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Center Number: _____

Participant Number: _____

Participant's Initials: _____
first middle last

Phone Screen

Directions: Give the caller a brief overview of the study. Explain that all study details will be made clear during Screening Visit 1. Ask for verbal consent to record personal information over the phone. Complete all phone screen questions in order to determine eligibility. If the caller is eligible, schedule them for Screening Visit 1.

Fill in blanks and check appropriate answers.

Verbal consent given by respondent: ☐ No ☐ Yes

Interviewer's initials: _____
first middle last

Date: ____/____/____ Source: _____ Age: ____
day month year

Last name: _____ First name: _____ DOB: ____/____/____
day month year

Address: _____ Zip: _____

Phone (home): _____ Phone (work): _____ E-mail: _____

Height: ____ ft ____ in Weight: ____ lbs BMI: _____ Gender: ☐ Male ☐ Female

Medical History

Have you been diagnosed with or ever experienced the following:	If Yes: Describe (being treated/how long ago/symptoms/type of/family history)
Heart attack, heart-related chest pain, or other heart condition	☐ No ☐ Yes →
Abnormal heart rhythm	☐ No ☐ Yes →
Cancer	☐ No ☐ Yes →
Shortness of breath or other breathing problem	☐ No ☐ Yes →
Diabetes (meds)	☐ No ☐ Yes →
High blood pressure (> 140/90)	☐ No ☐ Yes →
Anemia or other blood condition	☐ No ☐ Yes →
Thyroid or other metabolic disorder such as phenylketonuria	☐ No ☐ Yes →
Stomach or digestive disorders	☐ No ☐ Yes →
Immunologic disorder or AIDS	☐ No ☐ Yes →
Depression or any other psychiatric or neurologic disease	☐ No ☐ Yes →
Active liver disease and/or gallstones	☐ No ☐ Yes →
Kidney or urologic disorders	☐ No ☐ Yes →
Major abdominal or chest surgery	☐ No ☐ Yes →
Weight loss or gain of > 3 kg over the past 6 months	☐ No ☐ Yes →
Known metallic objects or implants in your body	☐ No ☐ Yes →
Anaphylaxis, severe allergies or asthma	☐ No ☐ Yes →

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Medications

- 1 Have you received medication for depression or any other psychiatric disease in the past year? ☐ No ☐ Yes → If Yes: Specify medications: _____
- 2 Have you received more than one episode of medication for depression or any other psychiatric disease ever? ☐ No ☐ Yes → If Yes: Specify medications: _____
- 3 Have you been treated with steroids in the last six months? ☐ No ☐ Yes
- 4 Have you been treated with steroids for more than a month in the past five years? ☐ No ☐ Yes
- 5 Do you currently use regular medications other than birth control pills? ☐ No ☐ Yes → If Yes: Specify medications: _____

Women

- 1 Are you currently pregnant or breast feeding? ☐ No ☐ Yes
- 2 Do you plan to have children in the next two years? ☐ No ☐ Yes
- 3 Do you use some form of birth control? ☐ No ☐ Yes → If Yes: Specify: _____

Physical Activity/Lifestyle

- 1 Over the past year, have you engaged in a regular program of physical fitness involving heavy physical activity more than 5 times per week?
(Examples of heavy physical activity include: jogging, running, riding fast on a bicycle for 30 minutes or more; heavy gardening or other chores for an hour or more; active games or sports such as handball or tennis for an hour or more.) ☐ No ☐ Yes → If Yes: Specify type and frequency of activity: _____

- 2 Have you used drugs recreationally within the past two years? ☐ No ☐ Yes
- 3 Have you smoked within the past twelve months? ☐ No ☐ Yes
- 4 Have you given blood in the last 30 days? ☐ No ☐ Yes
- 5 Are you currently participating in another interventional trial? ☐ No ☐ Yes
- 6 Are you currently practicing a vegan dietary lifestyle? ☐ No ☐ Yes
- 7 Do you anticipate difficulties adhering to special diets and clinical visits over a two year period? ☐ No ☐ Yes

Eligibility Information To be completed by the interviewer

Review above items marked "Yes" against Exclusion criteria. Then please mark the appropriate response below:

- Eligible: ☐ No → If No: Reason for not being eligible: _____
- ☐ Yes → If Yes: Is participant interested in participating? ☐ No ☐ Yes
- ☐ On hold → If on hold: For what reason? _____
- Contact to resume screening after being on hold: _____ / _____ / _____
day month year

Orientation (screening visit 1) scheduled: _____

Comments: _____

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SUBJNO = INVSITE||-||PATID

Screening Visit 1 Checklist

 1 Date of initial clinic visit for Screening Visit 1: ____ / ____ / ____ CLINICDT
day month year

Check completed items:

 Other Panel Item not displayed this page:
 RTNCLINIC<XYESNO>

 CHECKLST
 (TYPE 4)
2 ☐ Informed consent3 ☐ HIPAA authorization4 ☐ Study video5 ☐ Study brochure6 ☐ Weight and height measures, including BMI eligibility7 ☐ Demographic form8 ☐ Stanford Activity Assessment9 ☐ General Dietary Questionnaire10 ☐ Eating Inventory11 ☐ MAEDS12 ☐ SCID-II13 ☐ BDI-II14 ☐ Meeting with dietitian15 ☐ Meeting with study coordinator/manager16 ☐ Schedule Assessment Calendar17 ☐ Inclusion/Exclusion criteria review

18 Is the participant expected to return for Screening Visit 2? RETVST<XYESNO>

☐ No → If No: Provide reason (check all that apply):☐ Failed an eligibility criterion FAILELIG ALL<XYES>☐ Lost interest in the study LOSTINT☐ Will take too much time MUCHTIME☐ Scheduling conflicts with work or school SCHEDULE☐ Doesn't like the study's procedures DLKSTDPR☐ Doesn't want to be involved in a research study DWINVSTD☐ Unwilling to be randomized UNWILRAN☐ Lives too far away/transportation problems TRANPROB☐ Needs help with child care CHLDCARE☐ Refused with no explanation REFEXPLN☐ Other (specify): _____ OTHER OTHERSP<V:50>
 Item not Displayed this
 page:

UNABCONT

ADDVISIT<TUADVT>

☐ Yes → If Yes: Date of scheduled Screening Visit 2: ____ / ____ / ____ NXTVISDT
day month year

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Fax this form to DCRI Forms Management at (212) 606-7100

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: _____ / _____ / _____ **STUDYDT** **STUDYTM** **SINITIALS <V:3>**
day month year 00:00 to 23:59 Staff initials: _____
first middle last

OR Not done → Specify reason (use codelist below): _____ **STUDYND<TUND>** **DATEHDR (TYPE 4)**

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . _____ kg **WGHT1** **ALL <F:9:3>**

Weight 2: _____ . _____ kg **WGHT2** **WEIGHT (TYPE 4)**

Weight 3: _____ . _____ kg **WGHT3**

Weight of gown: _____ . _____ kg **GWGHT**

Height

Height (if the first two measurements are more than 0.1 cm apart, measure height a third time): **HEIGHT (TYPE 1)**

1 First height: _____ . _____ cm **HGHT1**

2 Second height: _____ . _____ cm **HGHT2**

3 Third height: _____ . _____ cm **HGHT3**

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Center Number: _____

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first middle last

Date: ____/____/____
day month year

Maintain completed form in participant file at site.

Please print.

Demographic Questionnaire

Name: _____
first name middle initial last name

Street address: _____

City: _____ State: _____ Zip: _____

Telephone (Home): (____) _____ - _____ (Work): (____) _____ - _____

Do you mind being called at work? ☐ No ☐ Yes

Best time to call, and where: _____

E-mail address: _____ Cell phone: (____) _____ - _____

Do you use e-mail regularly? ☐ No ☐ Yes → If Yes: How often? _____

Date of birth: ____/____/____ Age: _____
day month year

Social Security number: _____ - _____ - _____

Occupation: _____

Emergency Contact:

Name: _____
first name last name

Telephone: (____) _____ - _____ Relationship: _____

Primary Care Physician

Name: _____
first name last name

Street address: _____

City: _____ State: _____ Zip: _____

Telephone: (____) _____

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Demographics

DEMOG (TYPE 1)

1 Date of birth: _____ / _____ / _____ DOBDT
day month year

2 Sex: ☐₁ Male ☐₂ Female GENDER<TUGEND>

3 Ethnicity (check only one): ☐₁ Hispanic or Latino
☐₂ Not Hispanic or Latino
☐₃ Unknown (not reporting ethnicity) ETHNIC<TUETHN>

4 Race (check only one): ☐₁ American Indian or Alaska Native
☐₂ Asian
☐₃ Native Hawaiian or other Pacific Islander
☐₄ Black or African American
☐₅ White
☐₆ More than one race
☐₇ Unknown RACE<TURACE>

5 Marital status (check only one): ☐₁ Married ☐₄ Widowed
☐₂ Divorced ☐₅ Separated
☐₃ Single, never married ☐₆ Not married, but living with partner MARSTAT<TUMARS>

6 Living situation: Where do you live (check only one): ☐₁ House
☐₂ Apartment
☐₃ Shelter
☐₄ Dormitory
☐₉₈ Other (specify): _____ LIVSIT<TULVSI>
LIVOTHSP<V:50>

7 Education: What is the highest level of formal education that you have completed (check only one)?

(Note: If you have any questions as to which category you fall in, please contact the study representative.)

☐₁ Elementary school (0-8th grade)
☐₂ 9-11th grade
☐₃ 12th grade or GED
☐₄ Some college/Associates degree
☐₅ College (includes multiple degrees)
☐₆ Non-doctoral graduate degree
☐₇ Doctoral degree (M.D., J.D., Ph.D., etc.) EDUCATE<TUEDU>

8 Family income: What is the total annual income of your household (check only one): ☐₁ \$0-\$19,999
☐₂ \$20,000-\$39,999
☐₃ \$40,000-\$59,999
☐₄ \$60,000-\$79,999
☐₅ \$80,000-\$99,999
☐₆ Greater than \$100,000 FAMINC<TUFINC>

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Stanford Brief Physical Activity Survey

Section I On-The-Job Activity Please check the box next to the **one** statement that **best** describes the kinds of physical activity you usually performed while on this job this last year. If you are not gainfully employed outside the home but perform work around home **regularly**, indicate that activity in this section.

- ☐ **A** If you have no job or regular work, check box A and go on to Section II.
- ☐ **B** I spent most of the day sitting or standing. When I was at work, I did such things as writing, typing, talking on the telephone, assembling small parts, or operating a machine that takes very little exertion or strength. If I drove a car or truck while at work, I did not lift or carry anything for more than a few minutes each day.
- ☐ **C** I spent most of the day walking or using my hands and arms in work that required moderate exertion. When I was at work, I did such things as delivering mail, patrolling on guard duty, mechanical work on automobiles or other large machines, house painting, or operating a machine that requires some moderate activity work of me. If I drove a truck or lift, my job required me to lift and carry things frequently.
- ☐ **D** I spent most of the day lifting or carrying heavy objects or moving most of my body in some other way. When I was at work, I did such things as stacking cargo or inventory, handling parts or materials, or I did work like that of a carpenter who builds structures or a gardener who does most of the work without machines.
- ☐ **E** I spent most of the day doing hard physical labor. When I was at work, I did such things as digging or chopping with heavy tools, or carrying heavy loads (bricks, for example) to the place where they are to be used. If I drove a truck or operated equipment, my job also required me to do hard physical work most of the day with only short breaks.

Section II Leisure-Time Activity Please check the box next to the **one** statement that **best** describes the way you spent your leisure time during most of the last year.

- ☐ **F** Most of my leisure time was spent without very much physical activity. I mostly did things like watching television, reading or playing cards. If I did anything else, it was likely to be light chores around the house or yard, or some easy-going game like bowling or catch. Only occasionally, no more than once or twice a month, did I do anything more vigorous, like jogging, playing tennis or active gardening.
- ☐ **G** Weekdays, when I got home from work, I did few active things. But most weekends I was able to get outdoors for some light exercise—going for walks, playing a round of golf (without motorized carts) or doing some active chores around the house.
- ☐ **H** Three times per week, on the average, I engaged in some moderate activity—such as brisk walking or slow jogging, swimming or riding a bike—for 15–20 minutes or more. Or I spent 45 minutes to an hour or more doing moderately difficult chores—such as raking or washing windows, mowing the lawn or vacuuming—or playing games such as double tennis, or basketball.
- ☐ **I** During my leisure time over the past year, I engaged in a regular program of physical fitness involving some kind of heavy physical activity at least three times per week. Examples of heavy physical activity are: jogging, running or riding fast on a bicycle for 30 minutes or more; heavy gardening or other chores for an hour or more; active games or sports such as handball or tennis for an hour or more; or a regular program involving calisthenics and jogging or the equivalent for 30 minutes or more.
- ☐ **J** Over the past year, I engaged in a regular program of physical fitness along the lines described in the last paragraph (I) but I did it almost **daily**—five or more times per week.

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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): _____

Eating Inventory

1 When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal. ☐ True ☐ False

2 I usually eat too much at social occasions, like parties and picnics. ☐ True ☐ False

3 I am usually so hungry that I eat more than three times a day. ☐ True ☐ False

4 When I have eaten my quota of calories, I am usually good about not eating anymore. ☐ True ☐ False

5 Dieting is so hard for me because I just get too hungry. ☐ True ☐ False

6 I deliberately take small helpings as a means of controlling my weight. ☐ True ☐ False

7 Sometimes things just taste so good that I keep on eating even when I am no longer hungry. ☐ True ☐ False

8 Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat. ☐ True ☐ False

9 When I feel anxious, I find myself eating. ☐ True ☐ False

10 Life is too short to worry about dieting. ☐ True ☐ False

11 Since my weight goes up and down, I have gone on reducing diets more than once. ☐ True ☐ False

12 I often feel so hungry that I just have to eat something. ☐ True ☐ False

13 When I am with someone who is overeating, I usually overeat too. ☐ True ☐ False

14 I have a pretty good idea of the number of calories in common food. ☐ True ☐ False

15 Sometimes when I start eating, I just can't seem to stop. ☐ True ☐ False

16 It is not difficult for me to leave something on my plate. ☐ True ☐ False

17 At certain times of the day, I get hungry because I have gotten used to eating then. ☐ True ☐ False

18 While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it. ☐ True ☐ False

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Eating Inventory (continued)

- | | | | |
|----|---|--|---|
| 19 | Being with someone who is eating often makes me hungry to eat also. | ☐ ₁ True | ☐ ₀ False |
| 20 | When I feel blue, I often overeat. | ☐ ₁ True | ☐ ₀ False |
| 21 | I enjoy eating too much to spoil it by counting calories or watching my weight. | ☐ ₁ True | ☐ ₀ False |
| 22 | When I see a real delicacy, I often get so hungry that I have to eat right away. | ☐ ₁ True | ☐ ₀ False |
| 23 | I often stop eating when I am not really full as a conscious means of limiting the amount I eat. | ☐ ₁ True | ☐ ₀ False |
| 24 | I get so hungry that my stomach often seems like a bottomless pit. | ☐ ₁ True | ☐ ₀ False |
| 25 | My weight has hardly changed at all in the last ten years. | ☐ ₁ True | ☐ ₀ False |
| 26 | I am always hungry so it is hard for me to stop eating before I finish the food on my plate. | ☐ ₁ True | ☐ ₀ False |
| 27 | When I feel lonely, I console myself by eating. | ☐ ₁ True | ☐ ₀ False |
| 28 | I consciously hold back at meals in order not to gain weight. | ☐ ₁ True | ☐ ₀ False |
| 29 | I sometimes get very hungry late in the evening or at night. | ☐ ₁ True | ☐ ₀ False |
| 30 | I eat anything I want, any time I want. | ☐ ₁ True | ☐ ₀ False |
| 31 | Without even thinking about it, I take a long time to eat. | ☐ ₁ True | ☐ ₀ False |
| 32 | I count calories as a conscious means of controlling my weight. | ☐ ₁ True | ☐ ₀ False |
| 33 | I do not eat some foods because they make me fat. | ☐ ₁ True | ☐ ₀ False |
| 34 | I am always hungry enough to eat at any time. | ☐ ₁ True | ☐ ₀ False |
| 35 | I pay a great deal of attention to changes in my figure. | ☐ ₁ True | ☐ ₀ False |
| 36 | While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. | ☐ ₁ True | ☐ ₀ False |

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Eating Inventory (continued)

Please check one answer that is most appropriate to you for each question below.

