DELTA Protocol 2 Data Management System Forms

TITLE	FORM	VERSION
Pre-randomization		
Telephone Screening Visit Form	TSV	B
Eligibility Visit 1 Form	EV1	B
Eligibility Visit 2 Form	EV2	B
Apo E Genotype Form	*APE*	*B*
Post-randomization		
Participant Weekly Monitoring Form	PWM	B
Compliance Check Sheet	CCS	A
Drop-Out Form	DPO	B
Urine Collection Form	UCF	A
Laboratory Assays		
- at Local Lab	LBA	A
- *at MIBH*	*LBB*	*A*
- *at Columbia*	*LBC*	*A*
- *at PBRC*	*LBD*	*A*
Nutrient Data Form	*NDF*	*C*
Postprandial Post Meal Testing Form	PP1	A
Postprandial Standard Fat Load Form	PP2	A
Postprandial Studies Lab Assays (for both studies)		
- at Local Lab	PLA	A
- *at MIBH*	*PLB*	*A*
- *at Columbia*	*PLC*	*A*
- *at MIBH*	*PLL*	*A*

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

DELTA Protocol 2 Data Management System Forms
Key Fields for Data Entry

FORM	VERSION	ID	TIME POINT	SEQ
TSV	B	*	Today's Date	00
EV1	B	*	Today's Date	00
EV2	B	*	Today's Date	00
APE	B	*	Date of Assay	00
PWM	B	*	Monday's Date	00
CCS	A	*	Today's Date	00
DPO	B	*	Today's Date	00
UCF	A	*	Feeding Period Start Date	00
LBA	A	*	Feeding Period Start Date	00
LBB	A	*	Feeding Period Start Date	00
LBC	A	*	Feeding Period Start Date	00
LBD	A	*	Feeding Period Start Date	00
NDF	C	†	Cycle Start Date	00
PP1	A	*	Feeding Period Start Date	00
PP2	A	*	Feeding Period Start Date	00
PLA	A	*	Feeding Period Start Date	00
PLB	A	*	Feeding Period Start Date	00
PLC	A	*	Feeding Period Start Date	00
PLL	A	*	Feeding Period Start Date	00

* Participant DELTA ID for all records except CCS form.
† Composite ID assigned for NDF records.

DELTA Protocol 2
Data Management System Forms

July 9, 1996

DELTA
Dietary Effects on Lipoproteins and Thrombogenic Activity

Telephone Screening Form

Form Code: TSV
Version B 5/10/94

INTERVIEWER: Do not assign the DELTA ID until the Telephone Screening Visit is completed and you determine if the applicant is or is not eligible for Eligibility Visit 1. The assignment of the DELTA ID is as follows:

- **If the applicant is eligible for Eligibility Visit 1, then assign an ID from the set of IDs with sequence numbers 0100-0499. This ID will be used for this applicant throughout the screening visits until randomization. Blood tube labels are provided for these IDs.**
- **If the applicant is not eligible following the Telephone Screening Visit, then assign an ID from the set of IDs with sequence numbers 0500-1599. No other forms labels or blood tube labels are provided for these IDs.**

DELTA ID______________________________ Today's Date ____/____/____

1. Code Number of personnel completing form: ________

2. ____
   a. First Name b. MI c. Last Name

3. ____
   a. Street

   ____
   b. City c. State d. Zip Code

4. Home Telephone: ________________ area-###-#### 5. Work Telephone: ________________ area-###-####

   When is the best time to call? ______________________________

   Can you receive a call at work? YES NO

6. Date of Birth: ______________ mm/dd/yy 7. Age: _____ 8. Gender: M (male) F (female)

Telephone Screening Form

Form Code: TSV
Version B 5/10/94

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

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

b. If Other, describe:____

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

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

b. If Other, describe:____

11. Do you plan to remain in the area for the next year? YES NO

[If the answer TO QUESTION 11 is NO, then the applicant has become ineligible. Terminate the interview and complete questions 12-13.]

Telephone Screening Form

Form Code: TSV
Version B 5/10/94

INTERVIEWER: CONTINUE WITH QUESTION 22. COMPLETE THIS PAGE AFTER THE TELEPHONE SCREENING VISIT IS COMPLETE!

12a. Is applicant eligible following telephone screening?

[Circle the letter preceding selection.]
Y YES
N NO
R NEEDS MEDICAL REVIEW **[Enter question number(s) to be reviewed.]**

b.____, c.____, d.____

e. If YES to 12a, date of EV1 : _______ (mm/dd/yy) f. Time: _____ (hh:mm) g. AM PM

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

__/__/__ (date of medical review) ________(initials of MD)

13a. 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

[SEE EXCLUSION CODE LIST in the Forms Guide. Enter reason code numbers below.]

b._____, c._____, d._____

INTERVIEWER: SKIP THIS PAGE DURING THE TELEPHONE SCREENING INTERVIEW.

After Eligibility Visit 1 and Eligibility Visit 2 have been completed, return to this form and record the applicant's lab values, blood pressure, and height and weight in the spaces provided below.

APPLICANT'S LAB AND MEASUREMENT RESULTS

	EV1	EV2
14. TC	a. mg/dl	b. mg/dl
15.LDL	a. mg/dl	b. mg/dl
16.HDL	a. mg/dl	b. mg/dl
17. TG	a. mg/dl	b. mg/dl
18. INS	a. μU/ml	b. μU/ml
19. BP	a. systolic b. diastolic	c. systolic d. diastolic
20. HT	a. ft b. in	c. ft d. in
21. WT	a. lbs	b. lbs

Telephone Screening Form

Form Code: TSV
Version B 5/10/94

MEDICAL CONDITIONS

22. 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?

[Interviewer: 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 treated with medication	Y	N	U
d.	renal or kidney failure	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 use of steroid medication	Y	N	U
i.	gout requiring treatment	Y	N	U
j.	recent history of depression or mental illness requiring medication or treatment 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.	positive HIV test or Acquired Immune Deficiency Syndrome (AIDS)	Y	N	U
o.	cancer (active within last 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 determine eligibility status. 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.]

