogurt, mayonnaise, salad dressing, butter, margarine, frosting, rice, vegetables, whipped topping, gravy, and barbecue sauce).

You should refrigerate all perishable foods at a temperature between 35°F to 40°F as soon as possible. TO GO foods should not remain out of refrigeration for longer than one hour.

TO GO foods may contain perishable foods that require immediate freezing (for example: French bread pizza, lasagna, frozen fruit).

You should place frozen items into a freezer within one hour of pick-up.

5. *What if I must transport my TO GO foods for longer than one hour without refrigeration?*

You should use a cooler with an ice pack to transport or store TO GO foods when they will be without refrigeration for longer than one hour. Replace the ice as needed.

6. *How can I tell if my TO GO foods are spoiled?*

If any of your TO GO foods ever look or smell odd, your TO GO meal may be spoiled. Do NOT taste or eat the food that you think has spoiled.

7. *What do I do if I suspect some of my TO GO foods may be spoiled?*

Do not eat the perishable food items contained in the TO GO package if you suspect they may be spoiled. You should immediately notify us and follow our instructions on what to do next. We may provide you a replacement food, or give you instructions to eat your emergency meal or energy cookies.

8. *What should I do if I have a problem with my TO GO foods, such as an item is missing or extra when I compare the foods to my copy of the menu, or a drink has spilled?*

If you discover a problem with your TO GO foods, contact us as soon as possible to receive instructions on what to do.

9. *Do I need to cook my TO GO foods?*

We have cooked most of the TO GO items. You may choose to reheat your meals in a microwave, toaster oven, or conventional oven. A few items do require some cooking or heating, including: french bread pizza, lasagna, grits, oatmeal, and cream of wheat.

The packaging containers provided may not be suitable for heating. When you must transfer foods to appropriate cookware for reheating or cooking, be sure to use a spatula and transfer all of the food. Use the instructions provided on the food package or included with your copy of the menu. Should you have any further questions regarding cooking instructions, please ask.



DASH2 Recipes

Form #108 is a large document of multiple recipes. We will not be updating these in the manuals, since this is such a large, extensive document. If you need to refer to this document, you may print a copy for yourself.



SCALLION RICE (A & B)

"A" and B" Diet: Friday (1600, 2100, 2600, 3100, 3600, low, medium, high)

Calorie Level:	1600	2100	2600	3100	3600					
Recipe Increment:						X 9 for "A" X 5 for "B"	X 27 for "A" X 15 for "B"	X 36 for "A" X 20 for "B"	X 45 for "A" X 25 for "B"	X 54 for "A" X 30 for "B"
Rice, long grain, cooked, Uncle Ben's						1097	3291	4388	5485	6582
Scallions, chopped						73	219	292	365	365
Portion Weight "A"	100	100	130	200	250					
Portion Weight "B"	60	130	234	234	250					

Preparation Instructions:

1. Combine cooked rice and scallions.
2. Weigh into individual containers according to assigned weights for "A" and "B" diets.

The purpose of the Food Substitution Record is to track deviations from brand names identified for all DASH2 menus. As outlined in MOP Chapter 40, brand names identified on Table 40.5 should be used whenever possible. If those brands cannot be found, the substitutions should be recorded on form #109.

For each food item substituted, indicate the cohort # and the specific menu where the item used. Record the name of the item substituted and the dates covered by that substitution.

During Diet Committee conference calls, the committee will review substitution items and decide whether detailed nutrient information is required. The committee will also decide whether substitutions should be incorporated into the official substitution list (Table 40.5, Diet MOP Chapter 40).



Clinical Measurements

Your calendar of events for DASH2 will provide you with the dates clinical measurements will be taken. Below you will find a description of each of the measurements required.

Blood Pressure (BP): Your blood pressure will be measured using the same procedures as in your screening visits. *Once you actually are enrolled in the study you will no longer be told your blood pressure!* Please do NOT smoke, exercise, eat, or drink any beverage containing caffeine for 30 minutes before your blood pressure is measured. If you forget and do any of these things you will be required to sit and wait 30 minutes before your blood pressure can be taken. All blood pressure measurements must be completed before you receive your evening meal.

Ambulatory Blood Pressure (ABPM or 24-hour BP): You will wear the ambulatory blood pressure monitor for (3) 24-hour periods during the study. This monitor will be worn on your non-dominant arm (ex: left arm if you are right-handed) and is approximately the size of a walk-man. The blood pressure cuff will inflate every 30 minutes as measurements are taken. The monitor will be placed and instructions provided on the same evening as a regular blood pressure measurement is taken. Please refer to your calendar for a range of dates. Make sure and allow an extra 20 minutes on this night and to wear a short-sleeved shirt. You will be informed of what particular day this will occur in advance.

Fasting Blood Sample: A blood sample will be collected 3 times throughout the study. This measurement requires that you eat or drink nothing (water is allowed) after midnight the night before the morning you are scheduled to have your blood drawn. We also ask that you avoid alcohol for 2 days prior to your blood draw. A sign-up sheet will be provided to you the week before to schedule a time.

24-hour urine: Three 24-hour urine collections will be done during the study (see calendar for days). The urine will be collected in the same fashion as during the screening process. Urine collections are usually during the week. The specimen is to be returned to your study center the following day when you come in for your on-site meal. If a weekday is not convenient for you, please contact your study coordinator to make alternate arrangements.

Women of child-bearing age: 24-hour urine collections should NOT be done during the menstrual cycle. Please check your calendar if your period is due during a scheduled collection time. Notify your study coordinator in advance so your collection can be completed at an early time.

Questionnaires: There are several questionnaires to be completed during the study. The dates for these will also be listed on your calendar. These forms are to be completed at the same time blood pressure measurements are taken so please allot a few extra minutes for this. Clinic staff will be available to review these forms at the time they are completed if you have any questions.



Daily Diary Information

The following is a guide to completing the Daily Diary as well as more information on the guidelines for eating during DASH2. DASH2 participants are to complete the Daily Diary every day for the entire study. Forms should be returned before you leave your study site. You will be given diaries to take home over the weekend to be completed for Friday and Saturday meals. Follow the same pattern for filling these out as you do during the week days. Bring weekend diaries to your site on Monday to turn in at that meal time.