37	How often are you dieting in a conscious effort to control your weight?	☐ _0 Rarely	☐ _1 Sometimes	☐ _2 Usually	☐ _3 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	☐ _0 Rarely	☐ _1 Sometimes	☐ _2 Usually	☐ _3 Always
39	How often do you feel hungry?	☐ _0 Rarely	☐ _1 Sometimes	☐ _2 Usually	☐ _3 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	☐ _0 Rarely	☐ _1 Sometimes	☐ _2 Usually	☐ _3 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐ _0 Easy ☐ _2 Moderately difficult	☐ _1 Slightly difficult ☐ _3 Very difficult		
42	How conscious are you of what you are eating?	☐ _0 Not at all ☐ _2 Moderately	☐ _1 Slightly ☐ _3 Extremely		
43	How frequently do you avoid "stocking up" on tempting foods?	☐ _0 Almost never ☐ _2 Usually	☐ _1 Seldom ☐ _3 Almost always		
44	How likely are you to shop for low calorie foods?	☐ _0 Unlikely ☐ _2 Moderately likely	☐ _1 Slightly likely ☐ _3 Very likely		
45	Do you eat sensibly in front of others and splurge alone?	☐ _0 Never	☐ _1 Rarely	☐ _2 Often	☐ _3 Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐ _0 Unlikely ☐ _2 Moderately likely	☐ _1 Slightly likely ☐ _3 Very likely		
47	How frequently do you skip dessert because you are no longer hungry?	☐ _0 Almost never ☐ _2 At least once a week	☐ _1 Seldom ☐ _3 Almost every day		
48	How likely are you to consciously eat less than you want?	☐ _0 Unlikely ☐ _2 Moderately likely	☐ _1 Slightly likely ☐ _3 Very likely		
49	Do you go on eating binges though you are not hungry?	☐ _0 Never ☐ _2 Sometimes	☐ _1 Rarely ☐ _3 At least once a week		
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	☐ _0 Not like me ☐ _1 Little like me ☐ _2 Pretty good description of me ☐ _3 Describes me perfectly			
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	☐ _0 Eat whatever you want, whenever you want it ☐ _1 Usually eat whatever you want, whenever you want it ☐ _2 Often eat whatever you want, whenever you want it ☐ _3 Often limit food intake, but often "give in" ☐ _4 Usually limit food intake, rarely "give in" ☐ _5 Constantly limiting food intake, never "giving in"			

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
1 Fasting is a good way to lose weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
2 My sleep isn't as good as it used to be.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
3 I avoid eating for as long as I can.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
4 Certain foods are "forbidden" for me to eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
5 I can't keep certain foods in my house because I will binge on them.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
6 I can easily make myself vomit.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
7 I can feel that being fat is terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
8 I avoid greasy foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
9 It's okay to binge and purge once in a while.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
10 I don't eat certain foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
11 I think I am a good person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
12 My eating is normal.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
13 I can't seem to concentrate lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
14 I try to diet by fasting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
15 I vomit to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
16 Lately nothing seems enjoyable anymore.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
17 Laxatives help keep you slim.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
18 I don't eat red meat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
19 I eat so rapidly I can't even taste my food.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
20 I do everything I can to avoid being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
21 When I feel bloated, I must do something to rid myself of that feeling.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
22 I overeat too frequently.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
23 It's okay to be overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
24 Recently I have felt that I am a worthless person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
25 I would be very upset if I gained 2 pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
26 I crave sweets and carbohydrates.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
27 I lose control when I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
28 Being fat would be terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
29 I have thought seriously about suicide lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
30 I don't have any energy anymore.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
31 I eat small portions to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
32 I eat 3 meals a day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
33 Lately I have been easily irritated.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
34 Some foods should be totally avoided.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
35 I use laxatives to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
36 I am terrified by the thought of being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
37 Purging is a good way to lose weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
38 I avoid fatty foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

	Never	Very Rarely	Rarely	Some-times	Often	Very Often	Always
39 Recently I have felt pretty blue.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
40 I am obsessed with becoming overweight.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
41 I don't eat fried foods.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
42 I skip meals.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
43 Fat people are unhappy.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
44 People are too concerned with the way I eat.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
45 I feel good when I skip meals.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
46 I avoid foods with sugar.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
47 I hate it when I feel fat.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
48 I am too fat.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
49 I eat until I am completely stuffed.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
50 I hate to eat.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
51 I feel guilty about a lot of things these days.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
52 I'm very careful of what I eat.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
53 I can "hold off" and not eat even if I am hungry.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
54 I eat even when I am not hungry.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
55 Fat people are disgusting.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇
56 I wouldn't mind gaining a few pounds.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇

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Date completed: ____/____/____
day month year

Structured Clinical Interview for DSM-IV (SCID-II)

1	Have you avoided jobs or tasks that involved having to deal with a lot of people?	☐ No	☐ Yes
2	Do you avoid getting involved with people unless you are certain they will like you?	☐ No	☐ Yes
3	Do you find it hard to be "open" even with people are you close to?	☐ No	☐ Yes
4	Do you often worry about being criticized or rejected in social situations?	☐ No	☐ Yes
5	Are you usually quiet when you meet new people?	☐ No	☐ Yes
6	Do you believe that you're not as good, as smart, or as attractive as most other people?	☐ No	☐ Yes
7	Are you afraid to try new things?	☐ No	☐ Yes
8	Do you need a lot of advice or reassurance from other before you can make everyday decisions—like what to wear or what to order in a restaurant?	☐ No	☐ Yes
9	Do you depend on other people to handle important areas in your life such as finances, child care, or living arrangements?	☐ No	☐ Yes
10	Do you find it hard to disagree with people even when you think they are wrong?	☐ No	☐ Yes
11	Do you find it hard to start or work on tasks when there is no one to help you?	☐ No	☐ Yes
12	Have you often volunteered to do things that are unpleasant?	☐ No	☐ Yes
13	Do you usually feel uncomfortable when you are by yourself?	☐ No	☐ Yes
14	When a close relationship ends, do you feel you immediately have to find someone else to take care of you?	☐ No	☐ Yes
15	Do you worry a lot about being left alone to take care of yourself?	☐ No	☐ Yes
16	Are you the kind of person who focuses on details, order, and organization or likes to make lists and schedules?	☐ No	☐ Yes
17	Do you have trouble finishing jobs because you spend so much time trying to get things exactly right?	☐ No	☐ Yes
18	Do you or other people feel that you are so devoted to work (or school) that you have no time left for anyone else or for just having fun?	☐ No	☐ Yes
19	Do you have very high standards about what is right and what is wrong?	☐ No	☐ Yes
20	Do you have trouble throwing things out because they might come in handy some day?	☐ No	☐ Yes
21	Is it hard for you to let other people help you unless they agree to do things exactly the way you want?	☐ No	☐ Yes
22	Is it hard for you to spend money on yourself and other people even when you have enough?	☐ No	☐ Yes
23	Are you often so sure you are right that it doesn't matter what other people say?	☐ No	☐ Yes
24	Have other people told you that you are stubborn or rigid?	☐ No	☐ Yes

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first middle last

Structured Clinical Interview for DSM-IV (SCID-II) (continued)

25	When someone asks you to do something that you don't want to do, do you say "yes" but then work slowly or do a bad job?	☐ No	☐ Yes
26	If you don't want to do something, do you often just "forget" to do it?	☐ No	☐ Yes
27	Do you often feel that other people don't understand you, or don't appreciate how much you do?	☐ No	☐ Yes
28	Are you often grumpy and likely to get into arguments?	☐ No	☐ Yes
29	Have you found that most of your bosses, teachers, supervisors, doctors, and others who are supposed to know what they are doing really don't?	☐ No	☐ Yes
30	Do you often think that it's not fair that other people have more than you do?	☐ No	☐ Yes
31	Do you often complain that more than your share of bad things have happened to you?	☐ No	☐ Yes
32	Do you often angrily refuse to do what others want and then later feel bad and apologize?	☐ No	☐ Yes
33	Do you usually feel unhappy or that life is no fun?	☐ No	☐ Yes
34	Do you believe that you are basically an inadequate person and often don't feel good about yourself?	☐ No	☐ Yes
35	Do you often put yourself down?	☐ No	☐ Yes
36	Do you keep thinking about bad things that have happened in the past or worry about bad things that might happen in the future?	☐ No	☐ Yes
37	Do you often judge others harshly and easily find fault with them?	☐ No	☐ Yes
38	Do you think that most people are basically no good?	☐ No	☐ Yes
39	Do you almost always expect things to turn out badly?	☐ No	☐ Yes
40	Do you often feel guilty about things you have or haven't done?	☐ No	☐ Yes
41	Do you often have to keep an eye out to stop people from using you or hurting you?	☐ No	☐ Yes
42	Do you spend a lot of time wondering if you can trust your friends or the people you work with?	☐ No	☐ Yes
43	Do you find that it is best not to let other people know much about you because they will use it against you?	☐ No	☐ Yes
44	Do you often detect hidden threats or insults in things people say or do?	☐ No	☐ Yes
45	Are you the kind of person who holds grudges or takes a long time to forgive people who have insulted or slighted you?	☐ No	☐ Yes
46	Are there many people you can't forgive because they did or said something to you a long time ago?	☐ No	☐ Yes
47	Do you often get angry or lash out when someone criticizes or insults you in some way?	☐ No	☐ Yes
48	Have you often suspected that your spouse or partner has been unfaithful?	☐ No	☐ Yes

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Structured Clinical Interview for DSM-IV (SCID-II) (continued)

- | | | | |
|----|--|-----------------------------|------------------------------|
| 49 | When you are out in public and see people talking, do you often feel that they are talking about you? | ☐ No | ☐ Yes |
| 50 | Do you often get the feeling that things that have no special meaning to most people are really meant to give you a message? | ☐ No | ☐ Yes |
| 51 | When you are around people, do you often get the feeling that you are being watched or stared at? | ☐ No | ☐ Yes |
| 52 | Have you ever felt that you could make things happen just by making a wish or thinking about them? | ☐ No | ☐ Yes |
| 53 | Have you had personal experiences with the supernatural? | ☐ No | ☐ Yes |
| 54 | Do you believe that you have a "sixth sense" that allows you to know and predict things that others can't? | ☐ No | ☐ Yes |
| 55 | Does it often seem that objects or shadows are really people or animals or that noises are actually people's voices? | ☐ No | ☐ Yes |
| 56 | Have you had the sense that some person or force is around you, even though you cannot see anyone? | ☐ No | ☐ Yes |
| 57 | Do you often see auras or energy fields around people? | ☐ No | ☐ Yes |
| 58 | Are there very few people that you're really close to outside of your immediate family? | ☐ No | ☐ Yes |
| 59 | Do you often feel nervous when you are with other people? | ☐ No | ☐ Yes |
| 60 | Is it NOT important to you whether you have any close relationships? | ☐ No | ☐ Yes |
| 61 | Would you almost always rather do things alone than with other people? | ☐ No | ☐ Yes |
| 62 | Could you be content without ever being sexually involved with anyone? | ☐ No | ☐ Yes |
| 63 | Are there really very few things that give you pleasure? | ☐ No | ☐ Yes |
| 64 | Does it NOT matter to you what people think of you? | ☐ No | ☐ Yes |
| 65 | Do you find that nothing makes you very happy or very sad? | ☐ No | ☐ Yes |
| 66 | Do you like to be the center of attention? | ☐ No | ☐ Yes |
| 67 | Do you flirt a lot? | ☐ No | ☐ Yes |
| 68 | Do you often find yourself "coming on" to people? | ☐ No | ☐ Yes |
| 69 | Do you try to draw attention to yourself by the way you dress or look? | ☐ No | ☐ Yes |
| 70 | Do you often make a point of being dramatic and colorful? | ☐ No | ☐ Yes |
| 71 | Do you often change your mind about things depending on the people you're with or what you have just read or seen on TV? | ☐ No | ☐ Yes |
| 72 | Do you have lots of friends that you are very close to? | ☐ No | ☐ Yes |

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Structured Clinical Interview for DSM-IV (SCID-II) (continued)

73	Do people often fail to appreciate your very special talents or accomplishments?	☐ No	☐ Yes
74	Have people told you that you have too high an opinion of yourself?	☐ No	☐ Yes
75	Do you think a lot about the power, fame, or recognition that will be yours someday?	☐ No	☐ Yes
76	Do you think a lot about the perfect romance that will be yours someday?	☐ No	☐ Yes
77	When you have a problem, do you almost always insist on seeing the top person?	☐ No	☐ Yes
78	Do you feel it is important to spend time with people who are special or influential?	☐ No	☐ Yes
79	Is it very important to you that people pay attention to you or admire you in some way?	☐ No	☐ Yes
80	Do you think that it's not necessary to follow certain rules or social conventions when they get in your way?	☐ No	☐ Yes
81	Do you feel that you are the kind of person who deserves special treatment?	☐ No	☐ Yes
82	Do you often find it necessary to step on a few toes to get what you want?	☐ No	☐ Yes
83	Do you often have to put your needs above other people's?	☐ No	☐ Yes
84	Do you often expect other people to do what you ask without question because of who you are?	☐ No	☐ Yes
85	Are you NOT really interested in other people's problems or feelings?	☐ No	☐ Yes
86	Have people complained to you that you don't listen to them or care about their feelings?	☐ No	☐ Yes
87	Are you often envious of others?	☐ No	☐ Yes
88	Do you feel that others are often envious of you?	☐ No	☐ Yes
89	Do you find that there are very few people that are worth your time and attention?	☐ No	☐ Yes
90	Have you often become frantic when you thought that someone you really cared about was going to leave you?	☐ No	☐ Yes
91	Do your relationships with people you really care about have lots of extreme ups and downs?	☐ No	☐ Yes
92	Have you all of a sudden changed your sense of who you are and where you are headed?	☐ No	☐ Yes
93	Does your sense of who you are often change dramatically?	☐ No	☐ Yes
94	Are you different with different people or in different situations, so that you sometimes don't know who you really are?	☐ No	☐ Yes
95	Have there been lots of sudden changes in your goals, career plans, religious beliefs, and so on?	☐ No	☐ Yes
96	Have you often done things impulsively?	☐ No	☐ Yes
97	Have you tried to hurt or kill yourself or threatened to do so?	☐ No	☐ Yes
98	Have you ever cut, burned, or scratched yourself on purpose?	☐ No	☐ Yes

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first middle last

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Structured Clinical Interview for DSM-IV (SCID-II) (continued)

- | | | | |
|-----|---|-----------------------------|------------------------------|
| 99 | Do you have a lot of sudden mood changes? | ☐ No | ☐ Yes |
| 100 | Do you often feel empty inside? | ☐ No | ☐ Yes |
| 101 | Do you often have temper outbursts or get so angry that you lose control? | ☐ No | ☐ Yes |
| 102 | Do you hit people or throw things when you get angry? | ☐ No | ☐ Yes |
| 103 | Do even little things get you very angry? | ☐ No | ☐ Yes |
| 104 | When you are under a lot of stress, do you get suspicious of other people or feel especially spaced out? | ☐ No | ☐ Yes |
| 105 | Before you were 15, would you bully or threaten other kids? | ☐ No | ☐ Yes |
| 106 | Before you were 15, would you start fights? | ☐ No | ☐ Yes |
| 107 | Before you were 15, did you hurt or threaten someone with a weapon, like a bat, brick, broken bottle, knife, or gun? | ☐ No | ☐ Yes |
| 108 | Before you were 15, did you deliberately torture someone or cause someone physical pain and suffering? | ☐ No | ☐ Yes |
| 109 | Before you were 15, did you torture or hurt animals on purpose? | ☐ No | ☐ Yes |
| 110 | Before you were 15, did you rob, mug, or forcibly take something from someone by threatening him or her? | ☐ No | ☐ Yes |
| 111 | Before you were 15, did you force someone to have sex with you, to get undressed in front of you, or to touch you sexually? | ☐ No | ☐ Yes |
| 112 | Before you were 15, did you set fires? | ☐ No | ☐ Yes |
| 113 | Before you were 15, did you deliberately destroy things that weren't yours? | ☐ No | ☐ Yes |
| 114 | Before you were 15, did you break into houses, other buildings, or cars? | ☐ No | ☐ Yes |
| 115 | Before you were 15, did you lie a lot or "con" other people? | ☐ No | ☐ Yes |
| 116 | Before you were 15, did you sometimes steal or shoplift things or forge someone's signature? | ☐ No | ☐ Yes |
| 117 | Before you were 15, did you run away from home and stay away overnight? | ☐ No | ☐ Yes |
| 118 | Before you were 13, did you often stay out very late, long after the time you were supposed to be home? | ☐ No | ☐ Yes |
| 119 | Before you were 13, did you often skip school? | ☐ No | ☐ Yes |

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Date completed: ____/____/____
day month year

BDI-II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

- 1 **Sadness:**
 - ☐ I do not feel sad
 - ☐ I feel sad much of the time
 - ☐ I am sad all of the time
 - ☐ I am so sad or unhappy that I can't stand it
- 2 **Pessimism:**
 - ☐ I am not discouraged about my future
 - ☐ I feel more discouraged about my future than I used to be
 - ☐ I do not expect things to work out for me
 - ☐ I feel my future is hopeless and will only get worse
- 3 **Past failure:**
 - ☐ I do not feel like a failure
 - ☐ I have failed more than I should have
 - ☐ As I look back, I see a lot of failures
 - ☐ I feel I am a total failure as a person
- 4 **Loss of pleasure:**
 - ☐ I get as much pleasure as I ever did from the things I enjoy
 - ☐ I don't enjoy things as much as I used to
 - ☐ I get very little pleasure from the things I used to enjoy
 - ☐ I can't get any pleasure from the things I used to enjoy
- 5 **Guilty feelings:**
 - ☐ I don't feel particularly guilty
 - ☐ I feel guilty over many things I have done or should have done
 - ☐ I feel quite guilty most of the time
 - ☐ I feel guilty all of the time
- 6 **Punishment feelings:**
 - ☐ I don't feel I am being punished
 - ☐ I feel I may be punished
 - ☐ I expect to be punished
 - ☐ I feel I am being punished
- 7 **Self-dislike:**
 - ☐ I feel the same about myself as ever
 - ☐ I have lost confidence in myself
 - ☐ I am disappointed in myself
 - ☐ I dislike myself

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BDI-II (continued)

8 Self-criticalness:

- ☐₀ I don't criticize or blame myself more than usual
- ☐₁ I am more critical of myself than I used to be
- ☐₂ I criticize myself for all of my faults
- ☐₃ I blame myself for everything bad that happens

9 Suicidal thoughts or wishes:

- ☐₀ I don't have any thoughts of killing myself
- ☐₁ I have thoughts of killing myself but I would not carry them out
- ☐₂ I would like to kill myself
- ☐₃ I would kill myself if I had the chance

10 Crying:

- ☐₀ I don't cry any more than I used to
- ☐₁ I cry more than I used to
- ☐₂ I cry over every little thing
- ☐₃ I feel like crying, but I can't

11 Agitation:

- ☐₀ I am no more wound up or restless than usual
- ☐₁ I feel more restless or wound up than usual
- ☐₂ I am so restless or agitated that it's hard to stay still
- ☐₃ I am so restless or agitated that I have to keep moving or doing something

12 Loss of interest:

- ☐₀ I have not lost interest in other people or activities
- ☐₁ I am less interested in other people or things than before
- ☐₂ I have lost most of my interest in other people or things
- ☐₃ It's hard to get interested in anything

13 Indecisiveness:

- ☐₀ I make decisions about as well as ever
- ☐₁ I find it more difficult to make decisions than usual
- ☐₂ I have much greater difficulty in making decisions than I used to
- ☐₃ I have trouble making my decisions

14 Worthlessness:

- ☐₀ I do not feel I am worthless
- ☐₁ I don't consider myself as worthwhile and useful as I used to
- ☐₂ I feel more worthless as compared to other people
- ☐₃ I feel utterly worthless

15 Loss of energy:

- ☐₀ I have as much energy as ever
- ☐₁ I have less energy than I used to have
- ☐₂ I don't have enough energy to do very much
- ☐₃ I don't have enough energy to do anything

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first middle last

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BDI-II (continued)

16 Changes in sleeping pattern: ☐₀ I have not experienced any change in my sleeping pattern

☐₁ I sleep somewhat more than usual

☐₂ I sleep somewhat less than usual

☐₃ I sleep a lot more than usual

☐₄ I sleep a lot less than usual

☐₅ I sleep most of the day

☐₆ I wake up 1-2 hours early and can't get back to sleep

17 Irritability:

☐₀ I am no more irritable than usual

☐₁ I am more irritable than usual

☐₂ I am much more irritable than usual

☐₃ I am irritable all of the time

18 Changes in appetite:

☐₀ I have not experienced any change in my appetite

☐₁ My appetite is somewhat less than usual

☐₂ My appetite is somewhat greater than usual

☐₃ My appetite is much less than before

☐₄ My appetite is much greater than usual

☐₅ I have no appetite at all

☐₆ I crave food all of the time

19 Concentration difficulty:

☐₀ I can concentrate as well as ever

☐₁ I can't concentrate as well as usual

☐₂ It's hard to keep my mind on anything for very long

☐₃ I find I can't concentrate on anything

20 Tiredness or fatigue:

☐₀ I am no more tired or fatigued than usual

☐₁ I get more tired or fatigued more easily than usual

☐₂ I am too tired or fatigued to do a lot of the things I used to do

☐₃ I am too tired or fatigued to do most of the things I used to do

21 Loss of interest in sex:

☐₀ I have not noticed any recent change in my interest in sex

☐₁ I am less interested in sex than I used to be

☐₂ I am much less interested in sex now

☐₃ I have lost interest in sex completely

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Screening Visit 2 Checklist

1 Did participant return for Screening Visit 2?

☐ No → If No: Skip to question 15 and provide reason.