Telephone Screening Form

OTHER MEDICAL CONDITIONS

23. a. Do you have any other medical conditions not listed above?
YES NO **[If NO go to question 24]**

[If YES] Please list other medical conditions **[enter one per line]:**

b. ______________________________

c. ______________________________

d. ______________________________

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

MEDICATIONS

24. Do you take any type of doctor or self-prescribed medications? YES NO
[If NO go to question 30]

[If YES] What is the name of the medication that you take?

[Record both doctor and self-prescribed medications. Ask for spelling of medication if necessary.]

a. Medication	b. Prescribed by Doctor YES (Y) or NO (N)	c. Reason for taking medication
25.	Y N	
26.	Y N	
27.	Y N	
28.	Y N	
29.	Y N	

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

Telephone Screening Form

FOOD ALLERGIES

30. a. Do you have any food allergies? YES NO **[If NO go to question 31]**

[If YES] What foods are you allergic to?

b. ______________________________

c. ______________________________

d. ______________________________

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

31. a. Are there any foods you refuse to eat? YES NO **[If NO go to question 32]**
[If YES] What foods will you absolutely not eat? **[List below]**

b. ________________ c. ________________ d. ________________

SPECIAL DIETS

32. a. Are you on a special diet prescribed by a doctor for a medical condition?
YES NO **[If NO go to question 33]**

[If YES] Is it for:

[Read list of special diets and circle response YES, NO, UNSURE]

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

g. if other, specify____

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

Telephone Screening Form

Form Code: TSV
Version B 5/10/94

ALCOHOL CONSUMPTION

DEFINITION: 1 drink = a 5 oz. glass of wine, a 12 oz. can of beer, or 1.5 oz. of liquor, **(enter 0 for less than 1 drink per week)**

33. a. Do you drink alcoholic beverages? YES NO **[If NO go to question 34]**

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.]

HEIGHT AND WEIGHT

[See Height and Weight cutpoint tables in the Forms Guide.]

34. What is your height without shoes? a. ft: ____ b. in: ____

35. a. What is your weight without shoes? lbs: ____

b. Is the applicant's weight recorded in question #35a greater than the upper weight limit for the applicant's height in the height/weight tables? YES NO

36. 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

[If the answer to question 35b is yes, 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].

Telephone Screening Form

WOMEN BORN AFTER 1943 ONLY

37. Are you pregnant or planning to become pregnant within the next year? YES NO

38. Are you breastfeeding? YES NO

39. Have you had a baby within the last 6 months? YES NO

If the answer to either question 37, or 38, or 39 is YES, then the applicant has become ineligible. If so, terminate the interview and complete questions 12 and 13.

Telephone Screening Form

[Interviewer: If applicant is still eligible at this point, read the general description of the DELTA Study in the Forms Guide and continue the interview.]

FURTHER INTEREST

40a. Based on your understanding of the study at this point, would you be interested in coming to the center to learn more about this study and to have some blood work done and your blood pressure checked to determine if you remain eligible?

YES **(go to question 41)** NO

[If NO] What is the reason? **[Circle YES or NO for reasons for not scheduling Eligibility Visit 1]:**

b.	Uninterested in general study protocol	YES	NO
c.	Unwilling to commit due to length of study	YES	NO
d.	Unwilling to come to feeding center for 2 meals each day for 5 days each week	YES	NO
e.	Unwilling to eat study food	YES	NO
f.	Unwilling to limit intake to study foods only	YES	NO
g.	Unwilling to allow maintenance of current body weight	YES	NO
h.	Lives too far from feeding center	YES	NO
i.	Travels out of town as part of job position or has travel plans for study period	YES	NO
j.	Unwilling to submit to frequency of blood draws	YES	NO
k.	Other (1. specify: ________________________________)	YES	NO

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

SCHEDULING ELIGIBILITY VISIT 1

Telephone Screening Form

41. If applicant is eligible at this point, schedule Eligibility Visit 1:

a. date:__________ (mm/dd/yy) b. time:______ (hh:mm) c. AM PM

Interviewer: Ask applicant to bring all medications, including diet supplements, over the counter medications, and any contraceptives, to Eligibility Visit 1. Inform applicant that he/she will need to fast before the visit. Read the following to the applicant:

"Fasting for DELTA means that you should not eat or drink anything except water for 10 hours before coming in for Eligibility Visit 1. Additionally, you should not use alcohol of any type for 48 hours before the visit."

42. Do the applicant's responses need medical review? YES NO

If applicant is interested, but responses need medical review, then tell applicant that he/she will be called back.

RETURN TO PAGE 3 AND COMPLETE QUESTIONS 12-13.

Telephone Screening Form

NOTE PAGE

DELTA ID:____________ DATE:___/___/___

NAME: ____
a) first b) middle c) last

PERSONNEL CODE NUMBER _________

DELTA

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

DELTA ID:____________________ **TODAY'S DATE:**____________

Medical review needed?	NO	YES		
Medical review done?	NO	YES	DATE________	MD INITIALS_______
Eligible after EV1?	NO	YES		
COMMENTS:				

Part I (Questions 1 - 21) - To be completed by applicant

Have you read and signed the screening consent form? If you haven't, contact a DELTA staff member.

1. ____
   a. First Name b. Middle Name c. Last Name
2. Date of Birth (mm/dd/yy):____________________
3. 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-###-####)

Eligibility Visit 1

4. What is your highest level of education completed? **[Please circle the letter preceding 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

5. a. What is your current employment status? **[Please circle the letter preceding 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. If Other, describe: ________________________________

6. Do you plan to remain in the area for the next year? **[Circle answer]** YES NO

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

7. 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 or 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	Y	N	U
If YES to Other foods, list below: l.__________, m.__________, n.__________			

8. Are there any foods that you absolutely won't eat? **[List each separately.]**

   a.__________ b.__________ c.__________

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

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 1.5 oz. of liquor.

