DELTA Protocol 1
Data Management System Forms

May 1, 1995

DELTA Protocol 1 Data Management System Forms

TITLE	FORM	VERSION
Pre-randomization		
Telephone Screening Visit Form	TSV	A
Eligibility Visit 1 Form (EV1)	V1A,V1B	A
Eligibility Visit 2 Form	EV2	A
Baseline Lipid Profile Form (at EV2)	LIP	A
Run-In Energy Estimates Form (optional, not keyed)	RIE	A
Apo E Genotype Form	*APE*	*A*
Post-randomization		
Participant Weekly Monitoring Form	PWM	A
Daily Food Record Form (not keyed by all centers)	DFR	A,B
Drop-Out Form	DPO	A
Sitting Blood Pressure Form (not used)	SBP	A
Date of Blood Draw Form (keyed at CSCC)	BDT	A
Endpoint Lipid Profile Form		
- at end of period 1 (exploratory)	EL1	A
- at end of period 3 (all periods)	ELP	A
Menu Composition Form	*NDF*	*A,B*
Unit Food Composition Form	*UNT*	*A*
Unit Oils Form	*UNO*	*A*
Lipoprotein Levels Form	*CLP*	*A*
Coagulation Factors Form (received as non-DMS formatted files)		
- at end of period 1 (exploratory)	*HM1*	*A*
- at end of period 3 (early Columbia only records)	*HEC*	*A*
- at end of period 3 (all periods, all centers)	*HEM*	*A*
Supplemental Funded Menstrual Calendars	*CAL*	*A*
Supplemental Funded Hormone Levels Form	*HMN*	*A*
Supplemental Funded Assays at Columbia	*SFC*	*A*
Supplemental Funded Assays at PBRC	*SFD*	*A*

Note: Forms in italics are keyed at the central agencies.

DELTA Protocol 1 Data Management System Forms

Key Fields for Data Entry

FORM	VERS	TIME POINT	SEQ
TSV	A	Today's Date	00
EV1	A	Today's Date	00
EV2	A	Today's Date	00
LIP	A	Date Blood Drawn	00
APE	A	Diet Period Start Date	00
PWM	A	Monday's Date	00
DPO	A	Date of Last Visit	00
ELP	A	Diet Period Start Date	00
CLP	A	Diet Period Start Date	00
CAL	A	Diet Period Start Date	00
HMN	A	Diet Period Start Date	00
BDT	A	Diet Period Start Date	00
HEM	A	Date Blood Drawn	00
SFC	A	Diet Period Start Date	00
SFD	A	Diet Period Start Date	00

DELTA

Form Code: TSV Version: A 6/15/93

Telephone Screening Form

DELTA ID: _____ 1. Today's Date: _____ (mm/dd/yy) 2. Personnel Code Number: ____

3. _____
a. First Name b. MI c. Last Name

4. _____
a. Street

_____
b. City c. State d. Zip Code

5. Home Telephone: _____ area-###-####

6. Work Telephone: _____ area-###-####

When is the best time to call? _____

Can you receive a call at work? YES NO

7. Date of Birth: _____ 8. Age: _____ 9. Gender: ___ (M/F)

10. a. What do you consider your race to be? [Circle letter preceding your selection]

A Caucasian (white)	F American Indian	K Pacific Islander
B African American (black)	G Asian Indian	L Other
C Hispanic	H Korean	(b. describe:_____)
D Mixed Race	I Vietnamese	M Did not respond
E Chinese	J Japanese	

11. a. How did you hear about this study? [Circle letter preceding your selection]

A Flyer	F Radio Talk Show	K Letter in Dept. Mailbox
B Poster	G TV PSA	L Physician or Nurse
C Newspaper Ad	H TV Talk Show	M Word of Mouth
D Newsletter Clip	I Letter by Mail	N Other
E Radio PSA	J Flyer in Paycheck	(b. describe: _____)

[Complete this section after telephone screening interview.]

12. a. Is applicant eligible following telephone screening? YES NO NEEDS MEDICAL REVIEW (R)

b. If YES to 12a, date of Eligibility Visit 1: _____ (mm/dd/yy) c. Time: _____ (hh:mm) d. AM PM

e. If NEEDS MEDICAL REVIEW to 12a, does the applicant remain eligible? YES NO

13. a. If this applicant has been excluded from the study, at which time point was the applicant excluded: [Circle letter preceding selection]

A Telephone Screening

B Eligibility Visit 1

C Eligibility Visit 2

Indicate reasons for exclusion: [Enter question number of exclusion, e.g. 14E or 32, left-justified] b. _____ c. _____ d. _____

MEDICAL CONDITIONS

14. Because certain medical conditions will interfere with our study, we need to ask the following questions. Do you have any of the following medical conditions? [Read list of medical conditions and circle response YES (Y), NO (N) if NO or NEVER TESTED, or UNSURE (U)]

a.	heart disease	Y	N	U
b.	diabetes	Y	N	U
c.	high blood pressure or hypertension	Y	N	U
d.	renal or kidney disease	Y	N	U
e.	gastrointestinal condition (Crohn's disease, irritable bowel syndrome, ulcer problems, bowel surgery)	Y	N	U
f.	history of blood clotting disorders	Y	N	U
g.	liver disease (cirrhosis)	Y	N	U
h.	condition that requires steroid medication	Y	N	U
i.	gout requiring treatment	Y	N	U
j.	recent history of depression or mental illness requiring medication within last 6 months	Y	N	U
k.	anemia	Y	N	U
l.	sickle cell anemia	Y	N	U
m.	lung disease, chronic bronchitis, emphysema	Y	N	U
n.	acquired immune deficiency syndrome (AIDS) or positive HIV test	Y	N	U
o.	cancer (active within 5 years)	Y	N	U

[If any medical condition was circled UNSURE, or item J was circled YES, then review by medical personnel is required to exclude the applicant from participation. If any item, other than J, was circled YES, then the applicant has become ineligible. If so, terminate the interview and complete questions 12-13.]

OTHER MEDICAL CONDITIONS

15. a. Do you have any other medical conditions not listed above? YES NO

If YES, list other medical conditions, one per line:

b. _____

c. _____

d. _____

[If any medical condition is listed, review by medical personnel is required.]

FOOD ALLERGIES

16. a. Do you have any food allergies? YES NO

If YES, list allergies, one per line:

b. _____

c. _____

d. _____

[If any food allergy is listed, review by medical personnel is required.]

SPECIAL DIETS

17. Are you on a special diet prescribed by a doctor for a medical condition? YES NO

If YES, is it: [Read list of special diets and circle response YES, NO, or UNSURE]

a.	diabetes	YES	NO	UNSURE
b.	heart disease	YES	NO	UNSURE
c.	hypertension or high blood pressure	YES	NO	UNSURE
d.	renal or kidney disease	YES	NO	UNSURE
e.	any other disease	YES	NO	UNSURE

[If any special diet is circled YES or UNSURE, review by medical personnel is required.]