Shaded area at the top of the page

(This area will be filled out for you in advance by DASH2 Study staff)

ID#: This is assigned to you and should be printed on the form for you. Please make sure you have received your own form.

DATE: Each day you will receive a daily diary. The diary will be dated for the previous day. Your answers to each of the questions should include the all the foods and beverages you consumed during that day specified on the diary.

Example

On Wednesday 2/18/98, you will receive a diary dated Tuesday 2/17/98.

You should include information about:

breakfast, lunch, dinner, snacks, beverages, and any other foods consumed on Tuesday.

Weight: Your weight will be taken BEFORE each meal is eaten. DASH2 staff will record this in this space.

Calorie level: Your assigned calorie level should be circled by DASH2 study staff.

Number of energy cookies distributed: This is the number of energy cookies that you are given to eat with your meal the next day.

Below the shaded area

Please answer all questions below and fill in any additional information requested.

Question #1. Did you eat at least one meal at the feeding site yesterday?

- Mark yes or no as to whether you ate the meal on-site.
- For weekend meals, you are not expected to eat on-site, and this should generally be recorded as no.

Question #2. Did you have any coffee, tea, or soda yesterday? If yes, what kind? (Give brand name and how much you consumed.)

- Review list of allowed beverages, amount of beverages that makes one serving, and the number of servings allowed. Caffeinated beverages are allowed in the amounts given on the list.
- Be sure to record the kind of beverage, whether or not it is caffeinated, and the amount in ounces consumed on the daily diary. The beverages listed here are not necessarily provided by the study, but may be purchased and consumed according to the guidelines.
- *Note:* a standard can of soda is 12 ounces, a cup is 8 ounces, and ½ cup is 4 ounces.
- Water is allowed in unlimited amounts and does not need to be recorded.

Question #3. Did you drink any alcoholic beverages yesterday? If yes, what kind and how much?

- Review the list of allowed alcoholic beverages and amounts and serving sizes. Record the kind and amount in ounces of alcoholic beverages.
- *Note:* a standard can of beer is 12 ounces.

Question #4. Did you eat any of the “energy cookies yesterday? If yes, how many?

- Energy cookies for DASH2 are cookies wrapped individually. They are distributed with your TO GO meals. They are used to help maintain your weight. You should eat the cookies distributed to you and record the number eaten on the daily diary.
- Also, you will all be given 2 energy cookies to put in your freezer. Eat these in situations when you are unusually hungry. When you eat these, record the number eaten on the diary in addition to any that you ate that were included in your daily meals. Request replacements for these when eaten.

- **Question #5.** Was there any food left over from what you were served yesterday? If yes, please list the kind and amount, and the reason.
- Eat all foods provided throughout the study period including breakfast, lunch, dinner and snacks (snacks are sometimes packed with the breakfast or lunch “to go” meals.)
- Everything edible is required to be consumed, including snacks.
- If you are unsure of what is edible, talk to DASH2 staff for directions (e.g., potato skin and apple skin IS EDIBLE, apple core/seeds, orange skin, gristle from meat is NOT edible).
- Clean up leftovers gravies and sauces with a piece of bread, rice, potato, or rubber spatula to make sure that you consume everything.
- Salad dressings, butter pats, and other small packaged items should be emptied completely and eaten.
- When transferring items from our containers to your plate, use a rubber spatula to insure that everything is transferred.

- Study foods cannot be shared with other study participants, friends, family members or others.

Question #6. Did you eat or drink any foods that are not allowed by DASH2 yesterday? If yes, please list the kind and amount, and the reason.

Participants are not to even try a bite of other foods or sip of fluids not provided by DASH2, with the exception of the “allowed beverages and seasonings.”

- All coffee, tea, or soda beverages should be recorded under question #2. The allowed amounts of free spices used do not need to be recorded. If other spices are used or amounts greater than allowed are used, record that information here.
- It is very important for the study that you eat all of the food provided and nothing else. If something happens to your food, or you accidentally or otherwise consume something you are not supposed to eat or drink, it is important that you tell us and record it on your form in as much detail as possible, **INCLUDING THE TYPE OF FOOD AND THE AMOUNT.**

Question #7. Did you take any vitamins, other dietary supplements, or over-the-counter medicines such as Tylenol or cold medications?

- record these types of medications taken here (see list of allowed medication provided in your packet).
- If other medications are needed, contact clinical staff prior to taking any. Record the use of all of these.
- Record use of Lactaid here. Let us know if you are lactose intolerant, or have trouble digesting dairy products and need Lactaid. We will provide this for you.
- No vitamin or mineral supplements are allowed; however, if one is taken for any reason, record intake.

Question #8. For women only. Are you menstruating today?

- **Women**, please answer daily *yes or no*. This information is used for weight monitoring purposes. Women keep in mind that your menstrual cycles may interfere with 24-hour urine collection. Please talk to a clinician regarding this issue if it applies to you.
- **Men**, please record *no* daily.

Question #9. Is there anything you would like for us to know regarding your participation in the study?

- Use this space to write anything here you’d like us to know. Or simply mark yes and discuss with staff if you would rather.
- If message is urgent, let the DASH2 staff know.

Shaded area in the right hand column

- The portion will be completed by the DASH2 staff. Please do not write in this area.

OTHER ISSUES:

- Especially during the first week of the study, let us know if you are too full or hungry so calories can be adjusted.
- Maintain normal activity/exercise pattern throughout the study. If a change occurs, record on diary immediately.
- You will be given one day's worth of meals and energy cookies. **These meals and cookies should be frozen and saved for an emergency.** You should let us know if a situation arises that you need to eat your emergency meal. This information should be recorded on the diary also. A new meal and energy cookies will be provided to you at the beginning of each feeding period. The old meal should be then discarded and replaced with new one.
- We will be looking for you every day at your scheduled time! If you do not expect to arrive on time, PLEASE call us as soon as possible so that we can make other arrangements!!!
- We hope you enjoy participating in DASH2. You are a valuable part of the study, and we want to make it a pleasant experience for you.