9. What is the total number of alcoholic drinks that you drink Monday through Thursday?________
10. What is the maximum number of alcoholic drinks that you usually drink in any one day Monday through Thursday? ______
11. What is the total number of alcoholic drinks that you drink Friday, Saturday, and Sunday?_______
12. What is the maximum number of alcoholic drinks that you usually drink in any one day Friday, Saturday, or Sunday? _______
13. Would you be willing to limit your intake of alcohol to no more than 5 drinks per week for the duration of the study? **[Circle your response.]** YES NO

14. 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
15. 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

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

16. 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. If Other, describe: ______________________

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

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

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

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

19. a. Do you currently smoke cigarettes? YES **[If YES go to 19b]** NO **[If NO go to 19c]**

b. If YES to 19a, on average, how many cigarettes do you smoke per day? _____ **[go to 20]**

c. Have you ever smoked cigarettes? YES **[If YES go to 19d]** NO **[If NO go to 20]**

d. If YES to 19c, how long has it been since your last cigarette? **[Circle letter preceding answer.]**

A Less than 1 year B 1 year or more

20. a. Do you exercise more than once a week or play sports regularly? YES NO

[If NO, go to question 21.]

If YES, describe the activity and enter the amount of time spent **per week** at this activity:

ACTIVITY (ENTER TIME IN HOURS AND MINUTES)

b. ______________________________ c. ______:______

d. ______________________________ e. ______:______

f. ______________________________ g. ______:______

h. ______________________________ i. ______:______

21a. Does your job require heavy physical labor? YES NO

b. If YES, describe______________________________

STOP!

PLEASE HAND THIS FORM TO THE DELTA INTERVIEWER TO INITIATE THE REMAINDER OF THE CLINIC VISIT.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

Part - II Clinic Data Form [Interviewer: Review Part I for any automatic exclusions. Questions? See Coordinator.]

22. 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 treatment or 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

Please be sure to answer 23 a, and b, and c!

23 a. Do you have thyroid disease or a thyroid problem? Y N U

b. Have you ever had treatment, such as radioactive iodine or surgery for a thyroid problem? Y N U

c. Are you taking any medication for your thyroid? **[If unsure, check medications.]** Y N U

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

Medical reviewer Initials:________ **Eligible:** YES NO **Date** ___/___/___

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

24. a. Are there any medical reasons that might interfere with your ability to participate? (Examples: hospitalized on a regular basis, scheduled surgery, family medical problems)
YES NO **[If NO go to question 25.]**

b. If YES, describe:______________________________

25. a. Are there any personal reasons that would keep you from participating? (Examples: family problems, vacation scheduled during study period, child care difficulties, religious reasons) YES NO **[If NO go to question 26.]**

b. If YES, describe:______________________________

26. a. Are there any professional reasons that would keep you from participating? (Examples: job related travel out of town, work irregular shifts or night shift)
YES NO **[If NO go to question 27.]**

b. If YES, describe:______________________________

If the answer to questions 24, or 25, or 26 is YES, inform Study Coordinator.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

WOMEN ONLY

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

    b. If YES to 27a, are you planning to stop? YES NO

    c. If NO to 27a, are you planning to start? YES NO

[Circle the letter preceding the response.]

28. What is your current menstrual status?
    - R Regular (normal) **[go to question 30]**
    - I Irregular **[go to question 29a]**
    - N Not menstruating **[go to question 29c]**

29. a. If you are menstruating irregularly, what is the reason?
    - A Undergoing menopause
    - B Other

    b. If Other, describe ______________________________

    c. If you are not menstruating, what is the reason?
    - A Natural menopause
    - B Hysterectomy
    - C Medication stopped period
    - D Other (d. describe ______________________________)

30. When did you have your last period?
    - A Less than 2 months ago
    - B 2 months to 6 months ago
    - C 6 months to 1 year ago
    - D 1 year but less than 3 years ago
    - E At least 3 years ago

31. 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 31a, are you currently taking estrogen? YES NO

    c. If NO to 31a, do you plan to start taking estrogen? YES NO

RESUME ASKING QUESTIONS OF ALL APPLICANTS.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

32. How often do you take antacids? **[Circle the letter preceding the response]**
    D Daily W Weekly O Occasionally N Never

33. How often do you take laxatives? **[Circle the letter preceding the response]**
    D Daily W Weekly O Occasionally N Never

34. Within the past six months, have you taken any medications on a regular basis prescribed by a doctor? YES NO **[Go to question 41.]**

If YES, Specify doctor-prescribed medications, including oral contraceptives, 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
35.	______	______	______	YES NO
36.	______	______	______	YES NO
37.	______	______	______	YES NO
38.	______	______	______	YES NO
39.	______	______	______	YES NO
40.	______	______	______	YES NO

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

41. 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.______

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

If the answer to question 42 is YES, inform the Study Coordinator.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

HEIGHT AND WEIGHT [SEE HEIGHT / WEIGHT CUTPOINT TABLES in the Forms Guide]

[Choose whether you will enter height/weight in customary units (ft-in/lb) or metric units (cm/kg). Only enter responses for questions 43-44 or 45-46.]

Customary Units

43. Height (without shoes) a. ft: _______ b. in: _______

44. a. Weight (without shoes) lbs: _______

    b. Is the applicant's weight recorded in question 44a greater than the upper weight limit for applicant's height in the ht/wt table? YES NO

Metric Units

45. Height (without shoes) cm: _______

46. a. Weight (without shoes) kg: _______

    b. Is the applicant's weight recorded in question 46a greater than the upper weight limit for applicant's height in the ht/wt table? 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

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

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

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.

48. Arm circumference (cm): ______

49. 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)

50. Pulse obliteration (a) ________ + 30 = peak inflation level (b) ________

51. Pulse: beats in 30 seconds _________ x 2 = _________ beats/minute

52. First blood pressure measurement: a. Systolic: _______ b. Diastolic: _______

53. Second blood pressure measurement: a. Systolic: _______ b. Diastolic: _______

54. Calculated average of first and second blood pressure measurements:

    Add the two values: _______ _______

    Divide sum by 2: a. Systolic: _______ b. Diastolic: _______

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

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

BLOOD DRAWING

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

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

57. How many hours since you last drank any alcohol? ______

58. Enter the current time: a. Time (hh:mm): ____:____ b. AM PM

59. Number of hours fasted: _____

[If applicant has not fasted for at least 10 hours, or has consumed alcohol within 48 hours, do not draw blood. Reschedule applicant in question 60.]