ALCOHOL CONSUMPTION

DEFINITION: 1 drink = a 5 oz. glass of wine, a 12 oz. can of beer, or a shot glass of liquor

18. a. Do you drink alcoholic beverages? YES NO

b. If YES, how many drinks do you usually have in a 7-day week? _____

[If the applicant usually drinks over 12 drinks in a 7-day week, then the applicant has become ineligible. If so, terminate the interview and complete questions 12-13.]

MEDICATIONS

19. Do you take any type of medication? YES NO

If YES, what is the name of the medication that you take? [Record both doctor prescribed and self-prescribed medications. Ask for spelling of medication if necessary.]

a. Medication	b. Prescribed by a Doctor YES(Y) or NO (N)	c. Reason for Taking Medication
20.	Y N	
21.	Y N	
22.	Y N	
23.	Y N	
24.	Y N	
25.	Y N	

[If YES was circled for any medication prescribed by a doctor, review by medical personnel is required.]

HEIGHT AND WEIGHT

[Choose whether you will enter height/weight in customary units (ft-in/lb) or metric units (cm/kg) and proceed to the questions following the appropriate Upper Weight Limit Table. Only enter responses for either questions 26-28 or 29-31.]

Upper Weight Limit Table in Customary Units (ft-in/lb)

Ht.	4'10"	4'11"	5'0"	5'1"	5'2"	5'3"	5'4"	5'5"	5'6"	5'7"
Wt.	153	158	164	169	175	181	186	192	198	204

Ht.	5'8"	5'9"	5'10"	5'11"	6'0"	6'1"	6'2"	6'3"	6'4"
Wt.	210	217	223	229	236	243	249	256	263

26. What is your height without shoes? a. ft: _____ b. in: _____

27. a. What is your weight without shoes? lbs: _____
    b. Is the applicant's weight recorded in question #27a greater than the upper weight limit for the applicant's height in the table above? YES NO

28. It is important that our participants not lose or gain weight in this study. Are you willing to participate in a study where your weight is maintained at the same level it is now? YES NO

[Proceed with instructions at the bottom of the page.]

Upper Weight Limit Table in Metric Units (cm/kg)

Ht.	148	150	152	154	156	158	160	162	164	166	168	170
Wt.	70	72	74	76	78	80	82	84	86	88	90	92

Ht.	172	174	176	178	180	182	184	186	188	190	192	194
Wt.	95	97	99	101	104	106	108	111	113	116	118	120

29. What is your height without shoes? cm: _____

30. a. What is your weight without shoes? kg: _____
    b. Is the applicant's weight recorded in question #30a greater than the upper weight limit for the applicant's height in the table above? YES NO

31. It is important that our participants not lose or gain weight in this study. Are you willing to participate in a study where your weight is maintained at the same level it is now? YES NO

[Proceed with instructions at the bottom of the page.]

[If the applicant's weight is greater than the upper weight limit, or the applicant is not willing to maintain the same weight during the study, then the applicant has become ineligible. If so, terminate the interview and complete questions 12-13.]

WOMEN BORN AFTER 1942 ONLY

32.	Are you pregnant or planning to become pregnant within the next year?	YES	NO
33.	Are you breastfeeding?	YES	NO
34.	Have you had a baby within the last 6 months?	YES	NO

[If applicant remains eligible, continue with general description of DELTA Study.]

Description of DELTA Study

The purpose of the DELTA Study is to compare the effects of 3 diets with different amounts of fat on the level of cholesterol and clotting factors in the blood. The length of the study is 8½ months. Participants will eat each diet for 8 weeks. There are breaks between the diet periods, including time off for Thanksgiving, Christmas, New Year's, Passover, and Easter holidays.

During the diet study, you will be required to eat only foods provided by the study staff. You will not be allowed to eat any other food. You will be required to eat two meals at the center each day, Monday through Friday. The other meal will be packaged at the center and taken out. Weekend meals will be packaged also. Extra foods for snacks will also be provided. You will be allowed a meal of your own choice once a week, which will be Saturday dinner.

The diets will be planned so that you do not gain or lose weight during the study.

During weeks 5, 6, 7, and 8 of each diet period, blood samples will be taken to provide research information on cholesterol, other blood fats, and blood clotting factors.

FURTHER INTEREST

35. Based on the description of the study I just read to you, would you be interested in coming to the center to learn more about this study and get your cholesterol and blood pressure checked? YES NO

If NO, what is the reason? [Circle response to reasons for not scheduling Eligibility Visit 1]:

a. Uninterested in general study protocol YES NO

b. Unwilling to commit due to length of study YES NO

c. Unwilling to come to feeding center for 2 meals each day for 5 days each week YES NO

d. Unwilling to eat study food YES NO

e. Unwilling to limit intake to study foods only YES NO

f. Unwilling to allow maintenance of current body weight YES NO

g. Lives too far from feeding center YES NO

h. Travels out of town as part of job position YES NO

i. Other (j. specify: _____) YES NO

[If applicant is not interested, terminate the interview and complete questions 12-13.

If applicant is interested and remains eligible to this point, then go to question 36 and schedule Eligibility Visit 1. Ask applicant to bring all medications, including diet supplements and any contraceptives, to Eligibility Visit 1.

If applicant is interested, but responses need medical review, then tell applicant that he/she will be called back. Go to question 37 and schedule time for callback.]

36. If applicant is eligible at this point, schedule Eligibility Visit 1: a. date: _____ (mm/dd/yy) b. time: _____ (hh:mm AM/PM)

37. Does applicant's responses need medical review? YES NO

If YES, when is the best time to call? _____

[Return to page 1 and complete questions 12 and 13.]

FOR OFFICE USE ONLY

DELTA ID: _____ 1. Today's Date: _____ (mm/dd/yy) 2. Personnel Code Number: _____

Medical review needed? YES NO
Medical review done? YES NO
Eligible? YES NO

Welcome to the DELTA Study! We want to thank you for your help and hope that you are one of the lucky applicants who become eligible for the study. It's people like you who make research studies possible that benefit the public and answer important public health questions.

Part I (Questions 3 - 23) - To be completed by applicant

Make sure you have completed the consent screening form

3. _____
a. First Name b. MI c. Last Name

4. Date of Birth (mm/dd/yy): _____

5. Contact in case of an emergency:

a. Name: _____

b. Address: _____

c. Town/City: _____ d. State: _____ e. Zip Code: _____

f. Home telephone: _____ (area-###-####) g. Work Telephone: _____ (area-###-####)

6. What is your highest level of schooling achieved? [Please circle the letter by your selection.]

A Eighth grade or less
B Trade school or business school instead of high school
C Some high school
D High school graduate
E Trade school or business school after graduating from high school
F Some college including 2-year degree
G Received bachelor's degree
H Graduate or professional education beyond the bachelor's degree
I Graduate or professional degree

7. a. What is your current employment status? [Please circle the letter by your selection.]