Daily Diary Information

You will be asked to complete a Daily Diary at the study site every day. We will give you diaries to complete at home for Friday and Saturday meals. Fill these out the same way you do at the study site during weekdays, and return them to us on Monday.

DIARY INSTRUCTIONS

Shaded area at the top of the page:

ID#:

DASH2 assigns this number and prints it on the form for you. Please make sure that you have received your own form.

Date:

Each day you will receive a Daily Diary dated for the previous day. Answer each of the questions for the date specified on the diary.

Example: On *Wednesday 2/18/98*, you will receive a diary dated *Tuesday 2/17/98*.

Please include information about: **breakfast, lunch, dinner, snacks, beverages, and any other foods consumed on Tuesday.**

Weight:

We will measure and record your weight in this space BEFORE each on-site meal.

Calorie level:

DASH2 staff will circle your assigned calorie level.

Number of energy cookies distributed:

This is the number of energy cookies that you were given to eat with your meals.

Below shaded area:

Please answer all questions below and fill in any additional information requested.

1. Did you eat at least one meal at the feeding site yesterday?

Mark yes or no. For weekend meals, you are not expected to eat on-site (record “no”).

2. Did you have any coffee, tea, or soda yesterday? If yes, what kind? (Give brand name and how much you consumed.)

Be sure to record the kind of beverage, if it is caffeinated, and amount consumed in ounces.

3. Did you drink any alcoholic beverages yesterday? If yes, what kind and how much?

Record the kind and amount of alcoholic beverages in ounces.

4. Did you eat any of the “energy cookies” yesterday? If yes, how many?

Please eat all the cookies distributed to you and record the number eaten.

5. Was there any food left over from what you were served yesterday? If yes, please list the kind and amount, and the reason.

Record kind, amount, and reason for any uneaten food.

6. Did you eat or drink any foods that are not allowed by DASH2 yesterday? If yes, please list the kind and amount, and the reason.

Record all coffee, tea, or soda beverages under question #2. If non-allowed spices, or amounts greater than allowed are used, record that information here.

If, for any reason, you consume something you are not supposed to eat or drink, record it on your form in as much detail as possible, including the type of food and the amount.

7. Did you take any vitamins, other dietary supplements, or over-the-counter medicines such as Tylenol or cold medications?

See list of allowed medications provided in your packet. If other medications are needed, contact DASH2 clinical staff prior to taking any. Record all used, including Lactaid here.

No vitamin or mineral supplements are allowed; however, if one is taken for any reason, record intake.

8. For women only: Are you menstruating today?

Women, Please answer daily, *yes or no*. This information is used for weight monitoring purposes. Your menstrual cycles may interfere with 24-hour urine collection. Please let us know if this applies to you.

Men, please record *no* daily.

9. Is there anything you would like for us to know regarding your participation in the study?

Use this space to write anything here you’d like us to know. Or simply mark yes and discuss with staff. If message is urgent, let the DASH2 staff know.

Shaded area in the right hand column

This portion will be completed by the DASH2 staff. Please do not write in this area.



Allowed Medications

Medications ALLOWED during DASH2.

Medical condition or symptom

Aches and pains	Tylenol Aspirin Ibuprofen (but not within 48 hours before BP measurement)
Indigestion	Amphogel Nephrox
Cold/flu/allergy	Tylenol, Extra strength tylenol Chlortrimeton Benadryl Hismanal Seldane Tavist Afrin, otrivin or Ayr nasal spray Robitussin (NOT Robitussin DM) Claritin Beconase nasal spray
Constipation	Correctol Senokot
Infections	Antibiotics
Hormones	Estrogen and progesterone (but don't start these meds or change dose during the study)
Other	Lactaid Beano

If you want to take any other medication, you must first discuss it with DASH2 study personnel. Many medications can interfere with the DASH2 study, so please ask first!



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Sun-Land Products Tel: 510-463-7562 Fax:	Pam Persham or Donna Super	Direct					
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
1. NTS Minisnacks (2570)	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	7 - 14 cases	24, ½ oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
NTS 6-packs (2010)	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	6 - 12 cases	24, 1½ oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
California apricots (7170)	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	20 - 40 cases	12, 6 oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Fruit Bits (7000)	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	7 - 14 cases	12, 6 oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Shipment: once per cohort			
Hormel	Marji McCullough (may be Eva Leung)	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Little Sizzlers Brown and Serve	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen	22-44 CS	12, 7oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Low Sodium Ham	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen	10-20 CS	1 lb	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Kellogg	Marji McCullough	Direct					
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Low sodium Corn Flakes	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	12-24	PC, 72, 11/16 oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		
Regular Corn Flakes	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	9-18	PC, 72, ¾ oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		
Frosted Mini Wheats	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	7-14	PC, 72, 1.25 oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		
Frosted Flakes	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	5-10	PC, 72 , 1 1/8 oz.	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		
Bran Flakes	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	3-6	PC, 72/CS	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Marji to organize once/year shipment. See attached table When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
McCormick Spice Company	Marji McCullough	Direct					
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Spices	See attached table			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 1/99		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study
McCormick Spice Company
Quantity Estimates for Donation Year 1 of DASH2*

*Note: Baltimore and Duke are starting with much larger groups than Boston and Baton Rouge

SPICE	Container Size	Boston	Baton Rouge	Baltimore	Duke
Black pepper, grd	16 oz	1.5 lb	1.5 lb	3.0 lb	3.0 lb
White pepper, grd	18 oz	1.5 lb	1.5 lb	3.0 lb	3.0 lb
Cayenne pepper, grd	14 oz	1.5 lb	1.5 lb	3.0 lb	3.0 lb
Basil, ground	12 oz	7.4 oz	7.4 oz	14.75 oz	14.75 oz
Celery seed	16 oz	5.4 oz	5.4 oz	10.8 oz	10.8 oz
Cinnamon, grd	16 oz	4.5 lb	4.5 lb	9 lb	9 lb
Dill weed, dry	5 oz	10.25 oz	10.25 oz	21 oz	21 oz
Garlic powder	19 oz	1.75 lb	1.75 lb	3.5 lb	3.5 lb
Mustard, ground	16 oz	2 lb	2 lb	4 lb	4 lb
Mustard seed	22 oz	6 oz	6 oz	12 oz	12 oz
Onion flakes, dehydrated	17 oz	4 lb	4 lb	8 lb	8 lb
Onion powder	20 oz	2 lb	2 lb	4 lb	4 lb
Parsley flakes	10 oz	1.2 lb	1.2 lb	2.4 lb	2.4 lb
Thyme	11 oz	8 oz	8 oz	1 lb	1 lb
Vanilla (imitation)	16 oz	20 bottles	20 bottles	40 bottles	40 bottles
Lemon (imitation)	16 oz	5 bottles	5 bottles	10 bottles	10 bottles
All purpose seasoning packets*	200/box	25 boxes	50 boxes	75 boxes	75 boxes
Lemon pepper blend seasoning packets*	200/box	25 boxes	50 boxes	75 boxes	75 boxes