60. 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, has had no alcohol in the last 48 hours, and has fasted at least 10 hours, send him/her for blood drawing.

LIPID SELECTION CRITERIA **[See Lipid and Insulin Cutpoint Tables in the Forms Guide.]**

61. a. TC _________ mg/dl
    b. HDL _________ mg/dl
    c. TG _________ mg/dl
    d. LDL _________ mg/dl (calculated)
    e. Are all lipid levels within eligible range for applicant's gender, race, age? YES NO

62. a. INS _________ μU-ml
    b. Is insulin level within eligible range for applicant's gender, race, age? YES NO

If the applicant's lipid and insulin levels are not within the eligible range, then the applicant will be ineligible. If so, terminate the interview. If the levels ARE within the eligible range, explain that continued eligibility will be dependent on the laboratory values meeting DELTA criteria for Protocol 2.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

SCHEDULING ELIGIBILITY VISIT 2

[Read the following to the applicant before scheduling for Eligibility Visit 2.]

"Fasting for DELTA means that you should not eat or drink anything except water for 10 hours before coming in for the Eligibility Visit 2. Additionally, you should not use alcohol of any type for 48 hours before your visit."

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?	Y	N
Was Part I of Eligibility Visit 1 completed?	Y	N
Was the DELTA Study explained and questions addressed?	Y	N
Were applicant's doctor-prescribed medications confirmed?	Y	N
Does applicant remain eligible for Eligibility Visit 2?	Y	N

ADMINISTRATIVE INFORMATION

63. Code Number of personnel completing this form ____________

64. a. Date scheduled for Eligibility Visit 2 (mm/dd/yy): ____________

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

REMINDER: Return to the Telephone Screening Visit form and record the lab values (questions 61 and 62 on this form) for all applicants. If the applicant has been excluded at this point, also complete question 13 on the TSV form.

Eligibility Visit 1

Form Code: EV1
Version B 5/10/94

NOTES

DELTA ID:_______________ DATE:____/____/____

NAME:____
first middle last

CODE NUMBER of personnel completing this form ________

DELTA

Dietary Effects on Lipoproteins and Thrombogenic Activity

Eligibility Visit 2

Form Code: EV2
Version B 5/10/94

DELTA ID: ____________ Today's Date: ___/___/___

NAME: ____
First Middle Last

Has the applicant read and signed the screening consent 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.

1. Arm circumference (cm): __________

2. 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)

3. Pulse: beats in 30 seconds __________ x 2 = __________ beats/minute

4. Pulse obliteration (a) _________ + 30 = peak inflation level (b) _________

5. First blood pressure measurement: a. Systolic: _______ b. Diastolic: _______

6. Second blood pressure measurement: a. Systolic: _______ b. Diastolic: _______

7. Calculation of average blood pressure:
   (add two values) _______ _______

   (divide sum by 2) a. Systolic: _______ b. Diastolic: _______

8. Is average systolic blood pressure >140 or average diastolic blood pressure >90?

   YES NO

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

Eligibility Visit 2

Form Code: EV2
Version B 5/10/94

WAIST AND HIP CIRCUMFERENCE

[See the DELTA Forms Guide for the procedure for measuring waist and hip circumference. Round the readings and average to the nearest whole numbers.]

	a. Reading 1	b. Reading 2	c. Average
9. Waist circumference (cm)	a. ________	b. ________	c. ________
10. Hip circumference (cm)	a. ________	b. ________	c. ________

APPLIANCES AVAILABILITY

11. 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 or oven or toaster oven	YES	NO

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

a. refrigerator	YES	NO
b. freezer	YES	NO
c. microwave or oven or toaster oven	YES	NO

[If any of the answers to questions 11-12 are NO, inform Study Coordinator.]

Eligibility Visit 2

BLOOD DRAWING

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

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

14. How many hours since you last consumed any alcohol? ______

15. Enter the current time:

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

16. Number of hours fasted: ______

[If applicant has not fasted for at least 10 hours or has consumed alcohol in the last 48 hours, do not draw blood. 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, send him/her for blood drawing.

Eligibility Visit 2

Form Code: EV2
Version B 5/10/94

LIPID and INSULIN SELECTION CRITERIA

18. a. TC ____________ mg/dl

b. HDL ____________ mg/dl

c. TG ____________ mg/dl

d. LDL ____________ mg/dl (calculated)

e. INS ____________ μU-ml

Use the Lipid/ Insulin Eligibility Program to answer question 19. The EV2 Lipid and Insulin cutpoint tables are provided in the Forms Guide. **These cutpoints are based on the AVERAGE of EV1 and EV2 measurements.]**

19a. Based on the Lipid / Insulin Eligibility Program results for the average of EV1 and EV2 lipid measurements, is the applicant still eligible?

[Circle answer] YES NO

b. Based on the Lipid / Insulin Eligibility Program results for the average of EV1 and EV2 insulin measurements, is the applicant still eligible?

[Circle answer] YES NO NA (not applicable)

REMINDER: Return to page 4 of the Telephone Screening Visit Form and record the EV2 lab results from question 18 on this form for all applicants. If the applicant has been excluded after EV2, also complete question 13 on the Telephone Screening Visit Form.

20. Code number of personnel completing this form__________

Eligibility Visit 2

Form Code: EV2
Version B 5/10/94

NOTE PAGE

DELTA ID:________________ DATE:____/____/____

NAME:____
first middle last

PERSONNEL CODE NUMBER ________

Participant Weekly Monitoring

Form Code: PWM
Version B 5/10/94

DELTA ID: ______________	Monday's DATE: ___/___/___ [THIS WEEK] (mm/dd/yy)

1. Code Number of personnel completing this form: _______

BLOOD DRAW
[Complete numbers 2-4 during weeks 5, 6, 7.]