A Working a full-time job
B Working a part-time job
C Full-time or part-time student; not working
D Student working full-time or part-time
E Homemaker/Volunteer
F Retired
G Unemployed
H Disabled
I Other (b. describe: _____)

8. Do you plan to remain in the area for the next 10 months? YES NO

9. Do you have any allergies or sensitivities to any of the following foods?
[Read each of the following foods and circle your response]
YES (Y), NO (N), or UNSURE (U)

a. Meat, fish, poultry	Y	N	U
b. Shellfish	Y	N	U
c. Milk or dairy products	Y	N	U
d. If YES to milk or dairy products, is this a milk allergy?	Y	N	U
e. If YES to milk or dairy products, is this a lactose intolerance?	Y	N	U
f. Eggs	Y	N	U
g. Fruit	Y	N	U
h. Vegetables	Y	N	U
i. Nuts	Y	N	U
j. Chocolate	Y	N	U
k. Other foods (l. describe: _____)	Y	N	U

We would like to ask you a few questions about your alcohol consumption...

DEFINITION: 1 drink = a 5 oz. glass of wine, a 12 oz. can of beer, or a shot glass of liquor	
10.	What is the total number of alcoholic drinks that you drink Monday through Thursday?____
11.	What is the maximum number of alcoholic drinks that you usually drink <u>in any one day</u> Monday through Thursday? ____
12.	What is the total number of alcoholic drinks that you drink Friday, Saturday, and Sunday?____
13.	What is the maximum number of alcoholic drinks that you usually drink <u>in any one day</u> Friday, Saturday, and Sunday? ____
14.	Would you be willing to limit your intake to 5 drinks per week during the duration of the study? [Circle your response] YES NO

15.	Are you taking any vitamins, minerals or other nutritional supplements? [An interviewer will ask you to list any nutritional supplements in Part II.] YES NO
16.	Because some nutritional supplements may interfere with study results, would you be willing to stop taking this supplement if you qualify for this study? YES NO

17. Are you currently on any of the following special diets ***prescribed by a doctor*** for a medical condition? [For each special diet listed below, circle YES or NO]

a. Weight loss	YES	NO	
b. Low salt or low sodium	YES	NO	
c. Diabetic	YES	NO	
d. Heart disease	YES	NO	
e. Lower blood pressure	YES	NO	
f. Weight gain	YES	NO	
g. Vegetarian	YES	NO	
h. Renal disease	YES	NO	
i. Allergy	YES	NO	
j. Other	YES	NO	(k. describe: _____)

18. a. Are you on a self-prescribed diet? YES NO

b. If YES, describe the self-prescribed diet:_____

19. Have you lost or gained more than 10 pounds within the past two months? YES NO

20. a. Have you ever smoked cigarettes? YES NO

b. If YES to 20a, do you now smoke cigarettes? YES NO

c. If YES to 20b, on average, how many cigarettes do you smoke per day? _____

21. If you have quit smoking, how many years has it been since your last cigarette? [Please circle the letter by your selection.]

A Less than 1 year
B 1 year or more

22. a. Do you exercise or play sports regularly? YES NO

If YES, please describe:

Activity	Number of Hours Per Week
b. _____	c. _____
d. _____	e. _____
f. _____	g. _____
h. _____	i. _____

23. Does your job require heavy physical labor? YES NO

End of Part I

Please hand your form to your clinic interviewer to initiate the remainder of the clinic visit.

Part II - Clinic Data Form

24. Because certain medical conditions will interfere with our study, we need to ask the following questions. Do you have any of the following medical conditions? [Read list of medical conditions and circle response YES (Y), NO (N) if NO or NEVER TESTED, or UNSURE (U)]

a.	heart disease	Y	N	U
b.	diabetes	Y	N	U
c.	high blood pressure or hypertension	Y	N	U
d.	renal or kidney disease	Y	N	U
e.	gastrointestinal condition (Crohn's disease, irritable bowel syndrome, ulcer problems, bowel surgery)	Y	N	U
f.	history of blood clotting disorders	Y	N	U
g.	liver disease (cirrhosis)	Y	N	U
h.	condition that requires steroid medication	Y	N	U
i.	gout requiring treatment	Y	N	U
j.	recent history of depression or mental illness requiring medication within last 6 months	Y	N	U
k.	anemia	Y	N	U
l.	sickle cell anemia	Y	N	U
m.	lung disease, chronic bronchitis, emphysema	Y	N	U
n.	acquired immune deficiency syndrome (AIDS) or positive HIV test	Y	N	U
o.	cancer (active within 5 years)	Y	N	U

25. a. Do you have thyroid disease or a thyroid problem? YES NO UNSURE

b. Have you ever had treatment, such as radioactive iodine or surgery, for a thyroid problem? YES NO UNSURE

c. Are you taking any medication for your thyroid? YES NO UNSURE

[If UNSURE, check the medications]

[If any medical condition was circled YES or UNSURE, then review by medical personnel is required to exclude applicant from participation.]

Medical reviewer _____ **Exclude** _____ **Include**
Initial **Initial**

26. a. Are there any medical reasons that would keep you from participating? YES NO

b. If YES, describe: _____

27. a. Are there any personal reasons that would keep you from participating? YES NO

b. If YES, describe: _____

28. a. Are there any professional reasons that would keep you from participating? YES NO

b. If YES, describe: _____

WOMEN ONLY

29. a. Are you currently taking an oral contraceptive? YES NO

b. If YES to 29a, are you planning to stop? YES NO

c. If NO to 29a, are you planning to start? YES NO

30. What is your current menstrual status? [Circle the letter by your selection.]

R Regular (normal)
I Irregular
N None

31. a. If you are menstruating irregularly, what is the reason? [Circle the letter by your selection.]

A Undergoing menopause
B Other (b. describe: _____)

c. If you have stopped menstruating, what is the reason? [Circle the letter by your selection.]

A Natural menopause
B Hysterectomy
C Medication stopped period
D Other (d. describe: _____)

32. When did you have your last period? [Circle the letter by your selection.]

A Less than 2 months ago
B 2 months to 6 months ago
C More than 6 months to 1 year ago
D More than 1 year but less than 3 years ago
E At least 3 years ago

WOMEN ONLY (continued)

33.	a. Are you taking or have you ever taken estrogen? [Estrogen or female hormones for hot flashes or symptoms of menopause]	YES	NO
	b. If YES to 33a, are you currently taking estrogen?	YES	NO
	c. If NO to 33a, do you plan to start taking estrogen?	YES	NO

[Resume asking questions of all applicants.]