*Needs for seasonings tend to be regional, and in Boston we don't have a lot of storage space

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: Once per cohort shipment				
Elwood	Marji McCullough	Direct	When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Zero dressing	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	2-4 cases	12 gm PC, 200/CS	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98		
Low Salt mayonnaise	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	3-6 cases	12 gm PC, 200/CS	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Shipment once per cohort			
Quaker	Marji McCullough	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Grits, instant	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	38-76	Boxes 12, 12 oz /cs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Grits, quick	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	8-16	Lbs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Oatmeal instant - cinnamon spice	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	10-20	boxes	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Oatmeal quick	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	5-10	lbs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Nabisco	Marji McCullough	Direct					
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Fleischman's Salt free Margarine	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen	45-90	lbs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Fleischman's Regular Margarine	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen	35-70	lbs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Planters mixed unsalted nuts	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	93-170	lbs 16 oz cans	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Unsalted oil roasted peanuts	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	15-30	lbs	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Once per cohort			
Best Foods	Marji McCullough	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Hellman's Mayonnaise	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	15 - 25	12 gm pc	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Hellman's Mayonnaise	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	30- 50	32 oz jar	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
Corn oil	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	25- 45	16 oz bottle	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Marji has prearranged shipments per cohort			
FAX: 209-549-8267	Stacey Kollmeyer	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Almonds	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	35-56 lbs	25 gm	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 7/98 1/99 7/99		
Almonds	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	4-5 lbs	1 lb bags	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 7/98 1/99 7/99		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: This may be a one-time donation. Marji will follow up.			
Fifty 50 Foods, Inc.	Marji McCullough	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
50/50 Peanut butter	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	2-3 cs	12- 18 oz ea	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Marji will organize shipments 1 x/cohort			
Diamond Crystal	Marji McCullough	Direct		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
LS Chicken Gravy mix	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	1	CS	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		
LS Beef Gravy mix	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	2	bags	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: Fax order 2 weeks in advance using special form				
Curtice Burns Telephone: 716-383-2452 Fax: 716-383-8253	Larry Hahn	Direct	When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Frozen vegetables Spinach Turnip greens	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Collard greens Peas	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Green beans Summer squash Cauliflower	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Carrots Zucchini Dried green peppers	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input checked="" type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: Use company form. Fax order at least 10 days in advance.				
Cabot Creamery Telephone: 802-563-2231 x216 Fax: 802-563-3240	Val DuCharme	Direct	When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
75% reduced fat cheddar cheese	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		12, 6oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Sharp cheddar cheese	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		12, 8oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Butter salted pc	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		5 gm 8 lb per case	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Salted butter - bulk	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		36 lb per case	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Unsalted butter - bulk	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		18 lb per case	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Regular sour cream	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		12, 16oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
Nonfat sour cream	<input type="checkbox"/> Dry <input checked="" type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen		12, 16oz	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method		Comments: Shipment once per cohort When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.			
Proctor & Gamble	Marji McCullough	Direct					
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Jif creamy peanut butter	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	3-6 cases	18 oz jars	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98		

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



Dietary Approaches to Stop Hypertension 2 (DASH2) Study

Food Donations Tracking Form							
Company/ Division Address/Telephone	Contact Person	Distribution Method	Comments: Marji will organize once/year shipment				
Hershey Foods	Marji		When there is a range of cases listed, Duke and Baltimore receive a larger shipment than Boston and Baton Rouge.				
Food Item	Storage Requirements	Amount	Units	Correct Contents Confirmed*	Expected Delivery Date	Date Received	Initials
Ronzoni spaghetti	<input checked="" type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen	12	20, 16oz pkg case	<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete	1/98 6/98 1/99 6/99		
	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			
	<input type="checkbox"/> Dry <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen			<input type="checkbox"/> Units <input type="checkbox"/> Food Items <input type="checkbox"/> Complete			

*Check the boxes when the order is received and correct (e.g., correct number of units, correct food items and complete order received).



CONFIDENTIAL INFORMATION

Do not post this document or share with blinded staff.

<u>Flower</u>	<u>TX number</u>	<u>Diet</u>	<u>Sodium Sequence</u>
Carnation	1	Control	LMH
Daisy	2	Combination	LHM
Iris	3	Control	MLH
Lilac	4	Combination	MHL
Marigold	5	Control	HLM
Poppy	6	Combination	HML
Rose	7	Combination	LMH
Snapdragon	8	Control	LHM
Sunflower	9	Combination	MLH
Tiger-Lily	10	Control	MHL
Tulip	11	Combination	HLM
Violet	12	Control	HML



SV3 Follow Up
ID # _____

SV3 Follow Up Form

DONE ?

Fasting Blood Draw (store at 70°)

Participant Information Sheet
(Boston)

Eligibility Review Form (within 1 month of RI) **eligible** 1
ineligible 2

Weight

Other

Reviewed by (staff ID): _____

SV3 Follow Up Form

This form is for internal use only. It will not be entered.

The Eligibility Review form must be completed within one month of Run-in. If the participant filled out the original Eligibility questionnaire within 30 days of start of Run-in, this form does not need to be completed.

The other category is for any other items that need to be completed during this interim visit.



Food Substitution Facsimile Transmission Cover Sheet

TO:

FROM:

Catherine Champagne
Telephone: 504-763-2553
FAX: 504-763-3045

Shirley Craddick
Telephone: 503-335-6783
FAX: 503-335-2428

DATE:

TOTAL PAGES TRANSMITTED: ____ (include cover sheet)

MESSAGE: Please evaluate the food product below for permanent substitution to the DASH2 Menu.