☐ Yes → If Yes: Date of initial clinic visit for Screening Visit 2: ____/____/____
day month year

Display RTNCLINIC<XYESNO>

CHECKLST
(TYPE 4)

Check completed items:

2 ☐ Fasting blood sample

3 ☐ Urine sample

4 ☐ Vitals (temperature, pulse, blood pressure)

5 ☐ ECG

6 ☐ Medical and medication history

7 ☐ Concomitant medications log

8 ☐ Physical examination

9 ☐ Barriers interview

10 ☐ Body morph assessment

11 ☐ Additional interviews (SCID-II and/or IDED-IV)

12 ☐ Meeting with dietitian to review dietary screening questionnaire

13 ☐ 14-day food record procedure reviewed

14 ☐ Meeting with study coordinator/manager

15 Is the participant expected to return for Screening Visit 3?

☐ No → If No: Provide reason (check all that apply):

- ☐ Failed an eligibility criterion
- ☐ Lost interest in the study
- ☐ Will take too much time
- ☐ Scheduling conflicts with work or school
- ☐ Doesn't like the study's procedures
- ☐ Doesn't want to be involved in a research study
- ☐ Unwilling to be randomized
- ☐ Lives too far away/transportation problems
- ☐ Needs help with child care
- ☐ Refused with no explanation
- ☐ Unable to contact
- ☐ Other (specify): _____

Display UNABCONT

☐ Yes → If Yes: Date of scheduled Screening Visit 3: ____/____/____
day month year

SAME AS PAGE 3

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Fax this Form to DCRI Forms Management at (919) 668-7100

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Date completed: ____/____/____
day month year

No display STUDYND,
STUDYTM or SINITIALS

DATEHDR (TYPE 4)

Screening Medical History

List any clinically significant pre-existing condition(s).

Body System BODYSYS<TUBODY>	ASSESS<TUNCHY>		Assessments
	No	Yes	If Yes, Specify Diagnosis
1 Head, Ears, Eyes, Nose, Throat	☐ _0	☐ _1 →	MEDHIST (TYPE 4)PS
2 Dermatologic	☐ _0	☐ _1 →	YESEX<V:100>
3 Cardiovascular	☐ _0	☐ _1 →	
4 Respiratory	☐ _0	☐ _1 →	CODELIST TUNCHY 0 = NO/NOCHANGE 1 = YES
5 Gastrointestinal	☐ _0	☐ _1 →	
6 Endocrine/Metabolic	☐ _0	☐ _1 →	
7 Genitourinary	☐ _0	☐ _1 →	
8 Neurological	☐ _0	☐ _1 →	
9 Blood/Lymphatic	☐ _0	☐ _1 →	
10 Musculoskeletal	☐ _0	☐ _1 →	
11 Hepatic	☐ _0	☐ _1 →	
12 Drug Allergies	☐ _0	☐ _1 →	
13 Other Allergies	☐ _0	☐ _1 →	
14 Psychological/Psychiatric	☐ _0	☐ _1 →	
15 Other (including contraception methods, females only)	☐ _0	☐ _1 →	

Physician's Signature

Signature: _____ NOT DATABASED Date: _____ NOT DATABASED
day month year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Retain this form at site at secure location until participant reassessed at baseline visit.

Date completed: ____/____/____ SAME AS PAGE 23

DATEHDR (TYPE 4)

Medication History

Record any medications taken from 6 months prior through screening period, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Include any steroid use within the last 5 years.

Medication	Start Date	Stop Date	Indication
MEDNUM <I:2> 1 MEDS <V:100>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	PRIORMED (TYPE 4)R
2	____/____/____ day month year	MEDSTPDT ____/____/____ day month year OR ☐ Continuing	MEDCONT <XYES>
3	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	MEDIND <V:110>
4	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
5	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
6 WHODRUG_B2 WHONAME<V:80>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
7 WHOCODE <V:32> WORKFLOW <V:5> CODER <V:20>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
8 CODETM<DATETIME> CONFLVL <V:2> MATCHES <V:4>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
9	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
10 WHODRUG_ATC_B2 ATCTERM<V:110> ATCCODE<V:40> WORKFLO2<V:5>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
11 CODETM2<DATETIME> CONFLVL2<V:2> MATCHES2<V:4>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	
12 CODER2<V:20>	____/____/____ day month year	____/____/____ day month year OR ☐ Continuing	

Page Numbering: Sequentially number each page in the right hand corner, i.e. 24.1, 24.2, 24.3. Insert additional pages as needed.

Retain at site at secure location. Submit with Consentant Medication Log for Baseline Submission 1.

THIS PAGE NOT ENTERED

Center Number: _____

Participant Number: _____

Participant's Initials: _____
first middle last

Physical Examination

Date of examination: ____/____/____ OR Not done → Specify reason (use codelist below): _____
day month year

Body System	Assessments			If Abnormal or Not Done: Explain
	Normal	Abnormal	Not Done	
1 General appearance:	☐ _1	☐ _0 →	☐ _97 →	
2 Head, Ears, Eyes, Nose, Throat:	☐ _1	☐ _0 →	☐ _97 →	
3 Neck:	☐ _1	☐ _0 →	☐ _97 →	
4 Heart:	☐ _1	☐ _0 →	☐ _97 →	
5 Lungs:	☐ _1	☐ _0 →	☐ _97 →	
6 Abdomen:	☐ _1	☐ _0 →	☐ _97 →	
7 Lymph nodes:	☐ _1	☐ _0 →	☐ _97 →	
8 Extremities/Skin:	☐ _1	☐ _0 →	☐ _97 →	
9 Neurological:	☐ _1	☐ _0 →	☐ _97 →	
10 Musculoskeletal:	☐ _1	☐ _0 →	☐ _97 →	
	Normal	Abnormal	Not Done *	
11 Genitourinary:	☐ _1	☐ _0 →	☐ _97 →	
12 Breast:	☐ _1	☐ _0 →	☐ _97 →	

Physician's Signature

Signature: _____ Date: ____/____/____
year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

* Not done at this examination OR Referred participant to primary care physician for exam.

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

Do not submit to DCRI. Retain at site at secure location.

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Screening Visit 3 Checklist

1 Did participant return for Screening Visit 3?

☐ No → If No: Skip to question 5 and provide reason.

☐ Yes → If Yes: Date of initial clinic visit for Screening Visit 3: _____ / _____ / _____
day month year

CHECKLIST
(TYPE 4)

Check completed items:

2 ☐ Reviewed all lab results (blood, urine, and pregnancy test)

3 ☐ Repeated blood sample, if needed

4 ☐ 14-day food record collected and reviewed

SAME AS PAGE 22

5 Has the participant been contacted and agreed to additional visit (check only one)?

☐ No, no additional visits → If No additional visits: Provide reason (check all that apply):

- ☐ Failed an eligibility criterion
- ☐ Lost interest in the study
- ☐ Will take too much time
- ☐ Scheduling conflicts with work or school
- ☐ Doesn't like the study's procedures
- ☐ Doesn't want to be involved in a research study
- ☐ Unwilling to be randomized
- ☐ Lives too far away/transportation problems
- ☐ Needs help with child care
- ☐ Refused with no explanation
- ☐ Unable to contact
- ☐ Other (specify): _____

☐ Yes → If Yes: Additional visit scheduled (check only one):

☐ Screening Visit 4 → Date of scheduled Screening Visit 4: _____ / _____ / _____
day month year

☐ Baseline visit → Date of scheduled Baseline Visit: _____ / _____ / _____
day month year

Display
ADDVISIT<TUADVT>

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax this Form to DCRI Forms Management at (919) 668-7100

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Screening Visit 4 Checklist Optional—Submit this form only if Screening Visit 4 was scheduled

1 Did participant return for Screening Visit 4?

☐ No → If No: Skip to question 4 and provide reason.

☐ Yes → If Yes: Date of initial clinic visit for Screening Visit 4: ____/____/____
day month year

CHECKLIST
(TYPE 4)

Check completed items:

2 ☐ Reviewed all lab results (blood, urine, and pregnancy test)

3 ☐ 14-day food record collected and reviewed (if needed)

SAME AS PAGE 22

4 Has the participant been contacted and agreed to proceed with a Baseline Visit (check only one)?

☐ No → If No: Provide reason (check all that apply):

- ☐ Failed an eligibility criterion
- ☐ Lost interest in the study
- ☐ Will take too much time
- ☐ Scheduling conflicts with work or school
- ☐ Doesn't like the study's procedures
- ☐ Doesn't want to be involved in a research study
- ☐ Unwilling to be randomized
- ☐ Lives too far away/transportation problems
- ☐ Needs help with child care
- ☐ Refused with no explanation
- ☐ Unable to contact
- ☐ Other (specify): _____

☐ Yes → If Yes: Date of scheduled Baseline Visit: ____/____/____
day month year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax this Form to DCRI Forms Management at (919) 668-7100

Center Number: _____

Participant Number: _____

Participant's Initials: _____
first middle last**Informed Consent****1 Did participant present for baseline visit?**

RTNBL<XYESNO>

CONSENT (TYPE 1)

- ☐ No → If No: Specify reason (check only one):
- ☐ 1 Failed an eligibility criterion (participant no longer meets criteria) **FAILELIC**
 - ☐ 2 Lost interest in the study **LOSTINT**
 - ☐ 3 Will take too much time **MUCHTIME**
 - ☐ 4 Scheduling conflicts with work or school **SCHEDULE**
 - ☐ 5 Doesn't like the study's procedures **LIKSTDPR**
 - ☐ 6 Doesn't want to be involved in a research study **DWINVSTD**
 - ☐ 7 Unwilling to be randomized **UNWILRAN**
 - ☐ 8 Lives too far away/transportation problem **TRANPROB**
 - ☐ 9 Needs help with child care (update if need child care needs) **CHILDCARE**
 - ☐ 10 Refused with no explanation **REFEXPLN**
 - ☐ 11 Unable to contact **UNABCONT**
 - ☐ 98 Other (specify): _____ **OTHER** **OTHERSP<V:50>**

☐ Yes**2 Date and time study baseline informed consent signed:**

CONSNTDT

CONSNTTM

____ day / ____ month / ____ year 00:00 to 23:59

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Send to DCRI Forms Management • 2400 Pratt St. • Room 0311 Terrace Level • Durham NC 27705

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Informed Consent Detail

Tissue consent:

CONSENTD (TYPE 2)
PS

SUPPRESS SEQNO<1:3>

CNSNTDTL<TUCSTD>

Check only one

SEQNO<1:3> Sample type SAMPYTYPE<TUSAMT>	Check only one		
	Participant consent given for future studies by Calerie and external investigators	Participant consent given for future studies by Calerie	Participant consent not given
1 Blood archive	☐ ₁ 1=	☐ ₂ 2=	☐ ₃ 3=
2 Urine archive	☐ ₁	☐ ₂	☐ ₃
3 Muscle biopsy archive	☐ ₁	☐ ₂	☐ ₃
4 Fat biopsy archive	☐ ₁	☐ ₂	☐ ₃

<TUSAMT>

1= 1 BLOOD ARCHIVE

2= 2 URINE ARCHIVE

3= 3 MUSCLE BIOPSY ARCHIVE

4= 4 FAT BIOPSY ARCHIVE

<TUCSTD>

1= 1 EXTERNAL INVESTIGATORS

2= 2 CALERIE CONSENT

3= 3 CONSENT NOT GIVEN

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: ____/____/____ 00:00 to 23:59
day month year

Staff initials: _____
first middle last

OR Not done → Specify reason (use Codelist below): _____

DATEHDR (TYPE 4)

SAME AS PAGE 4

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ kg

WEIGHT (TYPE 4)

Weight 2: _____ kg

Weight 3: _____ kg

Weight of gown: _____ kg

Vital Signs

Assessment date and time: ____/____/____ VITALDT VITALTM 00:00 to 23:59
day month year

VITALS (TYPE 3)

If waist measurement not done → Specify reason (use codelist below): WUND<TUND>

SINTIALS

1 Natural waist measurement

(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: _____
first middle last

Natural waist measurement 1: _____ WMEAS1 cm

Natural waist measurement 2: _____ WMEAS2 cm

Natural waist measurement 3: _____ WMEAS3 cm

All measurements <F:9:3>
unless otherwise indicated

2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: _____ UMEAS1 cm

Umbilical point waist measurement 2: _____ UMEAS2 cm

Umbilical point waist measurement 3: _____ UMEAS3 cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

PULSE<I:3>

PULND<TUND>

PINTIAL <V:3>

TEMP

TMPND<TUND>

TINTIAL <V:3>

4 Temperature: _____ °C OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

RESP<I:2>

RESPND<TUND>

RINTIAL <V:3>

5 Respirations: _____ per minute OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

BPARM<TUARM>

BPINTIAL <V:3>

6 Blood pressure (check only one): ☐ Left arm ☐ Right arm

Staff initials: _____
first middle last

6a Blood pressure 1: _____ mm Hg
systolic diastolic

BP1TM
00:00 to 23:59

OR Not done →

BPND<TUND>

Specify reason (use codelist below): _____

6b Blood pressure 2: _____ mm Hg
systolic diastolic

BP2TM
00:00 to 23:59

6c Blood pressure 3: _____ mm Hg
systolic diastolic

BP3TM
00:00 to 23:59

ALL TIMES ASSOCIATED WITH
VITALDT

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

Send to DCRI Forms Management • 2400 Pratt St. • Room 0311 Terrace Level • Durham NC 27705

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time	Findings	Staff Initials
DATEHDR (TYPE 4) ____/____/____ 00:00 to 23:59 day month year SAME AS PAGE 4 OR Not done → Specify reason (see codelist below): No display SINTIALS	ECG (TYPE 4) Is ECG (check only one): ECGFIND<TUECG> ☐ ₁ Normal ☐ ₂ Abnormal, not clinically significant (specify): _____ ECG2SP<V:50> ☐ ₃ Abnormal, clinically significant (specify): _____ ECG3SP<V:50>	SINTIALS first middle last

Safety Labs

Date and time of last meal: ____/____/____ 00:00 to 23:59 day month year LMEALDT LMEALTM SAMPDT SAMPTM			
Date and time of sample collection: ____/____/____ 00:00 to 23:59 day month year SAFETYLB (TYPE 4)			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	BLSMPCOL<XYESNO> ☐ ₀ No ☐ ₁ Yes	BLSMPND<TUND> _____	BLDINIT<V:3> first middle last
Urine	URSMPCOL<XYESNO> ☐ ₀ No ☐ ₁ Yes	URSMPPND<TUND> _____	URNINIT<V:3> first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Date completed: ____/____/____ SAME AS PAGE 23 DATEHDR (TYPE 4)
day month year

Abbreviated Medical History

List any clinically significant changes occurring since Screening medical history was completed.

Body System	Assessments		
	No Change	Yes	If Yes, Specify Diagnosis
1 Head, Ears, Eyes, Nose, Throat	☐ _0	☐ _1 →	MEDHIST (TYPE 4)PS
2 Dermatologic	☐ _0	☐ _1 →	
3 Cardiovascular	☐ _0	☐ _1 →	SAME AS PAGE 23
4 Respiratory	☐ _0	☐ _1 →	
5 Gastrointestinal	☐ _0	☐ _1 →	
6 Endocrine/Metabolic	☐ _0	☐ _1 →	
7 Genitourinary	☐ _0	☐ _1 →	
8 Neurological	☐ _0	☐ _1 →	
9 Blood/Lymphatic	☐ _0	☐ _1 →	
10 Musculoskeletal	☐ _0	☐ _1 →	
11 Hepatic	☐ _0	☐ _1 →	
12 Drug Allergies	☐ _0	☐ _1 →	
13 Other Allergies	☐ _0	☐ _1 →	
14 Psychological/Psychiatric	☐ _0	☐ _1 →	
15 Other	☐ _0	☐ _1 →	

Physician's Signature

Signature: _____ Date: ____/____/____
day month year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Physical Examination

Date of examination: ____/____/____
day month year

SAME AS PAGE 4

No display STUDYH, STUDYM

Staff initials: ____
first middle last

OR Not done → Specify reason (use codelist below): _____

DATEHDR (TYPE 4)

Body System PEXAM<TUPEXM>	Assessments			If Abnormal or Not Done: Explain
	Normal	Abnormal	Not Done	
1 General appearance:	☐ _1	☐ _0 →	☐ _97 →	PEXAM (TYPE 4)PS
2 Head, Ears, Eyes, Nose, Throat:	☐ _1	☐ _0 →	☐ _97 →	ABNDSP<V:200>
3 Neck:	☐ _1	☐ _0 →	☐ _97 →	
4 Heart:	☐ _1	☐ _0 →	☐ _97 →	
5 Lungs:	☐ _1	☐ _0 →	☐ _97 →	
6 Abdomen:	☐ _1	☐ _0 →	☐ _97 →	
7 Lymph nodes:	☐ _1	☐ _0 →	☐ _97 →	
8 Extremities/Skin:	☐ _1	☐ _0 →	☐ _97 →	
9 Neurological:	☐ _1	☐ _0 →	☐ _97 →	
10 Musculoskeletal:	☐ _1	☐ _0 →	☐ _97 →	
	Normal	Abnormal	Not Done*	
11 Genitourinary:	☐ _1	☐ _0 →	☐ _97 →	
12 Breast:	☐ _1	☐ _0 →	☐ _97 →	

Physician's Signature

Investigator: _____ NOT DATED NOT DATED
signature Date: ____/____/____
day month year

* Not done at this examination OR Referred participant to primary care physician for exam.

Not Done Codelist: 1 Participant CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 5 Not required

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . _____ kg

SAME AS PAGE 4

WEIGHT (TYPE 4)

Weight 2: _____ . _____ kg

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

Pregnancy Test

Complete only for females.