34. How often do you take antacids? [Circle the letter by your selection.]

D Daily
W Weekly
O Occasionally
N Never

35. How often do you take laxatives? [Circle the letter by your selection.]

D Daily
W Weekly
O Occasionally
N Never

36. Within the past six months, have you taken any medications on a regular basis **prescribed by a doctor?** YES NO

If YES, specify doctor-prescribed medications, one per line: [Enter names of medications with correct spellings.]

	a. Medication	b. Reason for Taking Medication	c. Date When Stopped (mm/dd/yy)	d. Plan To Resume
37.	_____	_____	_____	YES NO
38.	_____	_____	_____	YES NO
39.	_____	_____	_____	YES NO
40.	_____	_____	_____	YES NO
41.	_____	_____	_____	YES NO
42.	_____	_____	_____	YES NO

[Applicant's doctor-prescribed medications must be confirmed at this time.]

43. a. Within the past six months, have you taken any **self-prescribed** medication or nutritional supplements on a regular basis? YES NO

If YES, please list self-prescribed medications or supplements, one per line: [Enter names of medications with correct spellings.]

b. _____

c. _____

d. _____

e. _____

f. _____

g. _____

44. If you are taking self-prescribed medications or supplements, would you be willing to discontinue use of the self-prescribed medication for the duration of this study? YES NO

HEIGHT AND WEIGHT

[Choose whether you will enter height/weight in customary units (ft-in/lb) or metric units (cm/kg) and proceed to the questions following the appropriate Upper Weight Limit Table. Only enter responses for either questions 45-47 or 48-50.]

Upper Weight Limit Table in Customary Units (ft-in/lb)

Ht.	4'10"	4'11"	5'0"	5'1"	5'2"	5'3"	5'4"	5'5"	5'6"	5'7"
Wt.	153	158	164	169	175	181	186	192	198	204

Ht.	5'8"	5'9"	5'10"	5'11"	6'0"	6'1"	6'2"	6'3"	6'4"
Wt.	210	217	223	229	236	243	249	256	263

45. Height: [Without shoes] a. ft: _____ b. in: _____

46. a. Weight: [Without shoes] lbs: _____
    b. Is the applicant's weight recorded in question #46a greater than the upper weight limit for the applicant's height in the table above? YES NO

47. It is important that our participants not lose or gain weight in this study. Are you willing to participate in a study where your weight is maintained at the same level it is now? YES NO

[Proceed with instructions at the bottom of the page.]

Upper Weight Limit Table in Metric Units (cm/kg)

Ht.	148	150	152	154	156	158	160	162	164	166	168	170
Wt.	70	72	74	76	78	80	82	84	86	88	90	92

Ht.	172	174	176	178	180	182	184	186	188	190	192	194
Wt.	95	97	99	101	104	106	108	111	113	116	118	120

48. Height: [Without shoes] cm: _____

49. a. Weight: [Without shoes] kg: _____
    b. Is the applicant's weight recorded in question #49a greater than the upper weight limit for the applicant's height in the table above? YES NO

50. It is important that our participants not lose or gain weight in this study. Are you willing to participate in a study where your weight is maintained at the same level it is now? YES NO

[Proceed with instructions at the bottom of the page.]

[If the applicant's weight is greater than the upper weight limit, or the applicant is not willing to maintain the same weight during the study, then the applicant has become ineligible. If so, terminate the interview.]

SITTING BLOOD PRESSURE

[Measure the applicant's arm circumference and choose the appropriate cuff. After applying the cuff, the applicant must be quiet and remain continuously seated without legs crossed for 5 minutes before the two measurements. Wait 30 seconds after the 1st reading before taking the 2nd reading. Reminder: Peak inflation level = pulse obliteration + 30.]

51. Arm circumference (cm): _____

52. Cuff Size: [Circle the letter by your selection.]

    P Pediatric (<24.5 cm)
    R Regular adult (24.5-33 cm)
    L Large adult (33-40 cm)
    X X-large (>40 cm)

53. Pulse: beats in 30 seconds _____ x 2 = _____ beats/minute

54. First blood pressure measurement: a. Systolic: _____ b. Diastolic: _____

55. Second blood pressure measurement: a. Systolic: _____ b. Diastolic: _____

56. Computed average of first and second blood pressure measurements:

    a. Systolic: _____ b. Diastolic: _____

57. Is average systolic blood pressure >140 or average diastolic pressure >90? YES NO

RAPID SCREEN CHOLESTEROL CHECK

Cholesterol Cutpoints by Gender, Race, and Age

Eligible Ranges for Total Cholesterol (mg/dl)				
Age	White Men	Black Men	White Women	Black Women
20 - 24 years	157 - 231	149 - 223	See table below for ranges for women age 20-44 years	
25 - 34 years	169 - 248	162 - 245		
35 - 44 years	188 - 273	180 - 277		
45 - 54 years	198 - 286	189 - 293	198 - 288	199 - 302
55 - 64 years	199 - 289	189 - 293	209 - 303	208 - 315
65 - 74 years	191 - 281	180 - 277	217 - 314	214 - 318

Eligible Ranges for Total Cholesterol (mg/dl) Women Age 20 - 44				
Age	White Women		Black Women	
	Oral Contraceptive User	Non-user	Oral Contraceptive User	Non-user
20 - 29 years	167 - 238	155 - 227	168 - 238	156 - 227
30 - 44 years	187 - 266	175 - 255	189 - 275	176 - 264

58. Total cholesterol level (mg/dl): _____

59. Is cholesterol level within the eligible range for the applicant's gender, race, and age? YES NO

[If the applicant's cholesterol level is not within the eligible range, then the applicant has become ineligible. If so, terminate the interview.]

VISIT CHECKLIST

[The following questions should all be answered 'YES' before the applicant is scheduled for Eligibility Visit 2.]

Did the applicant read and sign the consent screening form?

Was Part I of Eligibility Visit 1 completed?

Was applicant given the DELTA Information Packet?

Was the DELTA Study explained and questions addressed?

Were applicant's doctor-prescribed medications confirmed?

Does applicant remain eligible for Eligibility Visit 2?

ADMINISTRATIVE INFORMATION

60. a. Date scheduled for Eligibility Visit 2 (mm/dd/yy): _____

b. Time scheduled for Eligibility Visit 2 (hh:mm): _____ c. AM PM

[Remind applicant to come back fasting at least 8 hours to Eligibility Visit 2.]