Food substitute product name: _____

Diet and food replacing: _____

Include a photocopy of the product label in the space below:



Action Planning Worksheet

GOAL: _____

PLAN: _____

HOW FEASIBLE IS THIS PLAN?
WHAT ARE THE BARRIERS THAT MIGHT INTERFERE?

ACTION STEPS: WHEN, WHAT, WHERE, AND HOW?

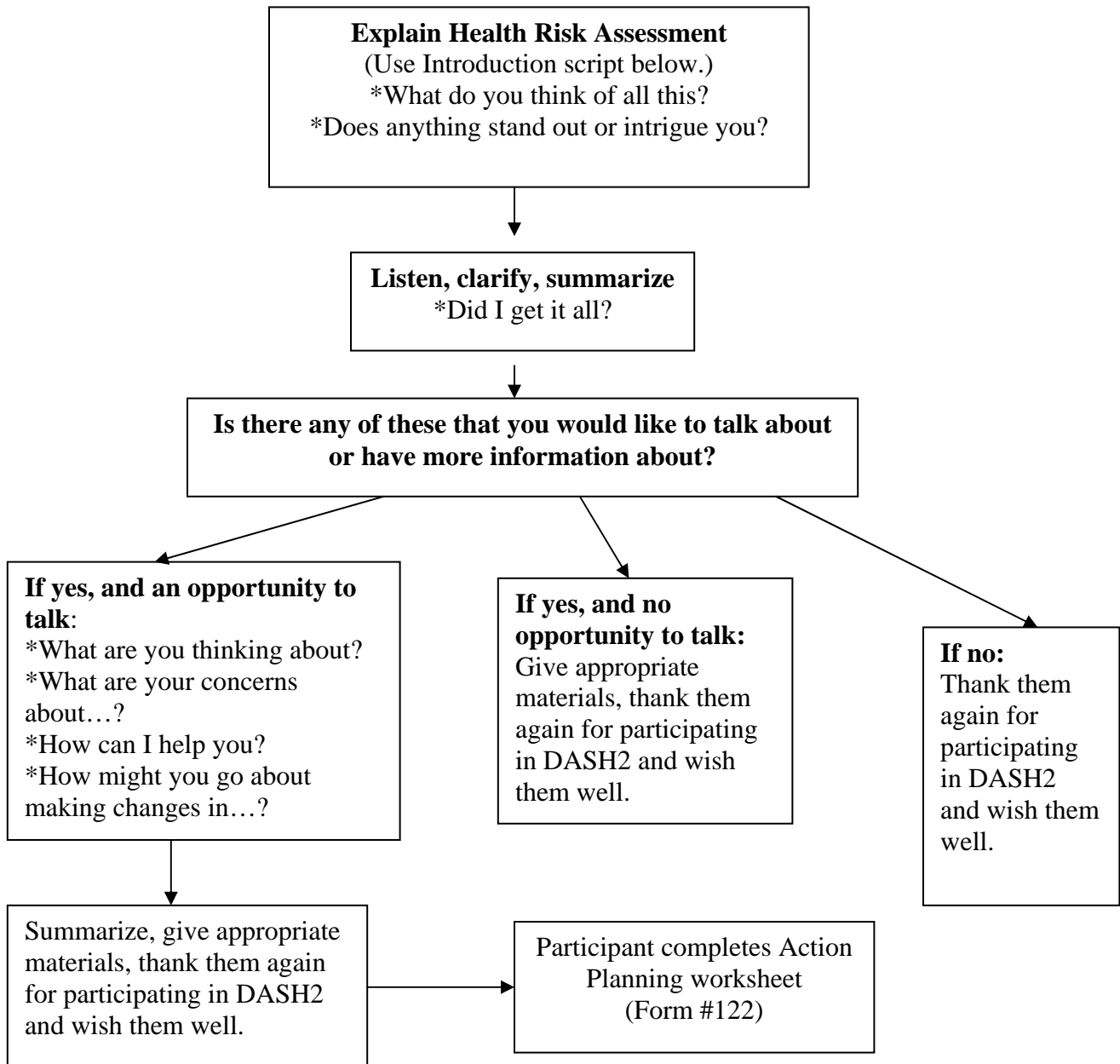
WHAT RESOURCES DO I NEED?

Action Planning Worksheet Administration

This form is designed to use during the Exit Interview. Use the form if the participant is interested in making a behavior change. The form is a guide to help the participant make a reasonable, concrete goal that is achievable. Have the participant complete the form at the interview. This allows the counselor to help the participant make a feasible goal and identify barriers that can interfere achieving the goal. The completed form is given to the participant. The data is not entered.



Exit Interview Flow



Introduction Script

We would like to thank you for your participation in DASH2. Your commitment and involvement have substantially contributed to our knowledge about the relationship between diet and blood pressure. At the end of the entire DASH2 study, you will receive all your personal information. At this point in the study, we would like to provide you with some personal feedback and information that may help you make choices about your health.

What I have given you is a personalized Health Risk Assessment. It is based on the information you provided us during the screening process for DASH2. It also includes the average of all your blood pressures during the time you have been involved with the study. The assessment includes recommendations for optimal health. This can help you decide if you want to make lifestyle changes that may benefit your health. We have additional information about any of these areas. Please feel free to request that information.

I would like to go through each of these items and you can follow along on your own assessment. It is divided into two parts. The first is based on dietary information and the second on other clinical and behavioral measurements.

The dietary feedback is based on the Food Frequency Questionnaire that you completed during screening. We have a copy of that questionnaire if you would like to look at it. This instrument is designed to look at food intake over a long period of time. It does not cover all foods that you consume. You will need to look at the feedback to see if it makes sense to you. For example, there are many vegetables that are not listed on the form. You may eat those regularly and it may not get counted. However, in general, it gives you a starting point.

The dietary recommendations on the Health Risk Assessment are based on the DASH diet. They may differ from other recommendations that you have seen. It is important to note that this pattern of eating has been proven to reduce blood pressure.