REPOTEN<XYESNO>

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ No

☐ Yes → If Yes: Date urine pregnancy test performed: _____ / _____ / _____
day month year

PRGTSTDT

Results: ☐ Negative

☐ Positive

PGRSLT<TURLT>

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Doubly Labeled Water (DLW)

- 1** Date and time of DLW dosing: _____ / _____ / _____ : _____
day month year 00:00 to 23:59
DLWSEDT DLWDSETM DLWHDR (TYPE 4)
Staff initials: _____
first middle last
SINITIALS
- OR Not done → Specify reason (use codelist below): _____
DLWND<TUND>
- 2** DLW dose mixture ID and bottle number: _____ - CA
DLWMAN<V:2> DLWBOTNO<I:3>
DLWMIX<I:5>
- 3** Exact weight of DLW mixture: _____ grams
DLWMIXWT<F:9:3>
- 4** Urine samples: _____
DLWCHT (TYPE 4)PS

Collection	Sample DLWSMPNO<TUDLW>	Date and Time Collected
Pre dosing (PD)	1 = PDa	_____ / _____ / _____ : _____ day month year 00:00 to 23:59 DLWCOLDT DLWCOLTM
	2 = PDb	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
Day 0 (Visit 2)	3 = D0a	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
	4 = D0b	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
Day 7 (Visit 3)	5 = D7a	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
	6 = D7b	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
Day 14 (Visit 4)	7 = D14a	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
	8 = D14b	_____ / _____ / _____ : _____ day month year 00:00 to 23:59

NOTE: INCLUDE THESE ITEMS IN THE DLWHDR PANEL ABOVE

- 5** Affix CRF page label(s) corresponding to this urine sample set:

Affix Label Here	DLWLBL1<V:15> Not displayed this page DLWLBL2<V:15>
------------------------	---

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

DXA Scan

- 1** Has the participant taken a calcium supplement today? DXASCAN (TYPE 4)
☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.
CALSUP<XYESNO>
- 2** Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?
☐ No ☐ Yes BARSTDY<XYESNO>

DXA Scan		DXA Rescan OR RENA<XYES> ☐ % NA
Date of scan: ____/____/____ DXADT day month year		Date of rescan: ____/____/____ REDXADT day month year
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply
WBDY ALL<XYES> ☐ Whole body	WBDYND ALL<TUND> _____	REWBDY ALL<XYES> ☐ Whole body
FARM ☐ Forearm	FARMND _____	REFARM ☐ Forearm
SPINE ☐ Spine	SPINEND _____	RESPINE ☐ Spine
HIP ☐ Hip	HIPND _____	REHIP ☐ Hip

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 36

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Date completed: ____/____/____ OR Not done → Specify reason (useodelist below): _____
day month year

SAME AS PAGE 32 - No Display SINTIALS **DATEHDR (TYPE 4)**

RAND SF-36

Instructions: This survey asks for your views about your health. This information will help keep track of how well you are able to do your usual activities. Please answer every question by placing a check "X" in the appropriate box. If you are unsure about how to answer a question, give the best answer you can. **RANDSF1 (TYPE 3)**

1 In general, would you say your health is: ☐₁ Excellent ☐₂ Very good ☐₃ Good ☐₄ Fair ☐₅ Poor

HEALTH<TUHLTH>

2 Compared to one year ago, how would you rate your health in general now?

- ☐₁ Much better now than 1 year ago
☐₂ Somewhat better now than 1 year ago
☐₃ About the same
☐₄ Somewhat worse now than 1 year ago
☐₅ Much worse now than 1 year ago

GHLTHNOW<TUGHLT>

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Yes, Limited A Lot **Yes, Limited A Little** **No, Not Limited At All**
ALL<TULIM>

3 Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

VIGORACT

☐₁

☐₂

☐₃

4 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

MODACT

☐₁

☐₂

☐₃

5 Lifting or carrying groceries

LIFTCARR

☐₁

☐₂

☐₃

6 Climbing several flights of stairs

CLIMBSEV

☐₁

☐₂

☐₃

7 Climbing one flight of stairs

CLIMB1

☐₁

☐₂

☐₃

8 Bending, kneeling or stooping

BENDING

☐₁

☐₂

☐₃

9 Walking more than a mile

WALKMILE

☐₁

☐₂

☐₃

10 Walking several blocks

WALKSBLK

☐₁

☐₂

☐₃

11 Walking one block

WALKBLCK

☐₁

☐₂

☐₃

12 Bathing or dressing yourself

BATHING

☐₁

☐₂

☐₃

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Rand SF-36 (continued)

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? RANDSF2 (TYPE 3)

ALL <TUYN>

Yes

No

13 Cut down on the **amount of time** you spent on work or other activities

☐₁

☐₂

CUTWORK1

14 Accomplished less than you would like

☐₁

☐₂

ACCOMLE1

15 Were limited in the **kind** of work or other activities

☐₁

☐₂

LIMWORK1

16 Had **difficulty** performing the work or other activities
(for example, it took extra effort)

☐₁

☐₂

DIFWORK1

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)

Yes

No

17 Cut down on the **amount of time** you spent on work or other activities

☐₁

☐₂

CUTWORK2

18 Accomplished less than you would like

☐₁

☐₂

ACCOMLE2

19 Didn't do work or other activities as **carefully** as usual

☐₁

☐₂

CAREFUL

20 During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

- ☐₁ Not at all
- ☐₂ Slightly
- ☐₃ Moderately
- ☐₄ Quite a bit
- ☐₅ Extremely

SOCIAL<TUSOCI>

21 How much **bodily** pain have you had during the **past 4 weeks**?

- ☐₁ None
- ☐₂ Very mild
- ☐₃ Mild
- ☐₄ Moderate
- ☐₅ Severe
- ☐₆ Very severe

BODPAIN<TUPAIN>

22 During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐₁ Not at all
- ☐₂ A little bit
- ☐₃ Moderately
- ☐₄ Quite a bit
- ☐₅ Extremely

INTERFE<TUSOCI>

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RAND SF-36 (continued)

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

RANDSF3 (TYPE 3)

ALL<TUTFRE>

How much of the time during the past 4 weeks...

All of the Time Most of the Time A Good Bit of the Time Some of the Time A Little of the Time None of the Time

23 Did you feel full of pep?

PEP

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

24 Have you been a very nervous person?

NERV

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

25 Have you felt so down in the dumps that nothing could cheer you up?

DOWN

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

26 Have you felt calm and peaceful?

CALM

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

27 Did you have a lot of energy?

ENERG

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

28 Have you felt downhearted and blue?

BLUE

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

29 Did you feel worn out?

WORN

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

30 Have you been a happy person?

HAPPY

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

31 Did you feel tired?

TIRED

☐₁ ☐₂ ☐₃ ☐₄ ☐₅ ☐₆

32 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

EMOTPROB<TUEMOT>

All of the Time Most of the Time Some of the Time A Little of the Time None of the Time

☐₁ ☐₂ ☐₃ ☐₄ ☐₅

How true or false is each of the following statements for you?

ALL<TUTFRA>

Definitely True Mostly True Don't Know Mostly False Definitely False

33 I seem to get sick a little easier than other people.

SICK

☐₁ ☐₂ ☐₃ ☐₄ ☐₅

34 I am healthy as anybody I know.

HEALTHYA

☐₁ ☐₂ ☐₃ ☐₄ ☐₅

35 I expect my health to get worse.

EHWORSE

☐₁ ☐₂ ☐₃ ☐₄ ☐₅

36 My health is excellent.

HEXCEL

☐₁ ☐₂ ☐₃ ☐₄ ☐₅

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Date: ____/____/____ OR Not done → Specify reason (use codelist below): _____ DATEHDR (TYPE 4)
day month year

BDI-II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

BDIQ (TYPE 4)

- 1 Sadness:**

SADNESS<TUSAD>

☐ I do not feel sad

☐ I feel sad much of the time

☐ I am sad all of the time

☐ I am so sad or unhappy that I can't stand it
- 2 Pessimism:**

PESSIMIS<TUPESS>

☐ I am not discouraged about my future

☐ I feel more discouraged about my future than I used to be

☐ I do not expect things to work out for me

☐ I feel my future is hopeless and will only get worse
- 3 Past failure:**

FAILURE<TUFAIL>

☐ I do not feel like a failure

☐ I have failed more than I should have

☐ As I look back, I see a lot of failures

☐ I feel I am a total failure as a person
- 4 Loss of pleasure:**

PLEASURE<TUPLEA>

☐ I get as much pleasure as I ever did from the things I enjoy

☐ I don't enjoy things as much as I used to

☐ I get very little pleasure from the things I used to enjoy

☐ I can't get any pleasure from the things I used to enjoy
- 5 Guilty feelings:**

GUILTY<TUGUIL>

☐ I don't feel particularly guilty

☐ I feel guilty over many things I have done or should have done

☐ I feel quite guilty most of the time

☐ I feel guilty all of the time
- 6 Punishment feelings:**

PUNISH<TUPUNI>

☐ I don't feel I am being punished

☐ I feel I may be punished

☐ I expect to be punished

☐ I feel I am being punished
- 7 Self-dislike:**

DISLIKE<TUDISL>

☐ I feel the same about myself as ever

☐ I have lost confidence in myself

☐ I am disappointed in myself

☐ I dislike myself

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BDI-II (continued)

8 Self-criticalness:

CRITICAL<TUCRIT>

- ☐₀ I don't criticize or blame myself more than usual
☐₁ I am more critical of myself than I used to be
☐₂ I criticize myself for all of my faults
☐₃ I blame myself for everything bad that happens

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

SUICIDAL<TUSUIC>

- ☐₀ I don't have any thoughts of killing myself
☐₁ I have thoughts of killing myself but I would not carry them out
☐₂ I would like to kill myself
☐₃ I would kill myself if I had the chance

10 Crying:

CRYING<TUCRY>

- ☐₀ I don't cry any more than I used to
☐₁ I cry more than I used to
☐₂ I cry over every little thing
☐₃ I feel like crying, but I can't

11 Agitation:

AGITATIO<TUAGIT>

- ☐₀ I am no more wound up or restless than usual
☐₁ I feel more restless or wound up than usual
☐₂ I am so restless or agitated that it's hard to stay still
☐₃ I am so restless or agitated that I have to keep moving or doing something

12 Loss of interest:

INTEREST<TUINTR>

- ☐₀ I have not lost interest in other people or activities
☐₁ I am less interested in other people or things than before
☐₂ I have lost most of my interest in other people or things
☐₃ It's hard to get interested in anything

13 Indecisiveness:

INDECISI<TUINDE>

- ☐₀ I make decisions about as well as ever
☐₁ I find it more difficult to make decisions than usual
☐₂ I have much greater difficulty in making decisions than I used to
☐₃ I have trouble making my decisions

14 Worthlessness:

WORTHLES<TUWORT>

- ☐₀ I do not feel I am worthless
☐₁ I don't consider myself as worthwhile and useful as I used to
☐₂ I feel more worthless as compared to other people
☐₃ I feel utterly worthless

15 Loss of energy:

ENERGY<TUENER>

- ☐₀ I have as much energy as ever
☐₁ I have less energy than I used to have
☐₂ I don't have enough energy to do very much
☐₃ I don't have enough energy to do anything

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BDI-II (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep

SLEEPING<TUSLEE>

BDIQ (TYPE 4)

- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time

IRRITABI<TUIRRI>

- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time

APPETITE<TUAPPE>

- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything

CONCENTR<TUCONC>

- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do

FATIGUE<TUFATI>

- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

SEXINTR<TUSEXI>

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DATEHDR (TYPE 4)

Profile of Mood States

Instructions: Please describe **how you feel right now** by checking one box for each of the words listed below.

POMS (TYPE 4) PS

	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1	Friendly	☐	☐	☐	☐	☐
2	Tense	☐	☐	☐	☐	☐
3	Angry	☐	☐	☐	☐	☐
4	Worn out	☐	☐	☐	☐	☐
5	Unhappy	☐	☐	☐	☐	☐
6	Clear-headed	☐	☐	☐	☐	☐
7	Lively	☐	☐	☐	☐	☐
8	Confused	☐	☐	☐	☐	☐
9	Sorry for things done	☐	☐	☐	☐	☐
10	Shaky	☐	☐	☐	☐	☐
11	Listless	☐	☐	☐	☐	☐
12	Peeved	☐	☐	☐	☐	☐
13	Considerate	☐	☐	☐	☐	☐
14	Sad	☐	☐	☐	☐	☐
15	Active	☐	☐	☐	☐	☐
16	On edge	☐	☐	☐	☐	☐
17	Grouchy	☐	☐	☐	☐	☐
18	Blue	☐	☐	☐	☐	☐
19	Energetic	☐	☐	☐	☐	☐
20	Panicky	☐	☐	☐	☐	☐

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Profile of Mood States (continued)

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
=21 Hopeless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=22 Relaxed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=23 Unworthy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=24 Spiteful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=25 Sympathetic	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=26 Uneasy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=27 Restless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=28 Unable to concentrate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=29 Fatigued	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=30 Helpful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=31 Annoyed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=32 Discouraged	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=33 Resentful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=34 Nervous	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=35 Lonely	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=36 Miserable	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=37 Muddled	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=38 Cheerful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=39 Bitter	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=40 Exhausted	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=41 Anxious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=42 Ready to fight	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
=43 Good-natured	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

POMS (TYPE 4)PS

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Profile of Mood States (continued)

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
= 44 Gloomy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 45 Desperate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 46 Sluggish	☐ _0	SAME AS PAGE 42		☐ _3	☐ _4
= 47 Rebellious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 48 Helpless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 49 Weary	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 50 Bewildered	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 51 Alert	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 52 Deceived	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 53 Furious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 54 Efficient	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 55 Trusting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 56 Full of pep	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 57 Bad-tempered	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 58 Worthless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 59 Forgetful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 60 Carefree	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 61 Terrified	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 62 Guilty	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 63 Vigorous	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 64 Uncertain about things	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
= 65 Bushed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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day month year

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DATEHDR (TYPE 4)

Perceived Stress Scale (PSS)

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.

PSS (TYPE 4)

ALL<TUPSS>

Never Almost Never Some-times Fairly Often Very Often

1 In the last month, how often have you felt that you were unable to control the important things in your life?

☐0 ☐1 ☐2 ☐3 ☐4

CTRLTHNG

2 In the last month, how often have you felt confident about your ability to handle your personal problems?

☐0 ☐1 ☐2 ☐3 ☐4

HANDPROB

3 In the last month, how often have you felt that things were going your way?

☐0 ☐1 ☐2 ☐3 ☐4

GOYOWAY

4 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

☐0 ☐1 ☐2 ☐3 ☐4

PILEHIGH

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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): _____
day month year SAME AS PAGE 36 DATEHDR (TYPE 4)

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month...

BEDHR<I:2>

PSQI1(TYPE 4)

1 When have you usually gone to bed?

BEDMIN<I:2>

00:00 to 23:59

2 How long (in minutes) has it taken you to fall asleep each night? _____ minutes FALLASLP<I:3>

3 When have you usually gotten up in the morning?

WAKEHR<I:2>

00:00 to 23:59

WAKEMIN<I:2>

4 How many hours of actual sleep did you get at night?

ACTSLP<F:9:3>

(This may be different than the number of hours you spend in bed.) ____ . ____ hours

5 During the past month, how often have you had trouble sleeping because you... (check only one answer per question)

Not during
the past
month

Less than
once
a week

Once or
twice
a week

3 or more
times
a week

ALL<TUSLP>

a Cannot get to sleep within 30 minutes

WITHIN30

☐ 0

☐ 1

☐ 2

☐ 3

b Wake up in the middle of the night or early morning

MIDNGHMC

☐ 0

☐ 1

☐ 2

☐ 3

c Have to get up to use the bathroom

GOBTHRM

☐ 0

☐ 1

☐ 2

☐ 3

d Cannot breathe comfortably

BREATHE

☐ 0

☐ 1

☐ 2

☐ 3

e Cough or snore loudly

SNORE

☐ 0

☐ 1

☐ 2

☐ 3

f Feel too cold

COLD

☐ 0

☐ 1

☐ 2

☐ 3

g Feel too hot

HOT

☐ 0

☐ 1

☐ 2

☐ 3

h Have bad dreams

BADDRM

☐ 0

☐ 1

☐ 2

☐ 3

i Have pain

PAIN

☐ 0

☐ 1

☐ 2

☐ 3

j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): _____

OTHER

☐ 0

☐ 1

☐ 2

☐ 3

6 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

MEDSTKN

☐ 0

☐ 1

☐ 2

☐ 3

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Pittsburgh Sleep Quality Index (PSQI) (continued)

	Never	Once or twice	Once or twice each week	3 or more times each week
7 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? AWKESOC<TUSLPB>	☐ _0	☐ _1	☐ _2	☐ _3

PSQI2 (TYPE 3)

	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8 During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done? KPENTHUS<TUSLPC>	☐ _0	☐ _1	☐ _2	☐ _3

	Very good	Fairly good	Fairly bad	Very bad
9 During the past month, how would you rate your sleep quality overall? SLPQLTY<TUSLPD>	☐ _0	☐ _1	☐ _2	☐ _3

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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): **DATEHDR (TYPE 4)**
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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about **sexual fantasies** or daydreams, while another inquires about the kinds of **sexual experiences** that you have. You are also asked about the nature of your **sexual arousal** and the quality of your **orgasm**. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "0 = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. **For each item, please check the scale number that best describes your personal experience.**

DISFEM1 (TYPE 4)PS

If you have any questions, please ask the person who gave you the inventory for help.