DELTA ID: _____ 1. Today's Date: _____ (mm/dd/yy) 2. Personnel Code Number: ____

Did the applicant read and sign the Participant Agreement? *YES* *NO*

Did the applicant read and sign the consent screening form? *YES* *NO*

SITTING BLOOD PRESSURE

[Measure the applicant's arm circumference and choose the appropriate cuff. After applying the cuff, the applicant must be quiet and remain continuously seated without legs crossed for 5 minutes before the two measurements. Wait 30 seconds after the 1st reading before taking the 2nd reading. Reminder: Peak inflation level = pulse obliteration + 30.]

3. Arm circumference (cm): _____

4. Cuff Size: [Circle the letter by your selection]
   - P Pediatric (<24.5 cm)
   - R Regular adult (24.5-33 cm)
   - L Large adult (33-40 cm)
   - X X-large (>40 cm)

5. Pulse: beats in 30 seconds _____ x 2 = _____ beats/minute

6. First blood pressure measurement: a. Systolic: _____ b. Diastolic: _____

7. Second blood pressure measurement: a. Systolic: _____ b. Diastolic: _____

8. Computed average of first and second blood pressure measurements:

   a. Systolic: _____ b. Diastolic: _____

9. Is average systolic blood pressure >140 or average diastolic pressure >90? YES NO

[If average systolic blood pressure is >140 or diastolic blood pressure is >90 on both Eligibility Visit 1 and Eligibility Visit 2, then the applicant has become ineligible. If so, terminate the interview.]

WAIST AND HIP CIRCUMFERENCE

[Refer to the manual of operations for instructions on measuring circumferences. Round the readings and average to the nearest whole numbers.]

		a. Reading 1	b. Reading 2	c. Average
10.	Waist circumference (cm)	_____	_____	_____
11.	Hip circumference (cm)	_____	_____	_____

APPLIANCES AVAILABILITY

12. Does the applicant have access to the following appliances at home? [For each appliance listed below, circle YES or NO]

a. refrigerator	YES	NO
b. freezer	YES	NO
c. microwave	YES	NO
d. stove/oven	YES	NO
e. toaster	YES	NO

13. Does the applicant have access to the following appliances at work? [For each appliance listed below, circle YES or NO]

a. refrigerator	YES	NO
b. freezer	YES	NO
c. microwave	YES	NO
d. stove/oven	YES	NO
e. toaster	YES	NO

[If the applicant has become ineligible, then terminate the interview.]

BLOOD DRAWING

14. When was the last time you ate or drank anything except water?

    a. Time (hh:mm): _____ b. AM PM

15. Enter the current time?

    a. Time (hh:mm): _____ b. AM PM

    Calculation of fasting time:

    (enter time from 15) _____

    (enter time from 14) _____

    (subtract for total fasting time) _____

16. Has applicant fasted at least 8 hours? YES NO

    [If NO, do not draw blood and reschedule applicant in question 17.]

17. a. Has applicant been rescheduled for blood drawing? YES NO

    If YES, enter scheduled date: b. Date: _____ (mm/dd/yy) c. Time: _____ (hh:mm) d. AM PM

[If the applicant remains eligible and has fasted at least 8 hours, send him/her for blood drawing.]

DELTA

Participant Weekly Monitoring Form

DELTA ID: _____ 1. Monday's Date: _____ (mm/dd/yy) 2. Personnel Code Number: ____

WEIGHT

[Participants are weighed before dinner, without shoes or coats.]

3. a. Date of first weekly weight: _____ (mm/dd/yy)

First weekly weight, either in lbs or kg: b. lbs: _____ or c. kg: _____

d. Current calorie level: _____

4. a. Date of second weekly weight: _____ (mm/dd/yy)

Second weekly weight, either in lbs or kg: b. lbs: _____ or c. kg: _____

d. Current calorie level: _____

EXERCISE

Exercise is recorded at the first weekly visit following the weekend.]

5. a. In the past week, has your exercise level changed? YES NO

b. If YES, how has your exercise level changed: [Circle letter preceding your selection]

A...More active
B...Less active
C...No exercise

ILLNESS

6. Have you been ill in the last week? YES NO [If NO, skip to question 9]

If YES, describe illness: _____

7. a. Did you take any medications for your illness? YES NO

If YES, specify the name of the medication and amount of medication:

b. Medication: _____ c. Total weekly amount: _____

d. Medication: _____ e. Total weekly amount: _____

f. Medication: _____ g. Total weekly amount: _____

ILLNESS (continued)

8. a. Did your eating change as a result of your illness? YES NO

b. If YES to 8a, how did your illness affect your eating: [Circle letter preceding your selection]
A...Ate more
B...Ate less
C...Could not eat

c. If YES to 8a, was a diet history taken? YES NO

d. If YES to 8a, was any action taken? YES NO

SMOKERS ONLY

9. a. In the last week, have your smoking habits changed? YES NO

[A change in smoking habits is defined as started smoking, stopped smoking, or increased or decreased smoking by at least 50 percent.]

b. If YES, how have your smoking habits changed: [Circle letter preceding your selection]
A...Smoking more
B...Smoking less
C...No longer smoking
D...Started smoking

WOMEN ONLY

10. a. Did you begin menstruating during the last week? YES NO

b. If YES, what date did you begin menstruating: _____
(mm/dd/yy)

DELTA

Drop-Out Form

DELTA ID: _____

1. Date of last visit: _____
   (mm/dd/yy)

2. a. First name: _____

   b. Middle name: _____

   c. Last name: _____

3. Reason for drop-out (circle only one):

   A Failure to comply with protocol (missing 2 meals, eating 3 self-selected meals greater than 40% fat, exceeding alcohol limits more than 1 time in a period)

   B Serious illness or death

   C Voluntary withdrawal

4. Detailed reason or comments: _____

5. Code number of person completing this form: _____

DELTA Protocol 1 Data Entry Screens for Laboratory Records with No Forms

Form as of 12/02/94 15:48:36

ID: FORM: LIP VERSION: A TIMEPT:

"Baseline Lipid Profile Form" (LIPA screen 1 of 1)

1. Date blood drawn: 08/01/93 A 2. Phlebotomist ID: __ EEE
mm/dd/yy

3. Sample ID: a. Period: _ E b. Week: _ E c. Sample #: _ EEE

8. Date blood analyzed: _____ EEE
mm/dd/yy

9. Total Cholesterol (mg/dl): ___ EEE

10. Triglycerides (mg/dl): ____ EEE

11. HDL Cholesterol (mg/dl): ___ EEE

12. Calculated LDL Cholesterol (mg/dl): ___ EEE

[LDL cholesterol will be calculated by the data entry system in fields 9-11 above.]