Now, let's look at these. There are four graphs at the top of the assessment. All of these represent different aspects of the DASH diet. The shaded area indicates the recommended range and the star represents where you are. The categories and their recommended ranges are servings of fruits and vegetables (8 or more per day recommended), percent of calories from fat (less than 30% recommended), level of sodium intake (less than 2400mg per day recommended), and servings of low-fat dairy products (2 or more per day recommended). In addition, we have listed the top five high-fat and the top five high-sodium foods that were in your diet.

Are there any questions about the graphs or the recommendations?

What do you think about this information?

Does anything jump out at you?

If participants ask for additional information about a specific item, offer the handout or pamphlet. You may want to give the one-sentence version to the whole group. For example, if someone asked about serving size for fruits and vegetables, you might say "A serving size is generally ½ cup but I do have a handout that provides more specific details."

We are available to talk with you individually about your assessment and any areas that you might like to work on. So keep those in mind.

At the bottom of the first page, your average weight and your height are given. We have provided a table that will allow you to look up the optimal weight for your height. It is important to note that the recommendations are based on the general population but will give you a good range to work with.

The second page of your assessment has additional information and recommendations on it. The first is cholesterol. This blood test was done during screening. The assessment will indicate your level and a recommendation based on that level.

The next item is blood pressure. The values listed are the average of all your blood pressure measurements during DASH2. During each feeding period, your blood pressure may have varied due to the different sodium levels; however, at this time of the study we cannot provide that information. As you know, if your blood pressure had risen to a level needing follow-up during the study, we would have referred you to your physician. The recommendations given are based on the average of your blood pressures.

Physical activity is the next item. For the duration of the study, we have asked that you keep your physical activity relatively constant. However, for your general health, it is recommended that you get at least 30 minutes of moderate to heavy activity five days a week.

Smoking was not an issue addressed directly by DASH2. As health care professionals, we consider it to be a very important issue. If you do smoke, we encourage you to consider quitting.

The last item on your feedback sheet is alcohol consumption. People who consumed more than 2 drinks per day were excluded from DASH2. In addition, the study asked that you not drink more than that for the duration of the study. So, for the most part, this is not an issue for the group. However, we wanted you to know that the current recommendations regarding alcohol are to keep consumption at or below this level on a regular basis.

We have information about all the areas listed on the feedback sheet. If you are interested, please ask us. We are also happy to talk with you about any of the topics. We recognize that making any lifestyle change can be difficult. The good news is that when you are ready to make any of the changes, many options are available to help you. If one method doesn't work, try another one. And any one change will make a difference in your health and your confidence. I encourage you to consider choosing an area to focus on and taking some small steps toward enhanced health.

Guidelines for Offering and Giving Advice

If the participant asks for your opinion or advice:

***Give brief, clear, professional advice.**

“I recommend that you consider increasing fruits and vegetables as a first step.”

***Emphasize the participant’s choice in any change. Avoid all “should” words.**

“From looking at your feedback sheet, I consider quitting smoking to be the best thing you could do for your health and encourage you to consider quitting. But of course, it is your choice.”

***Encourage exploration of options.**

“The good news is that there are many things you can do that will positively impact your health. I encourage you to look at the Health Risk Assessment and choose an area you feel ready to tackle.”

“If you decide to focus on lowering your blood cholesterol level, there are many ways to do that. You can examine the options and choose one that fits with your lifestyle.”

***Express confidence.**

“I’m confident that you will be able to find a way to make this change work for you.”

***Encourage a reasonable action plan.**

“Sometimes it takes a lot of small steps to get to the goal. For example, if you choose to work on increasing fruits and vegetables, you may set a long-term goal of 8 per day. But if you are currently at 3 per day now, you might consider working gradually toward 8, perhaps starting with just adding 1 per day. Changes in diet take time and every little bit helps.”

***Encourage the participant to do the problem solving.**

“What are some ways you might increase your physical activity?”

Exit Interview Flow Administration

The counseling can take place either in a group session or in an individual visit. The Exit Interview Flow (Form #123) is a guide describing the session steps, a script to help introduce the Health Risk Assessment, and guidelines for offering advice to participants, if they ask. This form is not used to collect data.



Exit Interview Height/Weight Table

At the bottom of the first page of your personalized health risk assessment is your average weight during the duration of DASH2 and your height. We encourage you to look at the table below for the recommendation for optimal weight for you. This information is based on the general population and is not specific for gender or race. But it will give you a good range to work with.

If your weight is within the optimal range, that is great news. Staying physically active and limiting the fat in your diet can help you stay within that range.

If your weight is either below or above the optimal range, we encourage you to consider making some lifestyle changes that will help you get to the optimal range. There are many options for doing that and we would be happy to discuss those with you.

Recommended Weight for Height

Height	Weight (in pounds)
4' 10"	91-119
4' 11"	94-124
5' 0"	97-128
5' 1"	101-132
5' 2"	104-137
5' 3"	107-141
5' 4"	111-146
5' 5"	114-150
5' 6"	118-155
5' 7"	121-160
5' 8"	125-164
5' 9"	129-169
5' 10"	132-174
5' 11"	136-179
6' 0"	140-184
6' 1"	144-189
6' 2"	148-195
6' 3"	152-200
6' 4"	156-205
6' 5"	160-211
6' 6"	164-216

Exit Interview Height/Weight Table

Distribute the Exit Interview Height/Weight Table (Form #124) with the Health Risk Assessment Report. At the bottom of the first page of the Health Risk Assessment is the participant's height and averaged weight. The participant can use the Exit Interview Height/Weight Table (Form #124) to determine his or her optimal weight for height. It is important to note the recommendations for the optimal weight for height are based on the general population and are not specific for gender or race. If the Health Risk Assessment report is mailed to the participant, include this form.



Dear

Congratulations on your completion of the Dietary Approaches to Stop Hypertension 2 (DASH2) trial! Your commitment and involvement have substantially contributed to our knowledge about the relationship between diet and blood pressure. We greatly appreciate your effort and want to provide you with some personal feedback and information that may help you make choices about your health.