Section 1—Sexual Cognition/Fantasy

During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person	☐	☐	☐	☐	☐	☐	☐	☐	☐
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)	☐	☐	☐	☐	☐	☐	☐	☐	☐
1.3 Erotic or romantic situations	☐	☐	☐	☐	☐	☐	☐	☐	☐
1.4 Caressing, touching, undressing, or foreplay	☐	☐	☐	☐	☐	☐	☐	☐	☐
1.5 Sexual intercourse, oral sex, touching to orgasm	☐	☐	☐	☐	☐	☐	☐	☐	☐

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PAGEID = 49

Center Number: _____ Participant Number: _____ Participant's Initials: first middle last

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 2—Sexual Arousal

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
6 = 2.1 Feel sexually aroused while alone	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
7 = 2.2 Actively seek sexual satisfaction	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
8 = 2.3 Feel sexually aroused with a partner	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
FEMALEQ<TUFQUE>	Never	Rarely	Sometimes	Usually	Always	DISFEM2 (TYPE 4)PS			
9 = 2.4 Have normal lubrication with masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	RESPONSE<TUDSFB>			
10 = 2.5 Have normal lubrication throughout sexual relations	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4				

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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 3—Sexual Behavior/Experiences SAME AS PAGE 48 DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
11 = 3.1 Reading or viewing romantic or erotic books or stories	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
12 = 3.2 Masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
13 = 3.3 Casual kissing and petting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
14 = 3.4 Sexual foreplay	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
15 = 3.5 Sexual intercourse, oral sex, etc.	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

Section 4—Orgasm FEMALEQ<TUFQUE> DISFEM3 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
16 = 4.1 Your ability to have an orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
17 = 4.2 The intensity of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
18 = 4.3 The ability to have multiple orgasms (if typical for you)	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
19 = 4.4 Feelings of closeness and togetherness with your partner	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
20 = 4.5 Your sense of control (timing) of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
21 = 4.6 Feeling a sense of relaxation and well-being after orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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PAGEID = 51

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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 5—Drive and Relationship

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22 = 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
	Not at all	Slightly	Moderately	Highly	Extremely	DISFEM3 (TYPE 4)PS			
23 = 5.2 During this period, how interested have you been in sex?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	SAME AS PAGE 50			
24 = 5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	DISFEM4 (TYPE 4)PS			
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
25 = 5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

FEMALEQ<TUFQUE>

RESPONSE<TUDSFD>

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PAGEID = 52

Center Number: _____ Participant Number: _____ Participant's Initials: _____
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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below):

SAME AS PAGE 36

DATEHDR (TYPE 4)

Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about **sexual fantasies** or daydreams, while another inquires about the kinds of **sexual experiences** that you have. You are also asked about the nature of your **sexual arousal** and the quality of your **orgasm**. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "0 = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. **For each item, please check the scale number that best describes your personal experience.**

If you have any questions, please ask the person who gave you the inventory for help. DISMALE1 (TYPE 4)PS

Section 1—Sexual Cognition/Fantasy

During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.3 Erotic or romantic situations	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.4 Caressing, touching, undressing, or foreplay	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.5 Sexual intercourse, oral sex, touching to orgasm	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 2—Sexual Arousal

SAME AS PAGE 52

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
6 = 2.1 A full erection upon awakening	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
7 = 2.2 A full erection during a sexual fantasy or daydream	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
8 = 2.3 A full erection while looking at a sexually arousing person, movie, or picture	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
9 = 2.4 A full erection during masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
10 = 2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 3—Sexual Behavior/Experiences SAME AS PAGE 52 DISMALE1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
11 = 3.1 Reading or viewing romantic or erotic books or stories	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
12 = 3.2 Masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
13 = 3.3 Casual kissing and petting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
14 = 3.4 Sexual foreplay	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
15 = 3.5 Sexual intercourse, oral sex, etc.	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

Section 4—Orgasm MALEQ<TUMQUE> RESPONSE<TUDSFC> DISMALE2 (TYPE 4)PS

	Not at all	Slightly	Moderately	Highly	Extremely
16 = 4.1 Your ability to have an orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
17 = 4.2 The intensity of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
18 = 4.3 The length or duration of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
19 = 4.4 The amount of seminal liquid that you ejaculate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
20 = 4.5 Your sense of control (timing) of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
21 = 4.6 Feeling a sense of relaxation and well-being after orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 5—Drive and Relationship

SAME AS PAGE 52

DISMALE1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22 = 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
	Not at all	Slightly	Moderately	Highly	Extremely	DISMALE2 (TYPE 4)PS			
23 = 5.2 During this period, how interested have you been in sex?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	SAME AS PAGE 54			
24 = 5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	DISMALE3 (TYPE 4)PS			
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
25 = 5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

MALEQ<TUMQUE>

RESPONSE<TUDSFD>

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PAGEID = 56

Center Number:
SAME AS PAGE 36

Participant Number:
DATEHDR (TYPE 4)

Participant's Initials:
first middle last

Date completed: / / OR Not done → Specify reason (useodelist below):
day month year

Food Cravings Questionnaire—Trait

Please indicate the extent to which you agree with each statement below, in general, by checking the appropriate box.

TRAIT<TUFCQA>	TRAITA<TUFCQB>	Never OR NA	Rarely	Some- times	Often	Usually	Always
1 Being with someone who is eating often makes me hungry.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
2 When I crave something, I know I won't be able to stop eating once I start.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
3 If I eat what I am craving, I often lose control and eat too much.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
4 I hate it when I give in to cravings.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
5 Food cravings invariably make me think of ways to get what I want to eat.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
6 I feel like I have food on my mind all the time.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
7 I often feel guilty for craving certain foods.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
8 I find myself preoccupied with food.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
9 I eat to feel better.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10 Sometimes, eating makes things seem just perfect.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11 Thinking about my favorite foods makes my mouth water.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
12 I crave foods when my stomach is empty.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
13 I feel as if my body asks for certain foods.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
14 I get so hungry that my stomach seems like a bottomless pit.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
15 Eating what I crave makes me feel better.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
16 When I satisfy a craving, I feel less depressed.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
17 When I eat what I am craving, I feel guilty about myself.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18 Whenever I have cravings, I find myself making plans to eat.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19 Eating calms me down.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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first middle last

Food Cravings Questionnaire—Trait (continued)

SAME AS PAGE 56	Never OR NA	Rarely	Some- times	Often	Usually	Always
=20 I crave foods when I am bored, angry, or sad.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=21 I feel less anxious after I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=22 If I get what I am craving, I cannot stop myself from eating it.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=23 When I crave certain foods, I usually try to eat them as soon as I can.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=24 When I eat what I crave, I feel great.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=25 I have no will power to resist my food crave.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=26 Once I start eating, I have trouble stopping.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=27 I can't stop thinking about eating, no matter how hard I try.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=28 I spend a lot of time thinking about whatever it is I will eat next.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=29 If I give in to a food craving, all control is lost.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=30 When I'm stressed out, I crave food.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=31 I daydream about food.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=32 Whenever I have a food craving, I keep on thinking about eating until I actually eat the food.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=33 If I am craving something, thoughts of eating it consume me.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=34 My emotions often make me want to eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=35 Whenever I go to a buffet, I end up eating more than what I needed.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=36 It is hard for me to resist the temptation to eat appetizing foods that are in my reach.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=37 When I am with someone who is overeating, I usually overeat too.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=38 When I eat food, I feel comforted.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
=39 I crave foods when I'm upset.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Food Cravings Questionnaire—State (FCQ—S)

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment **right now, at this very moment**. Notice that some questions refer to foods in general while others refer to one or more specific foods. Please respond to each item as honestly as possible.

FCQSTATE (TYPE 4)PS

STATEQ<TUFCQC>	STATEA<TUFCQD>	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1 I have an intense desire to eat [one or more specific foods].		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2 I'm craving [one or more specific foods].		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3 I have an urge for [one or more specific foods]		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4 Eating [one or more specific foods] would make things seem just perfect.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5 If I were to eat what I am craving, I am sure my mood would improve.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6 Eating [one or more specific foods] would feel wonderful.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7 If I ate something, I wouldn't feel so sluggish and lethargic.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8 Satisfying my craving would make me feel less grouchy and irritable.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9 I would feel more alert if I could satisfy my craving.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10 If I had [one or more specific foods], I could not stop eating it.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11 My desire to eat [one or more specific foods] seems overpowering.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
13 I am hungry.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14 If I ate right now, my stomach wouldn't feel as empty.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15 I feel weak because of not eating.		☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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SAME AS PAGE 36

Food Craving Inventory (FCI-II)

For each of the foods listed below, please check the appropriate box.

CRAVE (TYPE 4)PS

Note: A craving is defined as an intense desire to consume a particular food or food type that is difficult to resist.

Over the past month, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake FCIQ<TUCRVA>	☐	☐	☐	☐	☐
2 Pizza FCIA<TUCRVB>	☐	☐	☐	☐	☐
3 Fried chicken	☐	☐	☐	☐	☐
4 Gravy	☐	☐	☐	☐	☐
5 Sandwich bread	☐	☐	☐	☐	☐
6 Sausage	☐	☐	☐	☐	☐
7 French fries	☐	☐	☐	☐	☐
8 Cinnamon rolls	☐	☐	☐	☐	☐
9 Rice	☐	☐	☐	☐	☐
10 Hot dog	☐	☐	☐	☐	☐
11 Hamburger	☐	☐	☐	☐	☐
12 Biscuits	☐	☐	☐	☐	☐
13 Ice cream	☐	☐	☐	☐	☐
14 Pasta	☐	☐	☐	☐	☐
15 Fried fish	☐	☐	☐	☐	☐
16 Cookies	☐	☐	☐	☐	☐
17 Chocolate	☐	☐	☐	☐	☐
18 Pancakes or waffles	☐	☐	☐	☐	☐
19 Corn bread	☐	☐	☐	☐	☐
20 Chips	☐	☐	☐	☐	☐
21 Rolls	☐	☐	☐	☐	☐
22 Cereal	☐	☐	☐	☐	☐
23 Donuts	☐	☐	☐	☐	☐
24 Candy	☐	☐	☐	☐	☐
25 Brownies	☐	☐	☐	☐	☐
26 Bacon	☐	☐	☐	☐	☐
27 Steak	☐	☐	☐	☐	☐
28 Baked potato	☐	☐	☐	☐	☐

Not Done Code list: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below):

SAME AS PAGE 36

DATEHDR (TYPE 4)

Eating Inventory

1	When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal.	☐ True ☐ False
2	I usually eat too much at social occasions, like parties and picnics.	☐ True ☐ False
3	I am usually so hungry that I eat more than three times a day.	☐ True ☐ False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐ True ☐ False
5	Dieting is so hard for me because I just get too hungry.	☐ True ☐ False
6	I deliberately take small helpings as a means of controlling my weight.	☐ True ☐ False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐ True ☐ False
8	Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat.	☐ True ☐ False
9	When I feel anxious, I find myself eating.	☐ True ☐ False
10	Life is too short to worry about dieting.	☐ True ☐ False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐ True ☐ False
12	I often feel so hungry that I just have to eat something.	☐ True ☐ False
13	When I am with someone who is overeating, I usually overeat too.	☐ True ☐ False
14	I have a pretty good idea of the number of calories in common food.	☐ True ☐ False
15	Sometimes when I start eating, I just can't seem to stop.	☐ True ☐ False
16	It is not difficult for me to leave something on my plate.	☐ True ☐ False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐ True ☐ False
18	While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	☐ True ☐ False

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CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Eating Inventory (continued)

=19 Being with someone who is eating often makes me hungry to eat also. ☐ True ☐ False

=20 When I feel blue, I often overeat. SAME AS PAGE 60 TFOQA (TYPE 4)PS ☐ True ☐ False

=21 I enjoy eating too much to spoil it by counting calories or watching my weight. ☐ True ☐ False

=22 When I see a real delicacy, I often get so hungry that I have to eat right away. ☐ True ☐ False

=23 I often stop eating when I am not really full as a conscious means of limiting the amount I eat. ☐ True ☐ False

=24 I get so hungry that my stomach often seems like a bottomless pit. ☐ True ☐ False

=25 My weight has hardly changed at all in the last ten years. ☐ True ☐ False

=26 I am always hungry so it is hard for me to stop eating before I finish the food on my plate. ☐ True ☐ False

=27 When I feel lonely, I console myself by eating. ☐ True ☐ False

=28 I consciously hold back at meals in order not to gain weight. ☐ True ☐ False

=29 I sometimes get very hungry late in the evening or at night. ☐ True ☐ False

=30 I eat anything I want, any time I want. ☐ True ☐ False

=31 Without even thinking about it, I take a long time to eat. ☐ True ☐ False

=32 I count calories as a conscious means of controlling my weight. ☐ True ☐ False

=33 I do not eat some foods because they make me fat. ☐ True ☐ False

=34 I am always hungry enough to eat at any time. ☐ True ☐ False

=35 I pay a great deal of attention to changes in my figure. ☐ True ☐ False

=36 While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. ☐ True ☐ False

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Eating Inventory (continued)

Please check one answer that is most appropriate to you for each question below. TFEQB (TYPE 3)

37	How often are you dieting in a conscious effort to control your weight?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always	WTCONTR<TUFREQ>	
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always	WTFLUCT<TUFREQ>	
39	How often do you feel hungry?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always	OFTHUNG<TUFREQ>	
40	Do your feelings of guilt about overeating help you to control your food intake?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always	FEELGUIL<TUFREQ>	
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐ 1 Easy	☐ 2 Slightly difficult	☐ 3 Moderately difficult	☐ 4 Very difficult	EATDIFF<TUDIFF>	
42	How conscious are you of what you are eating?	☐ 1 Not at all	☐ 2 Slightly	☐ 3 Moderately	☐ 4 Extremely	CONSEAT<TUCONS>	
43	How frequently do you avoid "stocking up" on tempting foods?	☐ 1 Almost never	☐ 2 Seldom	☐ 3 Usually	☐ 4 Almost always	STOCKING<TUSTOC>	
44	How likely are you to shop for low calorie foods?	☐ 1 Unlikely	☐ 2 Slightly likely	☐ 3 Moderately likely	☐ 4 Very likely	LOWCAL<TULIKE>	
45	Do you eat sensibly in front of others and splurge alone?	☐ 1 Never	☐ 2 Rarely	☐ 3 Often	☐ 4 Always	SPLURG<TUSPLU>	
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐ 1 Unlikely	☐ 2 Slightly likely	☐ 3 Moderately likely	☐ 4 Very likely	EATSLow<TULIKE>	
47	How frequently do you skip dessert because you are no longer hungry?	☐ 1 Almost never	☐ 2 Seldom	☐ 3 At least once a week	☐ 4 Almost every day	DESSERT<TUDESS>	
48	How likely are you to consciously eat less than you want?	☐ 1 Unlikely	☐ 2 Slightly likely	☐ 3 Moderately likely	☐ 4 Very likely	EATLESS<TULIKE>	
49	Do you go on eating binges though you are not hungry?	☐ 1 Never	☐ 2 Rarely	☐ 3 Sometimes	☐ 4 At least once a week	BINGES<TUBING>	
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	☐ 1 Not like me	☐ 2 Little like me	☐ 3 Pretty good description of me	☐ 4 Describes me perfectly	BEHAVIOR<TUBEHA>	
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	☐ 0 Eat whatever you want, whenever you want it	☐ 1 Usually eat whatever you want, whenever you want it	☐ 2 Often eat whatever you want, whenever you want it	☐ 3 Often limit food intake, but often "give in"	☐ 4 Usually limit food intake, rarely "give in"	☐ 5 Constantly limiting food intake, never "giving in"

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day month year

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DATEHDR (TYPE 4)

Weight Efficacy Lifestyle Questionnaire (WEL)

This form describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you to identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to **successfully resist** the desire to eat. Check this number for each item.

WELQ (TYPE 4)PS

I am confident that:

WELQUES<TUWELQ>

Not confident at all that
you can resist the desire to eat

Very confident that
you can resist the desire to eat

WELANSW<TUWELA>

0 1 2 3 4 5 6 7 8 9

1 I can resist eating when I am anxious
(nervous).

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

2 I can control my eating on the weekends.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

3 I can resist eating even when I have to
say "no" to others.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

4 I can resist eating when I feel physically
run down.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

5 I can resist eating when I am watching TV.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

6 I can resist eating when I am depressed
(or down).

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

7 I can resist eating when there are many
different kinds of food available.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

8 I can resist eating even when I feel it is
impolite to refuse a second helping.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

9 I can resist eating even when I have a
headache.

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

I am confident that:	Not confident at all that you can resist the desire to eat					Very confident that you can resist the desire to eat				
	0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am reading.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11 I can resist eating when I am angry (or irritable).	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12 I can resist eating even when I am at a party.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13 I can resist eating even when others are pressuring me to eat.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14 I can resist eating when I am in pain.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15 I can resist eating just before going to bed.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16 I can resist eating when I have experienced failure.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
17 I can resist eating when high-calorie foods are available.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
18 I can resist eating even when I think others will be upset if I don't eat.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
19 I can resist eating when I feel uncomfortable.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
20 I can resist eating when I am happy.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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day month year

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DATEHDR (TYPE 4)

MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
MAEDQ<TUMAEY>							
MAEDA<TUMAEZ>							
=1 Fasting is a good way to lose weight.	☐	☐	☐	☐	☐	☐	☐
=2 My sleep isn't as good as it used to be.	☐	☐	☐	☐	☐	☐	☐
=3 I avoid eating for as long as I can.	☐	☐	☐	☐	☐	☐	☐
=4 Certain foods are "forbidden" for me to eat.	☐	☐	☐	☐	☐	☐	☐
=5 I can't keep certain foods in my house because I will binge on them.	☐	☐	☐	☐	☐	☐	☐
=6 I can easily make myself vomit.	☐	☐	☐	☐	☐	☐	☐
=7 I can feel that being fat is terrible.	☐	☐	☐	☐	☐	☐	☐
=8 I avoid greasy foods.	☐	☐	☐	☐	☐	☐	☐
=9 It's okay to binge and purge once in a while.	☐	☐	☐	☐	☐	☐	☐
=10 I don't eat certain foods.	☐	☐	☐	☐	☐	☐	☐
=11 I think I am a good person.	☐	☐	☐	☐	☐	☐	☐
=12 My eating is normal.	☐	☐	☐	☐	☐	☐	☐
=13 I can't seem to concentrate lately.	☐	☐	☐	☐	☐	☐	☐
=14 I try to diet by fasting.	☐	☐	☐	☐	☐	☐	☐
=15 I vomit to control my weight.	☐	☐	☐	☐	☐	☐	☐
=16 Lately nothing seems enjoyable anymore.	☐	☐	☐	☐	☐	☐	☐
=17 Laxatives help keep you slim.	☐	☐	☐	☐	☐	☐	☐
=18 I don't eat red meat.	☐	☐	☐	☐	☐	☐	☐
=19 I eat so rapidly I can't even taste my food.	☐	☐	☐	☐	☐	☐	☐

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

SAME AS PAGE 65	Never	Very Rarely	Rarely	Some-times	Often	Very Often	Always
=20 I do everything I can to avoid being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=21 When I feel bloated, I must do something to rid myself of that feeling.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=22 I overeat too frequently.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=23 It's okay to be overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=24 Recently I have felt that I am a worthless person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=25 I would be very upset if I gained 2 pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=26 I crave sweets and carbohydrates.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=27 I lose control when I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=28 Being fat would be terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=29 I have thought seriously about suicide lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=30 I don't have any energy anymore.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=31 I eat small portions to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=32 I eat 3 meals a day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=33 Lately I have been easily irritated.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=34 Some foods should be totally avoided.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=35 I use laxatives to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=36 I am terrified by the thought of being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=37 Purging is a good way to lose weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
=38 I avoid fatty foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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MAEDS (TYPE 4)PS

Participant's Initials: first middle last

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

	Never	Very Rarely	Rarely	Some-times	Often	Very Often	Always
SAME AS PAGE 65							
39 Recently I have felt pretty blue.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
40 I am obsessed with becoming overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
41 I don't eat fried foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
42 I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
43 Fat people are unhappy.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
44 People are too concerned with the way I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
45 I feel good when I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
46 I avoid foods with sugar.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
47 I hate it when I feel fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
48 I am too fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
49 I eat until I am completely stuffed.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
50 I hate to eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
51 I feel guilty about a lot of things these days.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
52 I'm very careful of what I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
53 I can "hold off" and not eat even if I am hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
54 I eat even when I am not hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
55 Fat people are disgusting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
56 I wouldn't mind gaining a few pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below):
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**. BSQ (TYPE 4) PS
Please read each question and check the box for the appropriate choice. Please answer all the questions.