Form as of 12/02/94 15:43:07

ID FORM: APE VERSION: A TIMEPT:

"Apoprotein E Genotyping Form" (APEA screen 1 of 1)

.. Date of Analysis: 01/10/94 AEE
mm/dd/yy

!. Genotype results: _ EEE

1.....E2/E2
2.....E3/E2
3.....E3/E3
4.....E3/E4
5.....E2/E4
6.....E4/E4
7.....other

3. Comments: _ EEE

Form as of 12/02/94 15:43:24

ID: FORM: BDT VERSION: A TIMEPT:

"Date of Blood Draws Form" (BDTA screen 1 of 1)

Diet Period Start Date: 01/10/94 AEE

[Enter period (P=1,2,3), week (W=5,6,7,8), sample (S=1,2).
Enter dates in format mm/dd/yy.]

Period: _ ENE

Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE
Week:_ ENE Sample:_ ENE Date of blood draw: _____ ENE

Comments? _ EEE

Form as of 12/02/94 15:47:13

ID: _ FORM: CAL VERSION: A TIMEPT:

"Menstrual Calendar" (CALA screen 1 of 1)

1. Period: _ EEE

2. Onset of first menstrual cycle: _____ EEE
   mm/dd/yy

3. Onset of second menstrual cycle: _____ EEE
   mm/dd/yy

4. Onset of third menstrual cycle: _____ EEE
   mm/dd/yy

5. Comments? _ EEE

6. Code number of person keying this form: __ EEE

```
 Form as of 12/02/94 15:51:04

   ID:        FORM: EL1   VERSION: A   TIMEPT:
_______________________________________________________________________________


                 "End of Period 1 Lipid Form" (EL1A screen 1 of 3)
Diet Period Start Date: 09/27/93 AEE

[ Enter week (W=5,6,7,8), sample (S=1,2).
 Units are mg/dL for Cholesterol. Triglyceride, and
 HDL-Cholesterol. Enter run dates in format mm/dd/yy.]


Week:_ ENE     Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE     Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE


===============================================================================


                 "End of Period 1 Lipid Form" (EL1A screen 2 of 3)
Week:_ ENE     Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE     Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE     Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE
```

```
Form as of 12/02/94 15:51:04

  ID:        FORM: EL1   VERSION: A   TIMEPT:
________________________________________________________________________________

                "End of Period 1 Lipid Form" (EL1A screen 3 of 3)
Week:_ ENE     Sample:_ ENE
Cholesterol:              ___ ENE  Run #:_____  ENE Run date:________  ENE
Triglycerides:            ____ ENE Run #:_____  ENE Run date:________  ENE
HDL Cholesterol:          ___ ENE  Run #:_____  ENE Run date:________  ENE
LDL:                      ___ EEE

Week:_ ENE     Sample:_ ENE
Cholesterol:              ___ ENE  Run #:_____  ENE Run date:________  ENE
Triglycerides:            ____ ENE Run #:_____  ENE Run date:________  ENE
HDL Cholesterol:          ___ ENE  Run #:_____  ENE Run date:________  ENE
LDL:                      ___ EEE

Week:_ ENE     Sample:_ ENE
Cholesterol:              ___ ENE  Run #:_____  ENE Run date:________  ENE
Triglycerides:            ____ ENE Run #:_____  ENE Run date:________  ENE
HDL Cholesterol:          ___ ENE  Run #:_____  ENE Run date:________  ENE
LDL:                      ___ EEE

Comments? _ EEE
```

```
 Form as of 12/02/94 15:50:22

    ID:          FORM: ELP   VERSION: A   TIMEPT:
________________________________________________________________________________


              "Endpoint Lipid Profile Form" (ELPA screen 1 of 3)
Diet Period Start Date: 01/10/94 AEE

[Enter period (P=1,2,3), week (W=5,6,7,8), sample (S=1,2).
 Units are mg/dL for Cholesterol, Triglyceride, and
 HDL-Cholesterol. Enter run dates in format mm/dd/yy.]

Period:    _ ENE

Week:_ ENE    Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE    Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE


================================================================================


              "Endpoint Lipid Profile Form" (ELPA screen 2 of 3)
Week:_ ENE    Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE    Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE

Week:_ ENE    Sample:_ ENE
Cholesterol:             ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:           ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:         ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                     ___ EEE
```

```
Form as of 12/02/94 15:50:22

   ID:        FORM: ELP   VERSION: A   TIMEPT:
________________________________________________________________________________

              "Endpoint Lipid Profile Form" (ELPA screen 3 of 3)
Week:_ ENE    Sample:_ ENE
Cholesterol:            ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:          ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:        ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                    ___ EEE

Week:_ ENE    Sample:_ ENE
Cholesterol:            ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:          ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:        ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                    ___ EEE

Week:_ ENE    Sample:_ ENE
Cholesterol:            ___ ENE  Run #:_____ ENE Run date:________ ENE
Triglycerides:          ____ ENE Run #:_____ ENE Run date:________ ENE
HDL Cholesterol:        ___ ENE  Run #:_____ ENE Run date:________ ENE
LDL:                    ___ EEE

Comments? _ EEE
```

```
Form as of 12/02/94 15:47:34

  ID:        FORM: CLP   VERSION: A   TIMEPT:
________________________________________________________________________________


           "Central Lipid Laboratory Form" (CLPA screen 1 of 3)
Diet Period Start Date: 01/10/94 AEE

[Enter period (P=1,2,3), week (W=5,6,7,8), sample (S=1,2).
 Units are mg/dL for Apo A-1, Apo B and Lp(a).  Enter run
 dates in format mm/dd/yy.]

Period:   _ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE


================================================================================


           "Central Lipid Laboratory Form" (CLPA screen 2 of 3)

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE

Week:     _ ENE     Sample:  _ ENE
Apo A-1: ___ ENE    Apo B:  ___ ENE     Run date:________ ENE
Lp(a):   ___ ENE    Run date:________ ENE
```

Form as of 12/02/94 15:47:34

ID: FORM: CLP VERSION: A TIMEPT:

"Central Lipid Laboratory Form" (CLPA screen 3 of 3)

Week: _ ENE Sample: _ ENE
Apo A-1: ___ ENE Apo B: ___ ENE Run date:_____ ENE
Lp(a): ___ ENE Run date:_____ ENE

Comments? _ EEE

```
Form as of 12/02/94 15:47:59

   ID:          FORM: HMN   VERSION: A   TIMEPT:
_______________________________________________________________________

                    "Hormone Level Form" (HMNA screen 1 of 3)
Diet Period Start Date: 01/10/94 AEE

[Enter period (P=1,2,3), week (W=5,6,7,8), sample (S=1,2).
 Enter run dates in format mm/dd/yy.]

Period:     _ ENE

Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE

Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE


=======================================================================


                    "Hormone Level Form" (HMNA screen 2 of 3)
Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE

Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE

Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE

Week:_ ENE      Sample:_ ENE
Estradiol (pg/mL):       ___ ENE   Run date:________ ENE
Progesterone (ng/mL):    _____ EN  Run date:________ ENE
LH (mIU/mL):             ____ ENE  Run date:________ ENE   E/P Ratio:___   EEE
```