The enclosed two-page Health Risk Assessment is based on the information you provided us during your participation in the study. The first page is the dietary feedback based on the Food Frequency Questionnaire you completed during screening. The recommendations are based on the DASH diet. There are four graphs at the top of the assessment. The shaded area indicates the recommended range and the star represents where you are. In addition, we have listed the top five high-fat and the top five high-sodium foods that you indicated you consume.

At the bottom of the first page is your height and averaged weight. A separate enclosed table allows you to look up the optimal weight for your height. It is important to note that the recommendations are based on the general population and are not specific to gender or race.

The second page of the assessment contains the additional information collected during screening:

- Blood cholesterol
- Blood pressure
The values listed are the **average** of all your blood pressure measurements. The recommendations are based on this average. Your blood pressure may have varied during the feeding periods, however, at this time of the study we cannot provide that information. At the end of the trial, you will receive all the blood pressure information and your diet assignment.
- Physical activity
- Smoking status
- Alcohol consumption

We encourage you to consider choosing an area to focus on and then taking some small steps toward enhanced health. We recognize that making any lifestyle changes can be difficult. The good news is that when you are ready to make changes, there are many options available to help you. Any one change will make a difference in your health and your confidence. If you would like to talk individually about your assessment and any areas that you might like to work on, please feel free to contact us.

Again, thank you very much for your participation in DASH2.

Best regards.

Enc.: Health Risk Assessment
Exit Interview Height/Weight Table (Form #124)

Health Risk Assessment Cover Letter

The Health Risk Assessment Cover Letter (Form #126) is used for the Exit Interview when the Health Risk Assessment is mailed to the participant. Attendance at the Exit Interview group session is not mandatory, but staff makes every effort to get participants to attend. When participants are unable to attend a group or individual session, the two-page Health Risk Assessment report is mailed with the cover letter (Form #126). The form number is suppressed since the form is a letter to the participants.



Name (trainee) _____

Staff ID # _____

Date _____ / _____ / _____

Food Preparation Checklist

	Yes	No	N/A	Comments
1. Follow correct procedures to measure three DASH2 foods using the metabolic kitchen scale				
Properly zero scale between weighing foods.				
Weigh food item within allowable weight range				
Use proper weighing techniques (gloves, plastic wrap to cover scale, levels scale)				
2. Produce a randomly selected DASH2 Recipe. (This applicable only to dietary staff who prepare recipes)				
Locate correct recipe (diet, sodium level, calorie level, and version specific) for production.				
Select correct batch amount or servings per calorie level to produce.				
Follow cooking procedures as outlined on recipe.				
Correctly measure gram amounts for each food item in recipe (specific for each calorie level)				
Correctly portion recipe for individual calorie levels.				
3. Prepare one randomly selected food item listed in DASH2 Diet MOP, Chapter 40.				
Follow correct food preparation method (defrosting, prepping, cooking, cooling, rinsing weighing, storing) for selected food item.				
4. Package and/or tray one randomly chosen DASH2 meal.				
Correct product is selected to be packed or trayed.				
Weights of food items packed or trayed are correct.				
Meal is properly labeled for distribution to participants, in manner identified by site.				
Meal packed or trayed is complete and correct. All documentation for completion of meal is made, as requested by each site.				

Passed:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lead Trainer Staff ID # _____	

Instructions for Completing Food Preparation Checklist

The Food Preparation Checklist is used to ensure that a trainee has acquired the skills required to successfully prepare food according to the DASH2 Diet MOP, Chapter 40, Food Procurement, Safety and Preparation.

All persons preparing or distributing food are trained and certified yearly.

The lead trainer sees that the trainee has been shown, demonstrates, and/or completes each item on the list. After completion of the training, complete the form as follows:

Check the box when the trainee completes each activity satisfactorily.

Name (trainee): Record the name of the person being trained.

Staff ID #: Record the DASH2 identification number of the person being trained.

Date: Record the date certification is complete.

Passed (Yes or No): Mark Yes or No depending on the outcome of the certification process.

Lead Trainer Staff ID#: Record the Lead Trainer identification number.

Store the form with other quality assurance forms for your site for audit purposes.



SALT and the DASH2 DIET

The amount of salt you eat in your diet has been carefully calculated by the DASH2 dietitians. It differs among all of the three 4-week feeding periods. You may notice the difference in the taste of the foods, and they may seem more or less salty than you are used to. It is important to remember that the diet with the most salt represents less than the typical salt intake of many Americans. Most people find that after a few days they adjust to the level of saltiness.

Salt in our diet comes from three main sources:

1. as a natural part of the food
2. added to foods during processing
3. added to food from a salt shaker

In order to get the specific amount of salt in your food which DASH2 requires, we

1. use foods that have minimal processing;
2. add weighed salt to your food;
3. serve salted broth (bouillon) as part of your diet.