2. Period **1 2 3** **[Circle correct number]**

3. Week **5 6 7** **[Circle correct number]**

4. Date of blood draw ___/___/___
   mm/dd/yy

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

5. 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: **1500 2000 2500 3000 3500** **[Circle correct number]**

6. 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: **1500 2000 2500 3000 3500** **[Circle correct number]**

Be sure to administer this form at the last blood draw of the period!

Participant Weekly Monitoring

[Interviewer: Ask the participant the rest of the questions based on their activities during the past week.]

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

7. a. In the past week, has your exercise level changed? YES NO **[If NO go to question 8]**

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

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

If the answer to question 7a is YES, inform the Study Coordinator.

MEDICATION

8. a. Have you taken any medications in the last week? YES NO **[If NO, go to question 9]**

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

   b. Medication: ________________ c. Total weekly amount: __________

   Reason ____

   d. Medication: ________________ e. Total weekly amount: __________

   Reason ____

   f. Medication: ________________ g. Total weekly amount: __________

   Reason ____

9. a. Have you taken any vitamin, mineral or other nutritional supplements in the past week?
   YES NO **[If NO go to question 10]**

   If YES, specify name and amount:

   b. Name: ________________ c. Total weekly amount: ____________

   d. Name: ________________ e. Total weekly amount: ____________

If the answer to either question 8 or 9 is YES, inform the Study Coordinator.

Participant Weekly Monitoring

Form Code: PWM
Version B 5/10/94

ILLNESS

10. Have you been ill in the last week? YES NO **[If NO go to question 12]**

    If YES, describe illness: ______________________________

    ____

11. a. In the past week did your eating change as a result of any illness?
    YES **[If Yes, enter reasons in space provided.]** NO **[If NO go to question 12]**

    ____

    ____

    b. If YES to 11a, was a diet history taken? YES NO

    c. If YES to 11a, was any action taken? YES NO

If the answer to question 11 is YES, inform the Study Coordinator.

SMOKING HABITS

12. a. In the last week, have your smoking habits changed? YES NO **[If NO go to question 13]**

    [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 the selection.]**

    A...Smoking more
    B...Smoking less
    C...Quit smoking
    D...Started smoking

If participant reports any changes in smoking habits, inform Study Coordinator.

Participant Weekly Monitoring

Form Code: PWM
Version B 5/10/94

WOMEN ONLY

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

b. If YES to 13a, what date did you begin menstruating: ________ (mm/dd/yy)

c. If YES to 13a, what day of the week did you begin menstruating?
(Circle the number preceding the answer)

1. Monday 2. Tuesday 3. Wednesday 4. Thursday

5. Friday 6. Saturday 7. Sunday

Be sure to administer this form at the last blood draw of the period!

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: C20000 **TODAY'S DATE: _____ / _____ / _____**

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation.				# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
			B	L	D	S			
1.									
2.									
3.									
4.									
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7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
	Personnel code # or Initials ▸								

Shaded area must be keyed into the DELTA DMS

TURN OVER FOR SIDE 2 ▸

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: C20000

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation.				# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
			B	L	D	S			
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		Personnel code # or Initials ►							

Shaded area must be keyed into the DELTA DMS

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: L20000

TODAY'S DATE: _____ / _____ / _____

(1)	Participant Name (Mask all participant names before sending this form to the Coordinating Center.)	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation.				# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
			B	L	D	S			
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	Personnel code # or Initials ▸								

Shaded area must be keyed into the DELTA DMS

TURN OVER FOR SIDE 2 ▸

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: L20000

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation. B	L	D	S	# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
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		Personnel code # or Initials ▸							

Shaded area must be keyed into the DELTA DMS

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: M20000 TODAY'S DATE: _____ / _____ / _____

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation.				# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
			B	L	D	S			
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Personnel code # or Initials ▸									

Shaded area must be keyed into the DELTA DMS

TURN OVER FOR SIDE 2 ▸

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: M20000

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation.				# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
			B	L	D	S			
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	Personnel code # or Initials ▸								

Shaded area must be keyed into the DELTA DMS

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: P20000

TODAY'S DATE: ____ / ____ / ____

(1)	Participant Name *(Mask all participant names before sending this form to the Coordinating Center.)*	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation. B	L	D	S	# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
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	Personnel code # or Initials ►								

Shaded area must be keyed into the DELTA DMS

TURN OVER FOR SIDE 2 ►

FORM CODE: CCS
VERSION A: 10/25/94

COMPLIANCE CHECK SHEET

CENTER ID: P20000

(1)	Participant Name (Mask all participant names before sending this form to the Coordinating Center.)	DELTA I.D. No. (2)	Any food or beverages left? Enter N for none, D for deviation. B	L	D	S	# of Unit Foods (from FBI form) (3)	# of Alc. bev. (from FBI form) (4)	Total kcal value of deviation (from deviation form) (5)
16.									
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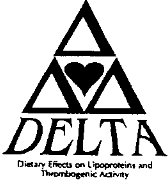
	Personnel code # or Initials ►								

Shaded area must be keyed into the DELTA DMS



Drop Out Form

Form Code: DPO
Version B 6/30/94

DELTA ID: ______________ **Today's Date**___/___/___

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. Any comments? Y [Yes] N [No] [Circle answer.] If Y, enter detailed reason or comments below:

____

____

____

____

____

____

____

5. Personnel code number: ______

Urine Collection Form
(Weeks 6 and 7)

Form Code: UCF
Version A 10/04/94

IMPORTANT: ***Before completing this form, verify that the participant has followed the instructions for Overnight Urine Collection. If the participant has not followed the instructions, give them a clean container and ask them to repeat the collection.***

DELTA ID: ________________ ***Feeding Period Start Date:*** ____/____/____

1. PERIOD:*____ *[Specify 1/2/3]

WEEK 6

2. Enter date and time of **last** urination before collection (from Urine Collection bottle):

   2a. Date ____/____/____ **[mm/dd/yy]** 2b. Time ____:____ **[hh:mm]** 2c. ____ **[AM/PM]**