Over the Past Four Weeks...	Never	Rarely	Some- times	Often	Very Often	Always
1 Has feeling bored made you brood about your shape?	☐	☐	☐	☐	☐	☐
2 Have you been so worried about your shape that you have been feeling that you ought to diet?	☐	☐	☐	☐	☐	☐
3 Have you thought that your thighs, hips, or bottom are too large for the rest of you?	☐	☐	☐	☐	☐	☐
4 Have you been afraid that you might become fat (or fatter)?	☐	☐	☐	☐	☐	☐
5 Have you worried about your flesh not being firm enough?	☐	☐	☐	☐	☐	☐
6 Has feeling full (e.g., after eating a large meal) made you feel fat?	☐	☐	☐	☐	☐	☐
7 Have you felt so bad about your shape that you have cried?	☐	☐	☐	☐	☐	☐
8 Have you avoided running because your flesh might wobble?	☐	☐	☐	☐	☐	☐
9 Has being with thin women/men made you feel self-conscious about your shape?	☐	☐	☐	☐	☐	☐
10 Have you worried about your thighs spreading out when sitting down?	☐	☐	☐	☐	☐	☐
11 Has eating even a small amount of food made you feel fat?	☐	☐	☐	☐	☐	☐
12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?	☐	☐	☐	☐	☐	☐
13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?	☐	☐	☐	☐	☐	☐
14 Has being naked, such as when taking a bath, made you feel fat?	☐	☐	☐	☐	☐	☐
15 Have you avoided wearing clothes which make you particularly aware of the shape of your body?	☐	☐	☐	☐	☐	☐
16 Have you imagined cutting off fleshy areas of your body?	☐	☐	☐	☐	☐	☐

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Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks... SAME AS PAGE 68	Never	Rarely	Sometimes	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19 Have you felt excessively large and rounded?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
20 Have you felt ashamed of your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
21 Has worry about your shape made you diet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
22 Have you felt happiest about your shape when your stomach has been empty?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
23 Have you thought that you are the shape you are because you lack self-control?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
25 Have you felt that it is not fair that other women/men are thinner than you?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
26 Have you vomited in order to feel thinner?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
28 Have you worried about your flesh being dimply?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
30 Have you pinched areas of your body to see how much fat is there?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
32 Have you taken laxatives in order to feel thinner?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
33 Have you been particularly self-conscious about your shape when in the company of other people?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
34 Has worry about your shape made you feel you ought to exercise?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

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PAGEID = 70

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (use codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

SAME AS PAGE 4

Weight 1: _____ . _____ kg

WEIGHT (TYPE 4)

Weight 2: _____ . _____ kg

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
 PARHDR (TYPE 4)

THIS ITEM NOT DATABASED

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ **PARDT** Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____ **PARND<TUND>**

1 Were you employed in the last seven days? **EMPLOY<XYESNO>** ☐ No → Skip to question 3 ☐ Yes **INTERVIEWER INITIALS:** _____ **SINTIALS**

2 If Yes: Which days (check all that apply)? **MON1** ☐ **TUES1** ☐ **WED1** ☐ **THURS1** ☐ **FRI1** ☐ **SAT1** ☐ **SUN1** **ALL <XYES>**

3 Which days do you consider your weekend, or non-work, days? **MON2** ☐ **TUES2** ☐ **WED2** ☐ **THURS2** ☐ **FRI2** ☐ **SAT2** ☐ **SUN2** **ALL <XYES>**

Day #	Day of Week	Date	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)			
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	
7	PARADAY<TUESDAY>	____/____/____ SDPARDT	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59										
6		INBED1TM-AWAKE1TM 00:00 to 23:59														
		INBED2TM-AWAKE2TM 00:00 to 23:59														
5			____/____/____	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59									
4			____/____/____	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59									
3		____/____/____	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59										
2		____/____/____	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59										
1	(1 week ago)	____/____/____	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59	____:____ to ____:____ 00:00 to 23:59										

THIS COLUMN NOT DATABASED

PARADAY<TUESDAY>

SDPARDT

INBED1TM-AWAKE1TM

INBED2TM-AWAKE2TM

ALL <1:3>

MORMOD

MORHARD

MORVHRD

AFTERMOD

AFTERHARD

AFTRVHRD

EVEHARD

EVEVHRD

ALL TIMES DERIVED USING SDPARDT

SEE NEXT PAGE FOR CALCULATIONS

PARADAY<TUESDAY>

SDPARDT

INBED1TM-AWAKE1TM

INBED2TM-AWAKE2TM

ALL <1:3>

MORMOD

MORHARD

MORVHRD

AFTERMOD

AFTERHARD

AFTRVHRD

EVEHARD

EVEVHRD

ALL TIMES DERIVED USING SDPARDT

SEE NEXT PAGE FOR CALCULATIONS

THIS COLUMN NOT DATABASED

SEE NEXT PAGE FOR CALCULATIONS

EVEVHRD

ALL TIMES DERIVED USING SPARDT

Not Done Code list: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

CALCULATIONS FOR 7dPAR

SLEEP TIME

AWAKE1TM AND AWAKE2TM ASSOCIATED WITH SDPARDT +1 when

(INBED1TM > 00:00 and INBED1TM < 06:00) or (INBED2TM > 00:00 and INBED2TM < 06:00)

SLP1TIME = (AWAKE1TM – INBED1TM) IF > 24, MINUS 24 HRS (Display times in hours)

SLP2TIME = (AWAKE2TM – INBED2TM) IF > 24, MINUS 24 HRS

TOTAL SLEEP TIME

TOTSLEEP = SLP2TM + SLP1TM

TOTAL WORK TIME

TOTWORK = (WRKSTPTM – WRKSTRTM) IF <0, ADD 24 HRS

ALL TIMES DERIVED USING SDPARDT

PAGEID = 72

Center Number: ____ Participant Number: ____ Participant's Initials: first middle last ____

Seven-Day Physical Activity Recall (PAR) (continued)

4 Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

PARQ (TYPE 4)

☐ ₁ More

☐ ₂ Less

☐ ₃ About the same

LSTWK<TUPHYS>

Interviewer: Please answer questions below and note any comments on interview.

5 Were there any problems with the Seven-Day PAR interview?

☐ ₀ No

PARPROB<XYESNO>

☐ ₁ Yes

6 Do you think this was a valid Seven-Day PAR interview?

☐ ₀ No

PARVLD<XYESNO>

☐ ₁ Yes

7 Were there any activities reported by the participant that you don't know how to classify?

☐ ₀ No

OTHACT<XYESNO>

☐ ₁ Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 73

Center Number: _____ Participant Number: _____ Participant's Initials: first middle last

6-Day Food Record

Complete below OR Not done → Specify reason (use Codelist below): **FOODND<TUND>** Staff initials: **SINTIALS**
first middle last

			Replacement Values FOODRCD (TYPE 4)PS		
Day of DLW	Date of Record	Record Quality (check only one) RECQUAL<TUQUAL>	Day of DLW	Date of Record	Record Quality (check only one)
DLWDAY<TUFDRD> = 1	____/____/____ day month year FDRECDT	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	88	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
= 2	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	99	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
= 3	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	100	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
= 4	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	111	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
= 5	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	122	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
= 6	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	133	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Clinic Weight

Weight date and time: ____/____/____ : ____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: first middle last
PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____

1 Were you employed in the last seven days? ☐ No ☐ Yes

2 If Yes: Which days (check all that apply)?

☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun
☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days?

Interviewer initials: _____

Day #	Day of Week	Date	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	(yesterday)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
6		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
5		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
4		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
3		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
2		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
1	(1 week ago)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____

SAME AS PAGE 71

PARCHT (TYPE 4)PS

Not Done Code list: 1 Participant

not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 76

Center Number: ____ Participant Number: ____ Participant's Initials: ____
first middle last

Seven-Day Physical Activity Recall (PAR) (continued)

- 4** Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

PARQ (TYPE 4)

- ☐ ₁ More
☐ ₂ Less
☐ ₃ About the same

SAME AS PAGE 72

Interviewer: Please answer questions below and note any comments on interview.

- 5** Were there any problems with the Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 6** Do you think this was a valid Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 7** Were there any activities reported by the participant that you don't know how to classify?

- ☐ ₀ No
☐ ₁ Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Handgrip Strength

Date and time of assessment: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): **SAME AS PAGE 4**

DATEHDR (TYPE 4)

1 Dynamometer handle position: **DYNO<I:2>**

HANDGRIP (TYPE 4)PS

2 Dominant hand (check only one): ☐ ₁ Left ☐ ₂ Right ☐ ₃ Ambidextrous

DOMHND<TUDOMH>

3 Handgrip strength:

Handgrip Strength TESTNO<TUPFT>	Zero Meter Check	Right Hand RIGHT<F:9:3>	Zero Meter Check	Left Hand LEFT<V:9:3>
= Test 1—peak force	☐ ₀	_____ kg	☐ ₀	_____ kg
= Test 2—peak force	☐ ₀	_____ kg	☐ ₀	_____ kg
= Test 3—peak force	☐ ₀	_____ kg	☐ ₀	_____ kg

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 78

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Isometric/Isokinetic Knee Extension and Flexion

Date and time of assessment: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): **SAME AS PAGE 4**

DATEHDR (TYPE 4)

1 Recent injury or pain—right knee? ☐ No ☐ Yes **RKIP<XYESNO>**

2 Recent injury or pain—left knee? ☐ No ☐ Yes **LKIP<XYESNO>**

ISOMETRC (TYPE 4)PS

3 Specify machine used (PBRC only): ☐ Cybex ☐ Biolex **MACHINE <TUSED>**

GRAVEFF<TUGRAV> RIGHTLEG<F:9:3>

LEFTLEG<F:9:3>

If Not Done, Specify Reason

All values corrected for gravity effect torque

Right Leg

Left Leg

(Use code list below)

See next page for
TUGRAV code list

3 60°/sec knee extension	2 =	peak torque	_____ N.m	_____ N.m	_____
	3 =	total work	_____ N.m	_____ N.m	
	4 =	average power	_____ watts	_____ watts	
4 60°/sec knee flexion	5 =	peak torque	_____ N.m	_____ N.m	_____
	6 =	total work	_____ N.m	_____ N.m	
	7 =	average power	_____ watts	_____ watts	
5 180°/sec knee extension	8 =	peak torque	_____ N.m	_____ N.m	_____
	9 =	total work	_____ N.m	_____ N.m	
	10 =	average power	_____ watts	_____ watts	
	11 =	work fatigue index	_____ %	_____ %	
6 180°/sec knee flexion	12 =	peak torque	_____ N.m	_____ N.m	_____
	13 =	total work	_____ N.m	_____ N.m	
	14 =	average power	_____ watts	_____ watts	
	15 =	work fatigue index	_____ %	_____ %	
7 Isometric knee extension: trial 1	16 =	peak torque	_____ N.m	_____ N.m	_____
	trial 2 17 =	peak torque	_____ N.m	_____ N.m	
	trial 3 18 =	peak torque	_____ N.m	_____ N.m	
8 Isometric knee flexion: trial 1	19 =	peak torque	_____ N.m	_____ N.m	_____
	trial 2 20 =	peak torque	_____ N.m	_____ N.m	
	trial 3	peak torque	_____ N.m	_____ N.m	

Not Done Code list: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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WHEN GETND IS ENTERED ON THE 1ST LINE ITEM OF EACH SECTION OF THIS PAGE (ITEMS 1, 4, 7, 11, 15, 18 FROM THE CODELIST BELOW), THE GETND APPLIES ALSO TO THE ITEMS THAT DIRECTLY FOLLOW THEM IN THE SECTION. DO NOT DERIVE

TUGRAV

1=KE60PT

2=KE60TW

3=KE60AP

4=KF60PT

5=KF60TW

6=KF60AP

7=KE180PT

8=KE180TW

9=KE180AP

10=KE180WFI

11=KF180PT

12=KF180TW

13=KF180AP

14=KF180WFI

15= IKE1

16= IKE2

17= IKE3

18=IKF1

19=IKF2

20=IKF3

PAGEID = 79

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Doubly Labeled Water (DLW)

1 Date and time of DLW dosing: _____ / _____ / _____ : _____
day month year 00:00 to 23:59 Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DLWHDR (TYPE 4)

2 DLW dose mixture ID and bottle number: _____ - _____ - _____ - CA

3 Exact weight of DLW mixture: _____ . _____ grams

DLWCHT (TYPE 4)PS

4 Urine samples: SAME AS PAGE 34 except
No Display Item 1 and 2 below

Collection	Sample	Date and Time Collected
	DLWSMPNO<TUDLW>	
Day 0 (Visit 4)	3 = D0a	____ / ____ / ____ : ____ day month year 00:00 to 23:59
	4 = D0b	____ / ____ / ____ : ____ day month year 00:00 to 23:59
Day 7 (Visit 5)	5 = D7a	____ / ____ / ____ : ____ day month year 00:00 to 23:59
	6 = D7b	____ / ____ / ____ : ____ day month year 00:00 to 23:59
Day 14 (Visit 7)	7 = D14a	____ / ____ / ____ : ____ day month year 00:00 to 23:59
	8 = D14b	____ / ____ / ____ : ____ day month year 00:00 to 23:59

5 Affix CRF page label(s) corresponding to this urine sample set:

Affix
Label
Here

DLWHDR (TYPE 4)

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 80

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: _____/_____/_____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (see Codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . _____ kg

SAME AS PAGE 4

Weight 2: _____ . _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 81

Center Number: _____ Participant Number: _____ Participant's Initials: _____

VO₂ Max

1 Date and time of test: _____ / _____ / _____ : _____ : _____
day month year 00:00 to 23:59
Staff initials: _____ first middle last

OR Not done → Specify reason (useodelist below): _____

2 At what time was the participant's last meal/snack eaten? _____
00:00 to 23:59

3 Rest ECG: Rhythm (check only one): ☐ 1 Sinus ☐ 2 Atrial fibrillation ☐ 99 Other
Ventricular conduction (check only one): ☐ 1 Normal ☐ 2 LBBB ☐ 3 RBBB

4 Heart rate (HR) data: Resting heart rate: _____ bpm
Age-predicted heart rate: _____ bpm
Heart rate (max): _____ bpm

5 Reason(s) for termination of testing (check all that apply):
☐ Symptom limited (dyspnea, fatigue)
☐ Angina/ischemia
☐ Serious arrhythmias (VT or SVT)
☐ Changes in blood pressure
☐ Ventricular ischemia (schedule stress image study, complete ventricular episode report)
☐ Orthopedic/extremity complaints (pains/cramps)
☐ Other (specify): _____

6 Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min, bi/trigeminy, NSVT [≥ 3 beats])?
☐ No
☐ Yes → If Yes: When did it occur (check all that apply)? ☐ During exercise ☐ During recovery

7 Peak VO₂: _____ L/min

8 Did the participant meet at least 2 of the 3 VO₂ max criteria (see box, right)?
☐ No
☐ Yes → If Yes: VO₂ max: _____ mL/kg/min _____ L/min

a Achieve a plateau in VO₂ (change ≤ 150 mL between the final two stages)

b RER ≥ 1.1

c HR max ± 5 bpm of age-predicted maximum

9 Exercise time: _____ minutes _____ seconds

10 Blood pressure at VO₂ peak/VO₂ max: _____ mm Hg
systolic diastolic

11 Borg RPE _____ (6-20)

12 Peak RER: _____

13 VE at VO₂ peak/VO₂ max: _____ L/min

14 VE/VO₂ at VO₂ peak/VO₂ max _____ L/min

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

Send to DCRI

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Durham NC 27705

Center Number: _____ Participant Number: _____ Participant's Initials: PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____

Interviewer initials: ____

☐ No → Skip to question 3 ☐ Yes

1 Were you employed in the last seven days?

2 If Yes: Which days (check all that apply)?

3 Which days do you consider your weekend, or non-work, days?

Day #	Day of Week	Date	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	(yester-day)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
6		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
5		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
4		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
3		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
2		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
1	(1 week ago)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____

PARCHT (TYPE 4)PS

SAME AS PAGE 71

Not Done Code list: 1 Participant refused

2

Not required

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PAGEID = 83

Center Number: ____ Participant Number: ____ Participant's Initials: ____
first middle last

Seven-Day Physical Activity Recall (PAR) (continued)

- 4** Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

- ☐ ₁ More
☐ ₂ Less
☐ ₃ About the same

PARQ (TYPE 4)

SAME AS PAGE 72

Interviewer: Please answer questions below and note any comments on interview.

- 5** Were there any problems with the Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 6** Do you think this was a valid Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 7** Were there any activities reported by the participant that you don't know how to classify?

- ☐ ₀ No
☐ ₁ Yes

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6-Day Food Record

Complete below OR Not done → Specify reason (use Codelist below): _____

Staff initials: _____

FOODRCD (TYPE 4)PS
Replacement Values

SAME AS PAGE 73

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	8	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
2	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	9	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
3	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	10	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
4	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	11	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
5	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	12	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
6	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	13	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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PAGEID = 85

Center Number: _____ Participant Number: _____ Participant's Initials: _____

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed? **WKSHTCMP<XYESNO>** **DTHADM1 (TYPE 3)**

☐ No

☐ Yes → If Yes: Were any Exclusion criteria met? ☐ No → Proceed with test

EXCLMET<XYESNO>

☐ Yes → STOP. Do not administer test.

2 Date of injection: **DTHADMDT** OR Not done → Specify reason (use codelist below): **DTHND<TUND>**

3 Injection by (initials): **DTHINIT<V:3>**

4 Arm injected: ☐ Right ☐ Left **ARM<TUDTHA>**

5 DTH results:

Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm.