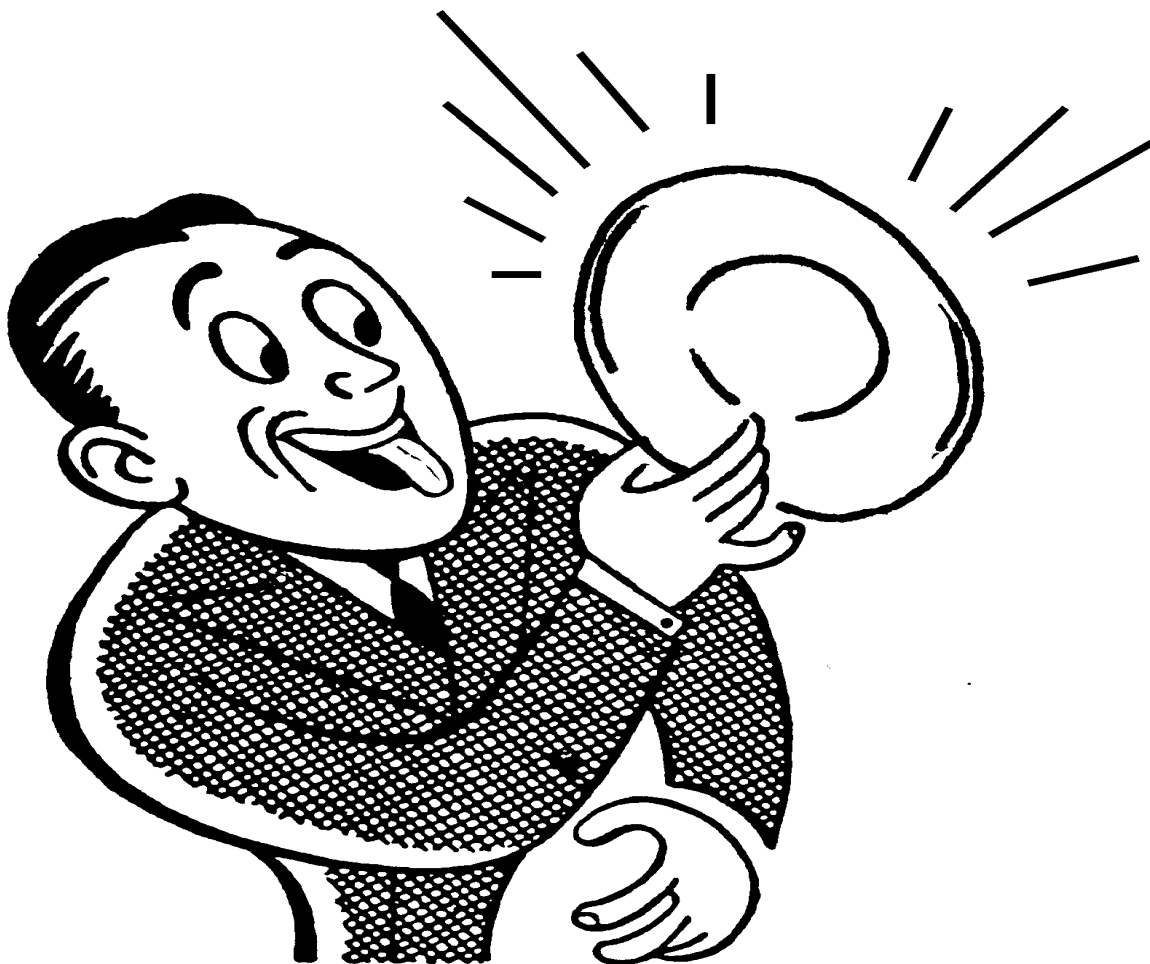
Leftover meat juices, gravies, sauces and broth are an important source of salt and other nutrients. This is why we ask that you use bread or a roll to mop up any leftover liquids and to finish all the broth.

We appreciate your efforts in helping DASH2 be successful. Thanks.



ID # _____
Date _____

THE CLEAN PLATE FORM



Did you "lick" your plate today?

Yes

₁

No

₂

Did you get your plate checked today?

₁₂

Checked by: _____

Staff ID: _____

ID: _____

Blood Pressure Medication Follow Up Form

Purpose: This form should only be completed if the participant answered “yes” to question 9 (Have you taken any medications to control your blood pressure in the last three months?) on the Eligibility Questionnaire (form # 6) and no other responses make that participant ineligible to continue with the study. Participants must be off blood pressure medications at least three months prior to randomization and one month prior to their SV1.

Date participant stopped taking BP medications:

___ ___ / ___ ___ / ___ ___

Stop date must be 1 month prior to



Date of SV1:

___ ___ / ___ ___ / ___ ___

Stop date must be 3 months prior to



Date of Randomization:

___ ___ / ___ ___ / ___ ___

Outcome:

- exclude from study
- okay to continue *

* Change “yes” response on form 6, question 9 to a “no”.
Fax a copy of this form and form # 6 to the CC.

Blood Pressure Medication Follow Up Form Administering Instructions

This form should only be completed if the participant answered “yes” to question 9 (Have you taken any medications to control your blood pressure in the last three months?) on the Eligibility Questionnaire (form # 6) and no other responses make that participant ineligible to continue with the study. Participants must be off blood pressure medications at least three months prior to randomization and one month prior to their SV1.

Date participant stopped taking BP medications:

Record date (MM/DD/YYYY) the participant stopped taking BP medications.

Date of SV1:

Record the participant’s SV1 visit date (MM/DD/YYYY).

Date of Randomization:

Record your sites projected randomization date (MM/DD/YYYY).

If the participant has been off medications one month prior to SV1 and three months prior to randomization (month is defined as a calendar month, i.e., January 21st to February 21st = 1 month), check the “okay to continue” box. You will then need to change the participant’s response to question 9, form #6 to a “no”. Do not obliterate the participant’s response. Cross through the original response, mark the correct response, record your initials, the date of change, and the following comment to document this change, “response changed due to BP Med follow up form”. Fax a copy of the eligibility questionnaire and the BP medication follow up form to the coordinating center.

This form is for internal use only. The data will not be entered into the DASH2 data entry system.

Adverse Events Classification Form Coding Instructions

ID: Copy participant ID number from the top of the Adverse Event form.

AE Date: Copy AE date from the top of the Adverse Event form.

Visit: Copy visit code from the top of the Adverse Event form.

Type of Event: Recode AE into one of the following four categories

1=Gastrointestinal

2=Cardiovascular/Neurological

3=Musculoskeletal

4=Other

Event Classification: Code AE as serious or not serious

Reviewed by: Record clinician signature and date

Entered by: Record data entry technician ID number (done after entry of form)

Serum:

Visit		Amount/vials/volume	Thawed okay	Cohort (s)
SV3	o	_____	o	_____
IFP /I	o	_____	o	_____
IFP /II	o	_____	o	_____
IFP /III	o	_____	o	_____

Plasma:

Visit		Amount/vials/volume	Thawed okay	Cohort (s)
SV3	o	_____	o	_____
IFP /I	o	_____	o	_____
IFP /II	o	_____	o	_____
IFP /III	o	_____	o	_____

Urine w/HCL:

Visit		Amount/vials/volume	Thawed okay	Cohort (s)
SV3	o	_____	o	_____
IFP /I	o	_____	o	_____
IFP /II	o	_____	o	_____
IFP /III	o	_____	o	_____

Urine w/o HCL:

Visit		Amount/vials/volume	Thawed okay	Cohort (s)
SV3	o	_____	o	_____
IFP /I	o	_____	o	_____
IFP /II	o	_____	o	_____
IFP /III	o	_____	o	_____