3. Enter date and time of **first morning urine** (from Urine Collection bottle):

   3a. Date ____/____/____ **[mm/dd/yy]** 3b. Time ____:____ **[hh:mm]** 3c. ____ **[AM/PM]**

4. Number of aliquots frozen:____ (should be 5)

5. Code number of person completing form:________

WEEK 7

6. Enter date and time of **last** urination before collection (from Urine Collection bottle):

   6a. Date ____/____/____ **[mm/dd/yy]** 6b. Time ____:____ **[hh:mm]** 6c. ____ **[AM/PM]**

7. Enter date and time of **first morning urine** (from Urine Collection bottle):

   7a. Date ____/____/____ **[mm/dd/yy]** 7b. Time ____:____ **[hh:mm]** 7c. ____ **[AM/PM]**

8. Number of aliquots frozen:____ (should be 5)

9. Code number of person completing form:________

Postprandial Post Meal Testing Form
(Week 6)

Form Code: PP1
Version A 5/31/94

DELTA ID: ______________ Feeding Period Start Date: ____/____/____

(PP1A screen 1 of 2)

[Enter dates in format mm/dd/yy and times in format hh:mm.]

1. Period:____ **[Specify 1/2/3]**

2. Date of postprandial study:____/____/____

3. Was fasting sample collected today for main study? **YES NO**
   [Circle either YES or NO. If YES, go to Q5.]

FASTING SAMPLE **[Q4 optional if using today's main study fasting sample]**

4. a. Time that fasting sample was collected:____:____ b. AM PM **[Circle response]**

   c. Number of tubes for fasting sample:____

   d. Code number of person drawing fasting blood:_______

5. a. Time that breakfast was started:____:____ b. AM PM **[Circle response]**

6. a. Time that breakfast was completed:____:____ b. AM PM **[Circle response]**

Postprandial Post Meal Testing Form
(Week 6)

Form Code: PP1
Version A 5/31/94

(PP1A screen 2 of 2)

BEFORE LUNCH SAMPLE **[4 hours after completion of breakfast]**

7. a. Time that before lunch sample was collected:____:____ b. AM PM **[Circle response]**

   c. Number of tubes for before lunch sample:____

   d. Code number of person drawing before lunch blood:_______

8. a. Time that lunch was started:____:____ b. AM PM **[Circle response]**

9. a. Time that lunch was completed:____:____ b. AM PM **[Circle response]**

BEFORE DINNER SAMPLE **[4 hours after completion of lunch]**

10. a. Time that before dinner sample was collected:____:____ b. AM PM **[Circle response]**

    c. Number of tubes for before dinner sample:____

    d. Code number of person drawing before dinner blood:_______

11. Comments? YES NO **[Circle response. If YES, enter comments below.]**

____

____

____

____

12. Code number of person completing this form:_______

Postprandial Post Meal Testing Form
(Week 6)

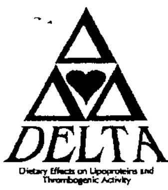
Form Code: PP1
Version A 5/31/94

NOTE PAGE

DELTA ID:________________ DATE:____/____/____

NAME:____
first middle last

PERSONNEL CODE NUMBER ________



Postprandial Standard Fat Load Form
(Week 7)

Form Code: PP2
Version A 5/31/94

DELTA ID: ________________ Feeding Period Start Date: ____/____/____

(PP2A screen 1 of 2)

[Enter dates in format mm/dd/yy and times in format hh:mm.]

1. Period:____ **[Specify 1/2/3]**

2. Date of postprandial study:____/____/____

3. Was fasting sample collected today for main study? YES NO
   [Circle either YES or NO. If YES, go to Q5.]

FASTING SAMPLE **[Q4 optional if using today's main study fasting sample]**

4. a. Time that fasting sample was collected:____:____ b. AM PM **[Circle response]**

   c. Number of tubes for fasting sample:_____

   d. Code number of person drawing fasting blood:_______

5. Weight of fat load offered to participant (gms): | | | | |

6. a. Time participant started drinking fat load:____:____ b. AM PM **[Circle response]**

(PP2A screen 2 of 2)

7. a. Time participant completed drinking fat load:____:____ b. AM PM **[Circle response]**

8. Weight of any fat load remaining (gms): | | | | |

4 HOUR SAMPLE

9. a. Time that 4 hour sample was collected:____:____ b. AM PM **[Circle response]**

   c. Number of tubes for 4 hour sample:____

   d. Code number of person drawing 4 hour blood:______

8 HOUR SAMPLE

10. a. Time that 8 hour sample was collected:____:____ b. AM PM **[Circle response]**

   c. Number of tubes for 8 hour sample:____

   d. Code number of person drawing 8 hour blood:______

11. Comments? YES NO **[Circle response. If YES, enter comments below.]**

____

____

____

____

12. Code number of person completing this form:______

Postprandial Standard Fat Load Form
(Week 7)

Form Code: PP2
Version A 5/31/94

NOTE PAGE

DELTA ID:________________ DATE:____/____/____

NAME:____
first middle last

PERSONNEL CODE NUMBER ________

DELTA Protocol 2
Data Entry Screens
for Laboratory Records with No Forms

July 9, 1996

ID: FORM: APE VERSION: B TIMEPT:

Apo E Genotype Form (APEB screen 1 of 1)

1. Apo E: _ E

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

2. Comments? _ E

ID: FORM: LBA VERSION: A TIMEPT:

Laboratory Assays at Local Lab (LBAA screen 1 of 2)

[Units are mg/dl for all analytes. Enter run dates in format mm/dd/yy.]