A = Largest diameter

DTHADM2 (TYPE 4)PS

B = Second diameter perpendicular to A

Antigen	24 Hour (@ Visit 4)			48 Hour (@ Visit 5)		
	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:
1 Normal saline	DIAMA<F:9:3>	DIAMB<F:9:3>	DTH2INIT<V:3>	_____ mm	_____ mm	
2 Tetanus toxoid (TT) (check only one): ☐ Tetanus toxoid (Sanofi-Pasteur) ☐ Other: _____ Lot #: LOTNUM<V:25>	_____ mm	_____ mm		_____ mm	_____ mm	TUTYPE CODELIST 1 = STANDARD 98 = OTHER
3 Candida (check only one): ☐ Candidin (AllerMed) ☐ Other: _____ Lot #: _____	_____ mm	_____ mm	first middle last (initials)	_____ mm	_____ mm	first middle last (initials)
4 Trichophyton (check only one): ☐ Trichophyton Allergic Extract (AllerMed) ☐ Other: _____ Lot #: _____	_____ mm	_____ mm		_____ mm	_____ mm	

TUANTI CODELIST

1 = NORMAL SALINE 24

2 = TETANUS TOXOID 24

3 = CANDIDA 24

4 = TRICHOPHYTON 24

5 = NORMAL SALINE 48

6 = TETANUS TOXOID 48

7 = CANDIDA 48

8 = TRICHOPHYTON 48

1 Participant refused 2 Clinician unable to perform 3 Physician not time 4 Instrument failure 5 Not required

Send to

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Clinic Weight

Weight date and time: ____/____/____ 00:00 to 23:59
day month year

Staff initials: _____
first middle last

OR Not done → Specify reason (use Codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Vital Signs

Assessment date and time: ____/____/____ 00:00 to 23:59
day month year

If waist measurement not done → Specify reason (use codelist below): _____

VITALS (TYPE 3)

1 Natural waist measurement

(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: _____
first middle last

Natural waist measurement 1: _____ cm

Natural waist measurement 2: _____ cm

SAME AS PAGE 29

Natural waist measurement 3: _____ cm

2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

4 Temperature: _____ °C OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

5 Respirations: _____ per minute OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

6 Blood pressure (check only one): ☐ Left arm ☐ Right arm

Staff initials: _____
first middle last

6a Blood pressure 1: _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

OR Not done →

Specify reason (use codelist below): _____

6b Blood pressure 2: _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

6c Blood pressure 3: _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Durham NC 27705

PAGEID = 87

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ No

SAME AS PAGE 33

☐ Yes → If Yes: Date urine pregnancy test performed: _____ / _____ / _____
day month year

Results: ☐ Negative

☐ Positive

Core Temperature

Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason (Use codelist below)
SINTIALS first middle last	CTSTRDT Start Date: _____ / _____ / _____ day month year	CTSTRTM Start Time _____ 00:00 to 23:59	CTND<TUND> _____
	CTSTPDT Stop Date: _____ / _____ / _____ day month year	CTSTPTM Stop Time _____ 00:00 to 23:59	

Inpatient Admission and Discharge

1 Inpatient admission date and time: _____ / _____ / _____ **ADMITDT** **ADMITTM**
day month year 00:00 to 23:59

2 Inpatient discharge date and time: _____ / _____ / _____ **DISCHDT** **DISCHTM**
day month year 00:00 to 23:59

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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PAGEID = 88

Center Number: _____ Participant Number: _____ Participant's Initials: first middle last
PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____

1 Were you employed in the last seven days? ☐ No → Skip to question 3 ☐ Yes

2 If Yes: Which days (check all that apply)?

☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun
☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days?

Interviewer initials: first middle last

Day #	Day of Week	Date	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	(yesterday)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
6		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
5		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
4		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
3		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
2		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
1	(1 week ago)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____

PARCHT (TYPE 4)PS

SAME AS PAGE 71

Not Done Code list: 1 Participant refused 2 Clinician un

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PAGEID = 89

Center Number: ____ Participant Number: ____ Participant's Initials: first middle last ____

Seven-Day Physical Activity Recall (PAR) (continued)

4 Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

PARQ (TYPE 4)

- ☐ ₁ More
☐ ₂ Less
☐ ₃ About the same

SAME AS PAGE 72

Interviewer: Please answer questions below and note any comments on interview.

5 Were there any problems with the Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

6 Do you think this was a valid Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

7 Were there any activities reported by the participant that you don't know how to classify?

- ☐ ₀ No
☐ ₁ Yes

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PAGEID = 90

Center Number: _____ Participant Number: _____ Participant's Initials: _____

Outcomes Labs

Date and time of last meal: _____ / _____ / _____ LMEALDT LMEALTM 00:00 to 23:59 OUTCMELB (TYPE 4)PS

Date and time sample collection started: _____ / _____ / _____ SAMPDT SAMPTM 00:00 to 23:59

Sample	Sample Complete?	If Not Done, Reason (Useodelist below)	Staff Initials
OTCMSAMP<TUOTCM>	SAMPCOL<XYESNO>		SAMPINIT
1 = Catecholamines	☐ No ☐ Yes	SAMPND<TUND>	first middle last
2 = Blood	☐ No ☐ Yes		first middle last
3 = Oral glucose tolerance test (OGTT)	☐ No ☐ Yes		first middle last
4 = Vaccinations appear on p.211			

If a sample is not obtained, indicate with a Not Done.

BIOPSY (TYPE 4)PS

Biopsy Labs

Sample	Date of Collection	If Not Done, Reason (Useodelist below)	Staff Initials
BIOPSY <TUBIOP>	BIOPSYDT	BIOPSYND<TUND>	BIOPINIT
1= Muscle biopsy	_____/_____/_____ day month year		first middle last
2= Fat biopsy	_____/_____/_____ day month year		first middle last

24-hour Urine Collection

Total Volume Collected	Date of Sample Collection	Time of Sample Collection	If Not Done, Reason (Useodelist below)	Staff Initials
TVOLURN<I:6> _____ mL	Start Date: URNSTRDT _____/_____/_____ day month year Stop Date: URNSTPDT _____/_____/_____ day month year	Start Time: URNSTRTM 00:00 to 23:59 Stop Time: URNSTPTM 00:00 to 23:59	URINE24 (TYPE 3) URNND<TUND>	URNINIT first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Panel Items not Displayed here appear on p.211:

HEPA, TD, PV ALL<XYES>

Panel Items not Displayed here appear on p.211:

HEPVAC<TUHVAC>

1= HAVRIX

2= VAQTA

98= OTHER

TETVAC<TUTVAC>

1= DECOVAC

98= OTHER

PNEUVAC<TUPVAC>

1= PNEUMOVAX

98= OTHER

SEE PAGE 211

HEPSPEC V:30

TETSPEC V:30

PNEUSPEC V:30

HEPLOT V:20

TETLOT V:20

PNEULOT V:20

PAGEID = 90A

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Sex Hormone

If Not Done → Specify reason (useodelist below): **STUDYN D DATEHDR (TYPE 4)**

Contraception method (females only):
No display STUDYDT, STUDYTM or SINIALS

☐ None OR Check all that apply: **OUTCME2 (TYPE 4)**
☐ Oral contraceptive → Specify: **ORALSP <V:50>**
Record on Concomitant Medications page
☐ Other → Specify (e.g., barrier, IUD): **OTHERSP <V:50>**

NONE <XYES>
ORAL <XYES>
OTHER <XYES>

Day 1	Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Day 1 of menses (females only)	MENSESDT			
Date and time of last meal (males only)	____/____/____ day month year	LMEALDT ____ 00:00 to 23:59		
Hormone level blood draw 1 (males only)	____/____/____ day month year	HDRAWDT ____ 00:00 to 23:59	HDRAWND<TUND> ____ first middle last	HDWINIT<V:3>
Hormone level blood draw 2 (females only) Progesterone level	HDRAW2DT	HDRAW2TM	HDRAW2ND<TUND> ____ first middle last	HDW2INIT <V:3>
Day 2	Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Date and time of last meal	LMEAL2DT	LMEAL2TM		
Hormone level blood draw 3 (females only) Progesterone level	HDRAW3DT	HDRAW3TM	HDRAW3ND<TUND> ____ first middle last	HDW3INIT<V:3>

DXA Scan

- 1** Has the participant taken a calcium supplement today? **DXASCAN (TYPE 4)**
☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.
- 2** Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?
☐ No ☐ Yes **SAME AS PAGE 35 - -**

For the area scanned section (below)

DXA Scan		DXA Rescan OR ☐ NA
Date of scan: ____/____/____ day month year	Date of rescan: ____/____/____ day month year	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply
☐ Whole body	_____	☐ Whole body

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

MOVED DXASCAN PANEL FROM PAGE 91

PAGEID = 91

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Metabolic Rate			
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
RMRVISIT<TURMR> Resting Metabolic Rate (RMR)—Visit 7 1 = RMR1	RMRDT ____ / ____ / ____ day month year	RMRND<TUND> ____	RMRINIT ____ first middle last
CARTID<TUCART> Cart ID	1= ☐ Tufts-003 (623-002) 2= ☐ Tufts-006 (623-006) 3= ☐ WASH U-001 (623-003) 4= ☐ WASH U-002 (623-004) 5= ☐ PBRC-016 (623-005) 6= ☐ PBRC-017 (623-001)		
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 8 2 = RMR2	____ / ____ / ____ day month year	____	____ first middle last
Cart ID	☐ Tufts-003 (623-002) ☐ Tufts-006 (623-006) ☐ WASH U-001 (623-003) ☐ WASH U-002 (623-004) ☐ PBRC-016 (623-005) ☐ PBRC-017 (623-001)		

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

RMR (TYPE 4)PS

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PAGEID = 92

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Randomization

Date of randomization: ____/____/____ **RANDOMDT**

RANDOM (TYPE 1)

Treatment Group

To which treatment group was the participant assigned (check only one):

☐ ₁ CR—calorie restricted

TGROUP<TUGRP>

☐ ₂ AL—ad libitum (control)

Intervention

Did participant start intervention?

SRTINVEN<XYESNO>

☐ ₀ No → Complete the Study completion/Early Discontinuation of Study Evaluation

☐ ₁ Yes → If Yes: Date intervention started: ____/____/____ **INVENTDT**

Staff Signature NOTE: Signature of staff that randomized participant

Signature: **NOT DATABASED**

Date: **NOT DATABASED**
day month year

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PAGEID = 93

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) day / month / year 00:00 to 23:59 SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐ ₁ Normal SAME AS PAGE 30 ☐ ₂ Abnormal, not clinically significant (specify): _____ ☐ ₃ Abnormal, clinically significant (specify): _____	first middle last

Safety Labs (Potassium Surveillance)

Date and time of sample collection: day / month / year 00:00 to 23:59 SAFETYLB (TYPE 4)			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ ₀ No ☐ ₁ Yes	Do not display LMEALDT LMEALTM URSMPCOL URSMPND URNINIT	SAME AS PAGE 30 first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

Clinic Weight

Weight date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (use Codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . _____ kg

SAME AS PAGE 4

Weight 2: _____ . _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

Vital Signs

Assessment date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

If waist measurement not done → Specify reason (use codelist below): _____

VITALS (TYPE 3)

1 Natural waist measurement

(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: _____
first middle last

Natural waist measurement 1: _____ . _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ . _____ cm

Natural waist measurement 3: _____ . _____ cm

2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: _____ . _____ cm

Umbilical point waist measurement 2: _____ . _____ cm

Umbilical point waist measurement 3: _____ . _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

4 Temperature: _____ . _____ °C OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

5 Respirations: _____ per minute OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

6 Blood pressure (check only one): ☐₁ Left arm ☐₂ Right arm

Staff initials: _____
first middle last

6a Blood pressure 1: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

OR Not done →

Specify reason (use codelist below): _____

6b Blood pressure 2: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

6c Blood pressure 3: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Center Number: _____ Participant Number: _____ Participant's Initials: _____

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) ____/____/____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (seeodelist below): _____	Is ECG (check only one): ☐ 1 Normal SAME AS PAGE 30 ☐ 2 Abnormal, not clinically significant (specify): _____ ☐ 3 Abnormal, clinically significant (specify): _____ OTHERSP <V:50>	first middle last

Safety Labs

Date and time of last meal: ____/____/____ 00:00 to 23:59 day month year			
Date and time of sample collection: ____/____/____ 00:00 to 23:59 day month year			
SAFETYLB (TYPE 4)			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	SAME AS PAGE 30 _____	first middle last
Urine	☐ 0 No ☐ 1 Yes	_____	first middle last

Contraception

If Not Done → Specify reason (use codelist below): CNTRAND<TUND>	
Contraception method (females only): NONE <XYES> ORAL <XYES> OTHER <XYES> No display STUDYDT, STUDYTM or SINIALS	☐ None OR Check all that apply: OUTCME2 (TYPE 4) ☐ Oral contraceptive → Specify: ORALSP <V:50> Record on Concomitant Medications page ☐ Other → Specify (e.g., barrier, IUD): OTHERSP <V:50>

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

SAME AS PAGE 90A WITH THE REMOVAL OF THE FOLLOWING FIELDS:

MENSESDT, HDRAWDT, LMEALDT, LMEALTM, HDWINIT, HDRAWND,
 HSW2INIT, HDRAW2TM, HDRAW2ND, HDRAW3ND, HD3INIT, HDRAW3DT,
 HDRAW3TM

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Center Number: _____ Participant Number: _____ Participant's Initials: first middle last _____

Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): ____
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

BDI-II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

BDIQ (TYPE 4)

- 1 **Sadness:**
 - ☐₀ I do not feel sad
 - ☐₁ I feel sad much of the time
 - ☐₂ I am sad all of the time
 - ☐₃ I am so sad or unhappy that I can't stand it
- 2 **Pessimism:**
 - ☐₀ I am not discouraged about my future
 - ☐₁ I feel more discouraged about my future than I used to be
 - ☐₂ I do not expect things to work out for me
 - ☐₃ I feel my future is hopeless and will only get worse
- 3 **Past failure:**
 - ☐₀ I do not feel like a failure
 - ☐₁ I have failed more than I should have
 - ☐₂ As I look back, I see a lot of failures
 - ☐₃ I feel I am a total failure as a person
- 4 **Loss of pleasure:**
 - ☐₀ I get as much pleasure as I ever did from the things I enjoy
 - ☐₁ I don't enjoy things as much as I used to
 - ☐₂ I get very little pleasure from the things I used to enjoy
 - ☐₃ I can't get any pleasure from the things I used to enjoy
- 5 **Guilty feelings:**
 - ☐₀ I don't feel particularly guilty
 - ☐₁ I feel guilty over many things I have done or should have done
 - ☐₂ I feel quite guilty most of the time
 - ☐₃ I feel guilty all of the time
- 6 **Punishment feelings:**
 - ☐₀ I don't feel I am being punished
 - ☐₁ I feel I may be punished
 - ☐₂ I expect to be punished
 - ☐₃ I feel I am being punished
- 7 **Self-dislike:**
 - ☐₀ I feel the same about myself as ever
 - ☐₁ I have lost confidence in myself
 - ☐₂ I am disappointed in myself
 - ☐₃ I dislike myself

SAME AS PAGE 39

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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PAGEID = 97

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

BDI-II (continued)

8 Self-criticalness:

- ☐ I don't criticize or blame myself more than usual
- ☐ I am more critical of myself than I used to be
- ☐ I criticize myself for all of my faults
- ☐ I blame myself for everything bad that happens

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

- ☐ I don't have any thoughts of killing myself
- ☐ I have thoughts of killing myself but I would not carry them out
- ☐ I would like to kill myself
- ☐ I would kill myself if I had the chance

SAME AS PAGE 40

10 Crying:

- ☐ I don't cry any more than I used to
- ☐ I cry more than I used to
- ☐ I cry over every little thing
- ☐ I feel like crying, but I can't

11 Agitation:

- ☐ I am no more wound up or restless than usual
- ☐ I feel more restless or wound up than usual
- ☐ I am so restless or agitated that it's hard to stay still
- ☐ I am so restless or agitated that I have to keep moving or doing something

12 Loss of interest:

- ☐ I have not lost interest in other people or activities
- ☐ I am less interested in other people or things than before
- ☐ I have lost most of my interest in other people or things
- ☐ It's hard to get interested in anything

13 Indecisiveness:

- ☐ I make decisions about as well as ever
- ☐ I find it more difficult to make decisions than usual
- ☐ I have much greater difficulty in making decisions than I used to
- ☐ I have trouble making my decisions

14 Worthlessness:

- ☐ I do not feel I am worthless
- ☐ I don't consider myself as worthwhile and useful as I used to
- ☐ I feel more worthless as compared to other people
- ☐ I feel utterly worthless

15 Loss of energy:

- ☐ I have as much energy as ever
- ☐ I have less energy than I used to have
- ☐ I don't have enough energy to do very much
- ☐ I don't have enough energy to do anything

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 98

Center Number: _____ Participant Number: _____ Participant's Initials: first middle last _____

BDI-II (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep

BDIQ (TYPE 4)

- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time

SAME AS PAGE 41

- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time

- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything

- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do

- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

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PAGEID = 99

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time DATEHDR (TYPE 4)	Findings ECG (TYPE 4)	Staff Initials
_____ / _____ / _____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): SAME AS PAGE 30 ☐ ₁ Normal ☐ ₂ Abnormal, not clinically significant (specify): _____ ☐ ₃ Abnormal, clinically significant (specify): _____	_____ first middle last

Safety Labs (Potassium Surveillance)

Date and time of sample collection: _____ / _____ / _____ 00:00 to 23:59 day month year			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ ₀ No ☐ ₁ Yes	SAME AS PAGE 93 _____	_____ first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

PAGEID = 100

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) ____/____/____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐ 1 Normal SAME AS PAGE 30 ☐ 2 Abnormal, not clinically significant (specify): _____ ☐ 3 Abnormal, clinically significant (specify): _____	_____ first middle last

Safety Labs (Potassium Surveillance)

Date and time of sample collection: ____/____/____ 00:00 to 23:59 day month year			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	SAME AS PAGE 93 _____	_____ first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Clinic Weight

Weight date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (use Codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . _____ kg

SAME AS PAGE 4

Weight 2: _____ . _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

Vital Signs

Assessment date and time: _____ / _____ / _____ : _____
day month year 00:00 to 23:59

If waist measurement not done → Specify reason (use codelist below): _____

VITALS (TYPE 3)

1 Natural waist measurement

(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: _____
first middle last

Natural waist measurement 1: _____ . _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ . _____ cm

Natural waist measurement 3: _____ . _____ cm

2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: _____ . _____ cm

Umbilical point waist measurement 2: _____ . _____ cm

Umbilical point waist measurement 3: _____ . _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

4 Temperature: _____ . _____ °C OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

5 Respirations: _____ per minute OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

6 Blood pressure (check only one): ☐₁ Left arm ☐₂ Right arm

Staff initials: _____
first middle last

6a Blood pressure 1: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

OR Not done →
 Specify reason (use codelist below): _____

6b Blood pressure 2: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

6c Blood pressure 3: _____ / _____ mm Hg Time: _____ : _____
systolic diastolic 00:00 to 23:59

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____ Participant Number: _____ Participant's Initials: _____

12-Lead ECG

Date and Time DATEHDR (TYPE 4)	Findings ECG (TYPE 4)	Staff Initials
_____ _____ _____ _____ _____ _____ _____ _____ _____ 00:00 to 23:59 SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐₁ Normal SAME AS PAGE 30 ☐₂ Abnormal, not clinically significant (specify): _____ ☐₃ Abnormal, clinically significant (specify): _____	_____ _____ _____

Safety Labs

Date and time of last meal: _____

Date and time of sample collection: _____

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ ₀ No ☐ ₁ Yes	SAME AS PAGE 30	_____
Urine	☐ ₀ No ☐ ₁ Yes	_____	_____

Outcomes Labs

Date and time of last meal: _____

Date and time sample collection started: _____

OUTCMELB (TYPE 4)PS

SAME AS PAGE 90

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
OTCMSAMP<TUOTCM> Blood Display only item 2= Blood	☐ ₀ No ☐ ₁ Yes	_____	_____

If a sample is not obtained, indicate with a Not Done.