Form as of 12/02/94 15:47:59

ID: FORM: HMN VERSION: A TIMEPT:

"Hormone Level Form" (HMNA screen 3 of 3)

Week:_ ENE Sample:_ ENE
Estradiol (pg/mL): ___ ENE Run date:_____ ENE
Progesterone (ng/mL): _____ EN Run date:_____ ENE
LH (mIU/mL): ____ ENE Run date:_____ ENE E/P Ratio:___ EEE

Week:_ ENE Sample:_ ENE
Estradiol (pg/mL): ___ ENE Run date:_____ ENE
Progesterone (ng/mL): _____ ENE Run date_____ ENE
LH (mIU/mL): ____ ENE Run date:_____ ENE E/P Ratio:___ EEE

Comments? _ EEE

Form as of 05/01/95 09:24:03

FORM: SFC VERSION: A TIMEPT:

Supplemental Funded Assays at Columbia (SFCA screen 1 of 1)

Units are mg/dl for all analytes. Enter run dates in forma

.. Feeding Period: _ ENE

WEEK 5:

2. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:_____ ENE
   e. HDL-2 (calculated):___ EEE

WEEK 6:

3. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:_____ ENE
   e. HDL-2 (calculated):___ EEE

WEEK 7:

4. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:_____ ENE
   e. HDL-2 (calculated):___ EEE

WEEK 8:

5. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:_____ ENE
   e. HDL-2 (calculated):___ EEE

6. Comments? _

Form as of 05/01/95 09:25:02

ID: FORM: SFD VERSION: A TIMEPT:

Supplemental Funded Assays at PBRC (SFDA screen 1 of 2)

[Enter run dates in format mm/dd/yy.]
1. Feeding Period: _ ENE

WEEK 5:
2. a. LDL size mode(nm):____ E b. LDL size median(nm):____ E c. LDL score:___ ENE
   d. LDL phenotype:_ E e. Run #:_____ E f. Run date:_____ ENE
3. a. HDL-2B (%):____ E b. HDL-2A (%):____ E c. HDL-2 (calculated):____ EEE
   d. HDL-3A (%):____ E e. HDL-3B (%):____ E f. HDL-3C (%):____ ENE
   g. HDL-3 (calculated):____ E h. Run #:_____ E i. Run date:_____ ENE
   j. Total % (calculated):_____ EEE

WEEK 6:
4. a. LDL size mode(nm):____ E b. LDL size median(nm):____ E c. LDL score:___ ENE
   d. LDL phenotype:_ E e. Run #:_____ E f. Run date:_____ ENE
5. a. HDL-2B (%):____ E b. HDL-2A (%):____ E c. HDL-2 (calculated):____ EEE
   d. HDL-3A (%):____ E e. HDL-3B (%):____ E f. HDL-3C (%):____ ENE
   g. HDL-3 (calculated):____ E h. Run #:_____ E i. Run date:_____ ENE
   j. Total % (calculated):_____ EEE

==========

Supplemental Funded Assays at PBRC (SFDA screen 2 of 2)

WEEK 7:
6. a. LDL size mode(nm):____ E b. LDL size median(nm):____ E c. LDL score:___ ENE
   d. LDL phenotype:_ E e. Run #:_____ E f. Run date:_____ ENE
7. a. HDL-2B (%):____ E b. HDL-2A (%):____ E c. HDL-2 (calculated):____ EEE
   d. HDL-3A (%):____ E e. HDL-3B (%):____ E f. HDL-3C (%):____ ENE
   g. HDL-3 (calculated):____ E h. Run #:_____ E i. Run date:_____ ENE
   j. Total % (calculated):_____ EEE

WEEK 8:
8. a. LDL size mode(nm):____ E b. LDL size median(nm):____ E c. LDL score:___ ENE
   d. LDL phenotype:_ E e. Run #:_____ E f. Run date:_____ ENE
9. a. HDL-2B (%):____ E b. HDL-2A (%):____ E c. HDL-2 (calculated):____ EEE
   d. HDL-3A (%):____ E e. HDL-3B (%):____ E f. HDL-3C (%):____ ENE
   g. HDL-3 (calculated):____ E h. Run #:_____ E i. Run date:_____ ENE
   j. Total % (calculated):_____ EEE

10. Comments? _ EEE

Form as of 01/13/95 11:24:45

ID: FORM: DFR VERSION: A TIMEPT:

"Daily Food Record" (DFRA screen 1 of 1)

3. Day of Week: __ EEE

4. a. Menu: __ EEE

   b. Calories: ____ EEE

   c. Diet: _ EEE

5. No. of study items not eaten: __ E 6. Other items: __ EEE

7. No. of alcoholic beverages: __ EEE

8. BREAKFAST: Was this a packed meal? _ EEE

9. LUNCH: Was this a packed meal? _ EEE

10. DINNER: Was this a packed meal? _ EEE

Form as of 01/13/95 11:24:08

ID: FORM: DFR VERSION: B TIMEPT:

"Daily Food Record" (DFRB screen 1 of 1)

3. Day of Week: __ EEE

4. a. Menu: __ EEE

   b. Calories: ____ EEE

   c. Diet: _ EEE

5. No. of study items not eaten: __ E 6. Other items: __ EEE

7. No. of alcoholic beverages: __ EEE

8. BREAKFAST: Was this a packed meal? _ EEE

9. LUNCH: Was this a packed meal? _ EEE

10. DINNER: Was this a packed meal? _ EEE

11. No. of Unit Foods eaten: _ EEE

Form as of 12/02/94 15:49:12

ID: FORM: NDF VERSION: A TIMEPT:

"Nutrient Data Form" (NDFA screen 1 of 6)

1. Date cycle began: 01/10/94 AEE
   mm/dd/yy

2. Report date: _____ EEE
   mm/dd/yy

3. Diet: _ EEE

4. Calorie level: ____ EEE

5. Cycle: __ EEE

6. Net wt (grams): _____ EEE

7. Moisture (percent)
   a. rep1: _____ EEE b. rep2: _____ EEE c. rep3: _____ EEE
   d. assay #: _____ EEE e. mean: _____ EEE

==========

"Nutrient Data Form" (NDFA screen 2 of 6)

8. Protein (g/100g dry wt)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE e. % kcal: ____ EEE

9. Ash (g/100g dry wt)
   a. rep1: ____ EEE b. rep2: ____ EEE c. assay #: _____ EEE
   d. mean: ____ EEE

10. Total fat (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. %kcal: ____ EEE

11. Cholesterol (mg/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

12. Dietary fiber (g/100g dry wt)
    a. rep1: ____ EEE b. rep2: ____ EEE c. assay #: _____ EEE
    d. mean: ____ EEE

Form as of 12/02/94 15:49:12

ID: FORM: NDF VERSION: A TIMEPT:

"Nutrient Data Form" (NDFA screen 3 of 6)

13. Carbohydrates
    a. g/100g dry: _____ EEE b. % kcal: ____ EEE

14. Total dry wt (grams): _____ EEE

15. Total kcal: _____ EEE

16. SFA (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE

17. MUFA
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE

18. PUFA
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE

==========

"Nutrient Data Form" (NDFA screen 4 of 6)

19. C18:3n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

20. C20:5n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

21. C22:6n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

22. C12:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

23. C14:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

"Nutrient Data Form" (NDFA screen 5 of 6)

24. C16:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

25. C18:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

26. C18:1 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

27. C18:2 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

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"Nutrient Data Form" (NDFA screen 6 of 6)

28. Were there missing meals or menus? _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

29. Were there any problems reported from field center: _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

30. Were there any problems with compositing? _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

31. Number of menus: __ EEE

32. Mean kcal / menu: _____ EEE

33. Mean cholesterol / menu: ____ EEE

34. Code number of person completing the form: __ EEE

Form as of 12/02/94 15:49:37

ID: FORM: NDF VERSION: B TIMEPT:

"Nutrient Data Form" (NDFB screen 1 of 6)

1. Date cycle began: 01/10/94 AEE
   mm/dd/yy

2. Report date: _____ EEE
   mm/dd/yy

3. Diet: _ EEE

4. Calorie level: ____ EEE

5. Cycle: __ EEE

6. Net wt (grams): _____ EEE

7. Moisture (percent)
   a. rep1: _____ EEE b. rep2: _____ EEE c. rep3: _____ EEE
   d. assay #: _____ EEE e. mean: _____ EEE

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"Nutrient Data Form" (NDFB screen 2 of 6)

8. Protein (g/100g dry wt)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE e. % kcal: ____ EEE

9. Ash (g/100g dry wt)
   a. rep1: ____ EEE b. rep2: ____ EEE c. assay #: _____ EEE
   d. mean: ____ EEE

10. Total fat (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. %kcal: ____ EEE

11. Cholesterol (mg/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

12. Dietary fiber (g/100g dry wt)
    a. rep1: ____ EEE b. rep2: ____ EEE c. assay #: _____ EEE
    d. mean: ____ EEE

Form as of 12/02/94 15:49:37

ID: FORM: NDF VERSION: B TIMEPT:

"Nutrient Data Form" (NDFB screen 3 of 6)

13. Carbohydrates
    a. g/100g dry: _____ EEE b. % kcal: ____ EEE

14. Total dry wt (grams): _____ EEE

15. Total kcal: _____ EEE

16. SFA (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE f. Norm % kcal:____ EEE

17. MUFA
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE f. Norm % kcal:____ EEE

18. PUFA
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % kcal: ____ EEE f. Norm % kcal:____ EEE

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"Nutrient Data Form" (NDFB screen 4 of 6)

19. C18:3n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

20. C20:5n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

21. C22:6n-3 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

22. C12:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

23. C14:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

"Nutrient Data Form" (NDFB screen 5 of 6)

24. C16:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

25. C18:0 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

26. C18:1 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

27. C18:2 (g/100g dry wt)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE e. % total fat: _____ EEE

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"Nutrient Data Form" (NDFB screen 6 of 6)

28. Were there missing meals or menus? _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

29. Were there any problems reported from field center: _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

30. Were there any problems with compositing? _ EEE
    [Specify YES (Y) or NO (N). If YES, describe in note log.]

31. Number of menus: __ EEE

32. Mean kcal / menu: _____ EEE

33. Mean cholesterol / menu: ____ EEE

34. Code number of person completing the form: __ EEE

35. n-3FA % kcal: _____ EEE

Form as of 12/02/94 15:51:54

ID: FORM: UNT VERSION: A TIMEPT:

"Unit Foods Record" (UNTA screen 1 of 3)

1. Feeding Period: _ EEE

2. Period Interval: _ EEE

3. Report date: _____ EEE
mm/dd/yy

4. Diet: _ EEE

5. Net wt (grams): _____ EEE

6. Total dry wt (grams): _____ EEE

7. No. units carrot muffins: __ EEE 8. No. units banana muffins: __ EEE

9. No. units bread: __ EEE 10. Total no. units: ___ EEE

11. Total kcal: _____ EEE 12. Mean kcal / unit: _____ EEE

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"Unit Foods Record" (UNTA screen 2 of 3)

13. Moisture (g/100g)
a. rep1: _____ EEE b. rep2: _____ EEE c. rep3: _____ EEE
d. assay #: _____ EEE e. mean: _____ EEE

14. Protein (g/100g dry wt)
a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
d. mean: _____ EEE e. % kcal: _____ EEE

15. Ash (g/100g dry wt)
a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
d. mean: _____ EEE

16. Total fat (g/100g dry wt)
a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
d. mean: _____ EEE e. % kcal: _____ EEE

17. Total carbohydrates
a. g/100g dry wt: _____ EEE b. % kcal: _____ EEE

Form as of 12/02/94 15:51:54

ID: FORM: UNT VERSION: A TIMEPT:

"Unit Foods Record" (UNTA screen 3 of 3)

18. Were there any problems in receipt of unit foods? _ EEE
    [Enter Y/N. If Y, describe in note log.]

19. Were there any problems reported from field center? _ EEE
    [Enter Y/N. If Y, describe in note log.]

20. Were there any problems with compositing? _ EEE
    [Enter Y/N. If Y, describe in note log.]

21. Code number of person keying this form: __ EEE

Form as of 12/02/94 15:51:36

ID: FORM: UNO VERSION: A TIMEPT:

"Unit Food Oils Record" (UNOA screen 1 of 3)

1. Report date: _____ EEE
   mm/dd/yy

2. Oil source: _ EEE

3. Diet: _ EEE

4. SFA (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

5. MUFA (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

6. PUFA (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

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"Unit Food Oils Record" (UNOA screen 2 of 3)

7. C12:0 (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

8. C14:0 (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

9. C16:0 (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

10. C18:0 (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

11. C18:1 (g/100g)
   a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
   d. mean: _____ EEE

Form as of 12/02/94 15:51:36

ID: FORM: UNO VERSION: A TIMEPT:

"Unit Food Oils Record" (UNOA screen 3 of 3)

12. C18:2 (g/100g)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

13. C18:3n-3 (g/100g)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

14. C20:5n-3 (g/100g)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

15. C22:6n-3 (g/100g)
    a. rep1: _____ EEE b. rep2: _____ EEE c. assay #: _____ EEE
    d. mean: _____ EEE

16. Comments? _ EEE

17. Code number of person keying this form: __ EEE