1. Feeding Period: _ E

WEEK 5:

2. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
3. a. Triglycerides: ____ E b. Run #:_____ E c. Run date:________ E
4. a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
5. a. LDL (calculated): ___ E
6. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
7. a. Uric Acid: ____ E b. Run #:_____ E c. Run date:________ E

==

Laboratory Assays at Local Lab (LBAA screen 2 of 2)

WEEK 6:

8. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
9 a. Triglycerides: ____ E b. Run #:_____ E c. Run date:________ E
1 a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
11. a. LDL (calculated): ___ E
12. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
13. a. Uric Acid: ____ E b. Run #:_____ E c. Run date:________ E

WEEK 7:

14. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
15. a. Triglycerides: ____ E b. Run #:_____ E c. Run date:________ E
16. a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
17. a. LDL (calculated): ___ E
18. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
19. a. Uric Acid: ____ E b. Run #:_____ E c. Run date:________ E

20. Comments? _ E

ID: FORM: LBB VERSION: A TIMEPT:

Laboratory Assays at MIBH (LBBA screen 1 of 2)
[Units are uU/ml for insulin, mg/dl for VLDL-C and Lp(a), mg/24h for Microalbumin. Enter run dates in format mm/dd/yy.]

1. Feeding Period: _ E

WEEK 5:

2. a. Insulin: ______ E b. Run #:______ E c. Run date:_________ E
3. a. Lp(a) ____ E b. Run #:______ E c. Run date:_________ E
4. a. Microalbumin: _____ E b. Run #:______ E c. Run date:_________ E

WEEK 6:

5. a. Insulin: ______ E b. Run #:______ E c. Run date:_________ E
6. a. VLDL-C: ____ E b. Run #:______ E c. Run date:_________ E
7. a. Lp(a): ____ E b. Run #:______ E c. Run date:_________ E
8. a. Microalbumin: _____ E b. Run #:______ E c. Run date:_________ E

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Laboratory Assays at MIBH (LBBA screen 2 of 2)

WEEK 7:

9. a. Insulin: ______ E b. Run #:______ E c. Run date:_________ E
10. a. VLDL-C: ____ E b. Run #:______ E c. Run date:_________ E
11. a. Lp(a): ____ E b. Run #:______ E c. Run date:_________ E
12. a. Microalbumin: _____ E b. Run #:______ E c. Run date:_________ E

13. Comments? _ E

ID FORM: LBC VERSION: A TIMEPT:

Laboratory Assays at Columbia (LBCA screen 1 of 1)
[Units are mg/dl for all analytes. Enter run dates in format mm/dd/yy.]

1. Feeding Period: _ E

WEEK 5:
2. a. Apo A-1:___ E b. Apo B:___ E c. Run #:_____ E d. Run date:________ E

WEEK 6:
3. a. Apo A-1:___ E b. Apo B:___ E c. Run #:_____ E d. Run date:________ E
4. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:________ E
   e. HDL-2 (calculated):___ E

WEEK 7:
5. a. Apo A-1:___ E b. Apo B:___ E c. Run #:_____ E d. Run date:________ E
6. a. HDL: ___ E b. HDL-3:___ E c. Run #:_____ E d. Run date:________ E
   e. HDL-2 (calculated):___ E

7. Comments? _ E

ID: FORM: LBD   VERSION: A   TIMEPT:

Laboratory Assays at PBRC (LBDA screen 1 of 2)
[Enter run dates in format mm/dd/yy.]

1. Feeding Period: _ E

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

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

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

8. Comments? _ E

ID: FORM: NDF VERSION: C TIMEPT:

Nutrient Data Form (NDFC screen 1 of 6)

1. Report date: ________ E
   mm/dd/yy
2. Diet: _ E
3. Calorie level: ____ E
4. Cycle: __ E
5. Net wt [grams]: _______ E
6. Moisture [g/100g]
   a. rep1: _____ E b. rep2: _____ E c. rep3: _____ E
   d. assay #: _____ E e. mean: _____ E

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Nutrient Data Form (NDFC screen 2 of 6)

[Questions 7 - 27 are reported as g/100g dry weight]

Analyte	Rep 1 (a)	Rep 2 (b)	Assay # (c)	Mean (Calculated) (d)
7. Protein:	_____ E	_____ E	_____ E	_____ E
8. Ash:	____ E	____ E	_____ E	____ E
9. Total fat:	_____ E	_____ E	_____ E	_____ E
10. Cholesterol:	______ E	______ E	_____ E	______ E
11. Tot Dietary Fiber:	____ E	____ E	_____ E	____ E

ID: FORM: NDF VERSION: C TIMEPT:

Nutrient Data Form (NDFC screen 3 of 6)

Analyte	Rep 1 (a)	Rep 2 (b)	Assay # (c)	Mean (Calculated) (d)
12. Starch:	______ E	______ E	______ E	______ E
13. Glucose:	______ E	______ E	______ E	______ E
14. Fructose:	______ E	______ E	______ E	______ E
15. Tot disaccharides:	______ E	______ E	______ E	______ E

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Nutrient Data Form (NDFC screen 4 of 6)

Analyte	Rep 1 (a)	Rep 2 (b)	Assay # (c)	Mean (Calculated) (d)
16. SFA:	________ E	________ E	______ E	________ E
17. MUFA:	________ E	________ E	______ E	________ E
18. PUFA:	________ E	________ E	______ E	________ E
19. C18:3n-3:	________ E	________ E	______ E	________ E
20. C20:5n-3:	________ E	________ E	______ E	________ E
21. C22:6n-3:	________ E	________ E	______ E	________ E
22. C12:0:	________ E	________ E	______ E	________ E
23. C14:0:	________ E	________ E	______ E	________ E
24. C16:0:	________ E	________ E	______ E	________ E

ID: FORM: NDF VERSION: C TIMEPT:

Nutrient Data Form (NDFC screen 5 of 6)

Analyte	Rep 1 (a)	Rep 2 (b)	Assay # (c)	Mean (Calculated) (d)
25. C18:0:	________ E	________ E	______ E	________ E
26. C18:1:	________ E	________ E	______ E	________ E
27. C18:2:	________ E	________ E	______ E	________ E

[For questions 32 - 34, specify YES or NO. If YES, describe in note log.]

28. Were there missing meals or menus? _ E

29. Were there any problems reported from field center kitchen staff: _ E

30. Were there any problems with compositing? _ E

31. Number of menus: __ E

32. Personnel code #: ___ E

ID: FORM: PLA VERSION: A TIMEPT:

Postprandial Studies Lab Assays at Local Lab (PLAA screen 1 of 4)
[Units are mg/dl for all analytes. Enter run dates in format mm/dd/yy.]

1. Feeding Period:_ E

POSTPRANDIAL POST MEAL TESTING (Questions 1-20) [1 handwritten corrected to 2]
FASTING SAMPLE (optional)

2. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
3. a. Triglycerides: ____ Eb. Run #:_____ E c. Run date:________ E
4. a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
5. a. LDL (calculated):___ E
6. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
7. a. Uric Acid: ____ Eb. Run #:_____ E c. Run date:________ E

BEFORE LUNCH SAMPLE

8. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
9. a. Triglycerides: ____ Eb. Run #:_____ E c. Run date:________ E
10. a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
11. a. LDL (calculated):___ E
12. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
13. a. Uric Acid: ____ Eb. Run #:_____ E c. Run date:________ E

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Postprandial Studies Lab Assays at Local Lab (PLAA screen 2 of 4)

BEFORE DINNER SAMPLE

14. a. Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
15. a. Triglycerides: ____ Eb. Run #:_____ E c. Run date:________ E
16. a. HDL Cholesterol: ___ E b. Run #:_____ E c. Run date:________ E
17. a. LDL (calculated):___ E
18. a. Glucose: ___ E b. Run #:_____ E c. Run date:________ E
19. a. Uric Acid: ____ Eb. Run #:_____ E c. Run date:________ E

20. Comments for Q2-19? _ E

ID: FORM: PLA VERSION: A TIMEPT:

Postprandial Studies Lab Assays at Local Lab (PLAA screen 3 of 4)

POSTPRANDIAL STANDARD FAT LOAD (Questions 21-39)

FASTING SAMPLE (optional)

21. a. Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
22. a. Triglycerides: ____ Eb. Run #:______ E c. Run date:_________ E
23. a. HDL Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
24. a. LDL (calculated):___ E
25. a. Glucose: ___ E b. Run #:______ E c. Run date:_________ E
26. a. Uric Acid: ____ Eb. Run #:______ E c. Run date:_________ E

4 HOUR SAMPLE

27. a. Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
28. a. Triglycerides: ____ Eb. Run #:______ E c. Run date:_________ E
29. a. HDL Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
30. a. LDL (calculated):___ E
31. a. Glucose: ___ E b. Run #:______ E c. Run date:_________ E
32. a. Uric Acid: ____ Eb. Run #:______ E c. Run date:_________ E

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Postprandial Studies Lab Assays at Local Lab (PLAA screen 4 of 4)

8 HOUR SAMPLE

33. a. Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
34. a. Triglycerides: ____ Eb. Run #:______ E c. Run date:_________ E
35. a. HDL Cholesterol: ___ E b. Run #:______ E c. Run date:_________ E
36. a. LDL (calculated):___ E
37. a. Glucose: ___ E b. Run #:______ E c. Run date:_________ E
38. a. Uric Acid: ____ Eb. Run #:______ E c. Run date:_________ E

39. Comments for Q21-38? _ E

ID: FORM: PLB VERSION: A TIMEPT:

Postprandial Studies Lab Assays at MIBH (PLBA screen 1 of 1)
[Units are uU/ml for Insulin. Enter run dates in format mm/dd/yy.]

1. Feeding Period:_ E

POSTPRANDIAL POST MEAL TESTING (Questions 2-5)

2a. Fasting Insulin (optl):_____ E b. Run #:_____ E c. Run date:________ E
3a. Before Lunch Insulin: _____ E b. Run #:_____ E c. Run date:________ E
4a. Before Dinner Insulin: _____ E b. Run #:_____ E c. Run date:________ E
5. Comments for Q2-4? _ E

POSTPRANDIAL STANDARD FAT LOAD (Questions 6-9)

6a. Fasting Insulin (optl):_____ E b. Run #:_____ E c. Run date:________ E
7a. 4 Hour Insulin: _____ E b. Run #:_____ E c. Run date:________ E
8a. 8 Hour Insulin: _____ E b. Run #:_____ E c. Run date:________ E
9. Comments for Q6-8? _ E

ID: FORM: PLC VERSION: A TIMEPT:

Postprandial Studies Lab Assays at Columbia (PLCA screen 1 of 1)
[Units are ug/dl for Retinyl ester. Enter run dates in format mm/dd/yy.]

1. Feeding Period:_ E

POSTPRANDIAL STANDARD FAT LOAD

2a. 4 hour Retinyl ester:____ E b. Run #:_____ E c. Run date:________ E

3a. 8 Hour Retinyl ester:____ E b. Run #:_____ E c. Run date:________ E

4. Comments for Q2-3? _ E

Form as of 07/10/96 20:14:22

ID: FORM: PLL VERSION: A TIMEPT:

Postprandial Studies Lp(a) Assays at MIBH (PLLA screen 1 of 1)
[Units are mg/dl for Lp(a). Enter run dates in format mm/dd/yy.]

1. Feeding Period:_ E

POSTPRANDIAL POST MEAL TESTING (Questions 2-5)

2a. Fasting Lp(a) (optl): ___ E b. Run #:_____ E c. Run date:________ E
3a. Before Lunch Lp(a): ___ E b. Run #:_____ E c. Run date:________ E
4a. Before Dinner Lp(a): ___ E b. Run #:_____ E c. Run date:________ E
5. Comments for Q2-4? _ E

POSTPRANDIAL STANDARD FAT LOAD (Questions 6-9)

6a. Fasting Lp(a) (optl): ___ E b. Run #:_____ E c. Run date:________ E
7a. 4 Hour Lp(a): ___ E b. Run #:_____ E c. Run date:________ E
8a. 8 Hour Lp(a): ___ E b. Run #:_____ E c. Run date:________ E
9. Comments for Q6-8? _ E