Contraception

If Not Done → Specify reason (use codelist below): _____

Contraception method (females only): SAME AS PAGE 95	☐ None OR Check all that apply: OUTCME2 (TYPE 4) ☐ Oral contraceptive → Specify: _____ Record on Concomitant Medications page ☐ Other → Specify (e.g., barrier, IUD): _____
---	---

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 103

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): ____
day month year

BDI-II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

BDIQ (TYPE 4)

SAME AS PAGE 39

- 1 **Sadness:**
 - ☐₀ I do not feel sad
 - ☐₁ I feel sad much of the time
 - ☐₂ I am sad all of the time
 - ☐₃ I am so sad or unhappy that I can't stand it
- 2 **Pessimism:**
 - ☐₀ I am not discouraged about my future
 - ☐₁ I feel more discouraged about my future than I used to be
 - ☐₂ I do not expect things to work out for me
 - ☐₃ I feel my future is hopeless and will only get worse
- 3 **Past failure:**
 - ☐₀ I do not feel like a failure
 - ☐₁ I have failed more than I should have
 - ☐₂ As I look back, I see a lot of failures
 - ☐₃ I feel I am a total failure as a person
- 4 **Loss of pleasure:**
 - ☐₀ I get as much pleasure as I ever did from the things I enjoy
 - ☐₁ I don't enjoy things as much as I used to
 - ☐₂ I get very little pleasure from the things I used to enjoy
 - ☐₃ I can't get any pleasure from the things I used to enjoy
- 5 **Guilty feelings:**
 - ☐₀ I don't feel particularly guilty
 - ☐₁ I feel guilty over many things I have done or should have done
 - ☐₂ I feel quite guilty most of the time
 - ☐₃ I feel guilty all of the time
- 6 **Punishment feelings:**
 - ☐₀ I don't feel I am being punished
 - ☐₁ I feel I may be punished
 - ☐₂ I expect to be punished
 - ☐₃ I feel I am being punished
- 7 **Self-dislike:**
 - ☐₀ I feel the same about myself as ever
 - ☐₁ I have lost confidence in myself
 - ☐₂ I am disappointed in myself
 - ☐₃ I dislike myself

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

Send to DCRI For _____ Durham NC 27705

PAGEID = 104

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

BDI-II (continued)

8 Self-criticalness:

- ☐ I don't criticize or blame myself more than usual
- ☐ I am more critical of myself than I used to be
- ☐ I criticize myself for all of my faults
- ☐ I blame myself for everything bad that happens

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

- ☐ I don't have any thoughts of killing myself
- ☐ I have thoughts of killing myself but I would not carry them out
- ☐ I would like to kill myself
- ☐ I would kill myself if I had the chance

SAME AS PAGE 40

10 Crying:

- ☐ I don't cry any more than I used to
- ☐ I cry more than I used to
- ☐ I cry over every little thing
- ☐ I feel like crying, but I can't

11 Agitation:

- ☐ I am no more wound up or restless than usual
- ☐ I feel more restless or wound up than usual
- ☐ I am so restless or agitated that it's hard to stay still
- ☐ I am so restless or agitated that I have to keep moving or doing something

12 Loss of interest:

- ☐ I have not lost interest in other people or activities
- ☐ I am less interested in other people or things than before
- ☐ I have lost most of my interest in other people or things
- ☐ It's hard to get interested in anything

13 Indecisiveness:

- ☐ I make decisions about as well as ever
- ☐ I find it more difficult to make decisions than usual
- ☐ I have much greater difficulty in making decisions than I used to
- ☐ I have trouble making my decisions

14 Worthlessness:

- ☐ I do not feel I am worthless
- ☐ I don't consider myself as worthwhile and useful as I used to
- ☐ I feel more worthless as compared to other people
- ☐ I feel utterly worthless

15 Loss of energy:

- ☐ I have as much energy as ever
- ☐ I have less energy than I used to have
- ☐ I don't have enough energy to do very much
- ☐ I don't have enough energy to do anything

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PAGEID = 105

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

BDI-II (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep

BDIQ (TYPE 4)

- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time

SAME AS PAGE 41

- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time

- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything

- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do

- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

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Participant's Initials: _____
first middle last

PAGEID = 106

Center Number: _____ Participant Number: _____ Participant's Initials: _____

Date completed: ____/____/____ SAME AS PAGE 36 DATEHDR (TYPE 4)
OR Not done → Specify reason (use codelist below): _____ MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
1 Fasting is a good way to lose weight.	☐	☐	☐	☐	☐	☐	☐
2 My sleep isn't as good as it used to be.	☐	☐	☐	☐	☐	☐	☐
3 I avoid eating for as long as I can.	☐	☐	☐	☐	☐	☐	☐
4 Certain foods are "forbidden" for me to eat.	☐	☐	☐	☐	☐	☐	☐
5 I can't keep certain foods in my house because I will binge on them.	☐	☐	☐	☐	☐	☐	☐
6 I can easily make myself vomit.	☐	☐	☐	☐	☐	☐	☐
7 I can feel that being fat is terrible.	☐	☐	☐	☐	☐	☐	☐
8 I avoid greasy foods.	☐	☐	☐	☐	☐	☐	☐
9 It's okay to binge and purge once in a while.	☐	☐	☐	☐	☐	☐	☐
10 I don't eat certain foods.	☐	☐	☐	☐	☐	☐	☐
11 I think I am a good person.	☐	☐	☐	☐	☐	☐	☐
12 My eating is normal.	☐	☐	☐	☐	☐	☐	☐
13 I can't seem to concentrate lately.	☐	☐	☐	☐	☐	☐	☐
14 I try to diet by fasting.	☐	☐	☐	☐	☐	☐	☐
15 I vomit to control my weight.	☐	☐	☐	☐	☐	☐	☐
16 Lately nothing seems enjoyable anymore.	☐	☐	☐	☐	☐	☐	☐
17 Laxatives help keep you slim.	☐	☐	☐	☐	☐	☐	☐
18 I don't eat red meat.	☐	☐	☐	☐	☐	☐	☐
19 I eat so rapidly I can't even taste my food.	☐	☐	☐	☐	☐	☐	☐

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
SAME AS PAGE 66							
20 I do everything I can to avoid being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
21 When I feel bloated, I must do something to rid myself of that feeling.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
22 I overeat too frequently.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
23 It's okay to be overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
24 Recently I have felt that I am a worthless person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
25 I would be very upset if I gained 2 pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
26 I crave sweets and carbohydrates.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
27 I lose control when I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
28 Being fat would be terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
29 I have thought seriously about suicide lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
30 I don't have any energy anymore.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
31 I eat small portions to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
32 I eat 3 meals a day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
33 Lately I have been easily irritated.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
34 Some foods should be totally avoided.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
35 I use laxatives to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
36 I am terrified by the thought of being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
37 Purging is a good way to lose weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
38 I avoid fatty foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

SAME AS PAGE 67	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
39 Recently I have felt pretty blue.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
40 I am obsessed with becoming overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
41 I don't eat fried foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
42 I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
43 Fat people are unhappy.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
44 People are too concerned with the way I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
45 I feel good when I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
46 I avoid foods with sugar.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
47 I hate it when I feel fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
48 I am too fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
49 I eat until I am completely stuffed.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
50 I hate to eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
51 I feel guilty about a lot of things these days.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
52 I'm very careful of what I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
53 I can "hold off" and not eat even if I am hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
54 I eat even when I am not hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
55 Fat people are disgusting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
56 I wouldn't mind gaining a few pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) ____/____/____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐ 1 Normal ☐ 2 Abnormal, not clinically significant (specify): _____ ☐ 3 Abnormal, clinically significant (specify): _____ SAME AS PAGE 30	first middle last

Safety Labs (Potassium Surveillance)

Date and time of sample collection: ____/____/____ 00:00 to 23:59 day month year			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	SAME AS PAGE 93 _____	first middle last

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

PAGEID = 110

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) ____ / ____ / ____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐ 1 Normal SAME AS PAGE 30 ☐ 2 Abnormal, not clinically significant (specify): _____ ☐ 3 Abnormal, clinically significant (specify): _____	_____ first middle last

Safety Labs (Potassium Surveillance)

Date and time of sample collection: ____ / ____ / ____ 00:00 to 23:59 day month year			
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	SAME AS PAGE 93 _____	_____ first middle last

SAFETYLB (TYPE 4)

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Clinic Weight

Weight date and time: ____/____/____ 00:00 to 23:59
day month year

Staff initials: _____
first middle last

OR Not done → Specify reason (use Codelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Vital Signs

Assessment date and time: ____/____/____ 00:00 to 23:59
day month year

If waist measurement not done → Specify reason (use codelist below): _____

VITALS (TYPE 3)

1 Natural waist measurement

(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: _____
first middle last

Natural waist measurement 1: _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ cm

Natural waist measurement 3: _____ cm

2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

4 Temperature: _____ °C OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

5 Respirations: _____ per minute OR Not done → Specify reason (use codelist below): _____

Staff initials: _____
first middle last

6 Blood pressure (check only one): ☐ Left arm ☐ Right arm

Staff initials: _____
first middle last

6a Blood pressure 1: _____/_____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

OR Not done →
Specify reason (use codelist below): _____

6b Blood pressure 2: _____/_____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

6c Blood pressure 3: _____/_____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

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Center Number: _____ Participant Number: _____ Participant's Initials: _____

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) ____/____/____ 00:00 to 23:59 day month year SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): ☐ ₁ Normal SAME AS PAGE 30 ☐ ₂ Abnormal, not clinically significant (specify): _____ ☐ ₃ Abnormal, clinically significant (specify): _____	_____ first middle last

Safety Labs

Date and time of last meal: ____/____/____ 00:00 to 23:59
 day month year

Date and time of sample collection: ____/____/____ 00:00 to 23:59
 day month year

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ ₀ No ☐ ₁ Yes	SAME AS PAGE 30	_____ first middle last
Urine	☐ ₀ No ☐ ₁ Yes	_____	_____ first middle last

Contraception

If Not Done → Specify reason (use codelist below): _____

Contraception method (females only): SAME AS PAGE 95	☐ None OR Check all that apply: OUTCME2 (TYPE 4) ☐ Oral contraceptive → Specify: _____ Record on Concomitant Medications page ☐ Other → Specify (e.g., barrier, IUD): _____
--	--

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Clinic Weight

Weight date and time: ____/____/____ 00:00 to 23:59
day month year

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ No

SAME AS PAGE 33

☐ Yes → If Yes: Date urine pregnancy test performed: ____/____/____
day month year

Results: ☐ Negative

☐ Positive

DXA Scan

1 Has the participant taken a calcium supplement today?

DXASCAN (TYPE 4)

☐ No

☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.

2 Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?

☐ No

☐ Yes

SAME AS PAGE 35

DXA Scan		DXA Rescan OR ☐ % NA
Date of scan: ____/____/____ day month year		Date of rescan: ____/____/____ day month year
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply
☐ Whole body	_____	☐ Whole body
☐ Forearm	_____	☐ Forearm
☐ Spine	_____	☐ Spine
☐ Hip	_____	☐ Hip

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Doubly Labeled Water (DLW)

DLWHDR (TYPE 4)

1 Date and time of DLW dosing: ____/____/____ : ____
day month year 00:00 to 23:59

Staff initials:

OR Not done → Specify reason (useodelist below): ____

SAME AS PAGE 34

2 DLW dose mixture ID and bottle number: _____ - _____ - _____ - CA

3 Exact weight of DLW mixture: _____ . _____ grams

DLWCHT (TYPE 4)PS

4 Urine samples:

Collection	Sample	Date and Time Collected
Pre dosing (PD)	PDa	____/____/____ : ____ day month year 00:00 to 23:59
	PDb	____/____/____ : ____ day month year 00:00 to 23:59
Day 0 (Visit 2)	D0a	____/____/____ : ____ day month year 00:00 to 23:59
	D0b	____/____/____ : ____ day month year 00:00 to 23:59
Day 7 (Visit 3)	D7a	____/____/____ : ____ day month year 00:00 to 23:59
	D7b	____/____/____ : ____ day month year 00:00 to 23:59
Day 14 (Visit 5)	D14a	____/____/____ : ____ day month year 00:00 to 23:59
	D14b	____/____/____ : ____ day month year 00:00 to 23:59

5 Affix CRF page label(s) corresponding to this urine sample set:

DISPLAY DLWLBL2

Affix
Test Sample
Label Here

Affix
Retest Sample
Label Here

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Center Number: _____ Participant Number: _____ Participant's Initials: _____

DATEHDR (TYPE 4)

Date completed: ____/____/____ OR Not done → Specify reason (useodelist below): _____

SAME AS PAGE 36

RAND SF-36

Instructions: This survey asks for your views about your health. This information will help keep track of how well you are able to do your usual activities. Please answer every question by placing a check "X" in the appropriate box. If you are unsure about how to answer a question, give the best answer you can.

RANDSF1 (TYPE 3)

1 In general, would you say your health is: ☐₁ Excellent ☐₂ Very good ☐₃ Good ☐₄ Fair ☐₅ Poor

2 Compared to one year ago, how would you rate your health in general now? ☐₁ Much better now than 1 year ago ☐₂ Somewhat better now than 1 year ago ☐₃ About the same ☐₄ Somewhat worse now than 1 year ago ☐₅ Much worse now than 1 year ago

SAME AS PAGE 36

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Yes, Limited A Lot Yes, Limited A Little No, Not Limited At All

3 **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports ☐₁ ☐₂ ☐₃

4 **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf ☐₁ ☐₂ ☐₃

5 Lifting or carrying groceries ☐₁ ☐₂ ☐₃

6 Climbing **several** flights of stairs ☐₁ ☐₂ ☐₃

7 Climbing **one** flight of stairs ☐₁ ☐₂ ☐₃

8 Bending, kneeling or stooping ☐₁ ☐₂ ☐₃

9 Walking **more than a mile** ☐₁ ☐₂ ☐₃

10 Walking **several blocks** ☐₁ ☐₂ ☐₃

11 Walking **one block** ☐₁ ☐₂ ☐₃

12 Bathing or dressing yourself ☐₁ ☐₂ ☐₃

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____

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Durham NC 27705

PAGEID = 116

Center Number: _____ Participant Number: _____ Participant's Initials: first middle last _____

Rand SF-36 (continued)

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

RANDSF2 (TYPE 3)

Yes No

13 Cut down on the **amount of time** you spent on work or other activities ☐₁ ☐₂

14 Accomplished less than you would like SAME AS PAGE 37 ☐₁ ☐₂

15 Were limited in the **kind** of work or other activities ☐₁ ☐₂

16 Had **difficulty** performing the work or other activities
(for example, it took extra effort) ☐₁ ☐₂

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)

Yes No

17 Cut down on the **amount of time** you spent on work or other activities ☐₁ ☐₂

18 Accomplished less than you would like ☐₁ ☐₂

19 Didn't do work or other activities as **carefully** as usual ☐₁ ☐₂

20 During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

☐₁ Not at all
☐₂ Slightly
☐₃ Moderately
☐₄ Quite a bit
☐₅ Extremely

21 How much **bodily** pain have you had during the **past 4 weeks**?

☐₁ None
☐₂ Very mild
☐₃ Mild
☐₄ Moderately
☐₅ Severe
☐₆ Very severe

22 During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐₁ Not at all
☐₂ A little bit
☐₃ Moderately
☐₄ Quite a bit
☐₅ Extremely

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Participant's Initials: first middle last _____

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RAND SF-36 (continued)

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

RANDSF3 (TYPE 3)

SAME AS PAGE 38

How much of the time during the past 4 weeks...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23 Did you feel full of pep?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
24 Have you been a very nervous person?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
25 Have you felt so down in the dumps that nothing could cheer you up?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
26 Have you felt calm and peaceful?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
27 Did you have a lot of energy?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
28 Have you felt downhearted and blue?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
29 Did you feel worn out?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
30 Have you been a happy person?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
31 Did you feel tired?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆
32 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?						
	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time	
	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	
How true or false is each of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False	
33 I seem to get sick a little easier than other people.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	
34 I am healthy as anybody I know.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	
35 I expect my health to get worse.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	
36 My health is excellent.	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	

CALERIE PHASE2 ANNOTATION V8.0 24FEB201208

Participant's Initials: first middle last _____

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Center Number: _____ Participant Number: _____ Participant's Initials: first middle last _____

Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): ____
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

BDI-II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

BDIQ (TYPE 4)

- 1 **Sadness:**
 - ☐₀ I do not feel sad
 - ☐₁ I feel sad much of the time
 - ☐₂ I am sad all of the time
 - ☐₃ I am so sad or unhappy that I can't stand it
- 2 **Pessimism:**
 - ☐₀ I am not discouraged about my future
 - ☐₁ I feel more discouraged about my future than I used to be
 - ☐₂ I do not expect things to work out for me
 - ☐₃ I feel my future is hopeless and will only get worse
- 3 **Past failure:**
 - ☐₀ I do not feel like a failure
 - ☐₁ I have failed more than I should have
 - ☐₂ As I look back, I see a lot of failures
 - ☐₃ I feel I am a total failure as a person
- 4 **Loss of pleasure:**
 - ☐₀ I get as much pleasure as I ever did from the things I enjoy
 - ☐₁ I don't enjoy things as much as I used to
 - ☐₂ I get very little pleasure from the things I used to enjoy
 - ☐₃ I can't get any pleasure from the things I used to enjoy
- 5 **Guilty feelings:**
 - ☐₀ I don't feel particularly guilty
 - ☐₁ I feel guilty over many things I have done or should have done
 - ☐₂ I feel quite guilty most of the time
 - ☐₃ I feel guilty all of the time
- 6 **Punishment feelings:**
 - ☐₀ I don't feel I am being punished
 - ☐₁ I feel I may be punished
 - ☐₂ I expect to be punished
 - ☐₃ I feel I am being punished
- 7 **Self-dislike:**
 - ☐₀ I feel the same about myself as ever
 - ☐₁ I have lost confidence in myself
 - ☐₂ I am disappointed in myself
 - ☐₃ I dislike myself

SAME AS PAGE 39

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BDI-II (continued)

8 Self-criticalness:

- ☐ I don't criticize or blame myself more than usual
☐ I am more critical of myself than I used to be
☐ I criticize myself for all of my faults
☐ I blame myself for everything bad that happens

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

- ☐ I don't have any thoughts of killing myself
☐ I have thoughts of killing myself but I would not carry them out
☐ I would like to kill myself
☐ I would kill myself if I had the chance

SAME AS PAGE 40

10 Crying:

- ☐ I don't cry any more than I used to
☐ I cry more than I used to
☐ I cry over every little thing
☐ I feel like crying, but I can't

11 Agitation:

- ☐ I am no more wound up or restless than usual
☐ I feel more restless or wound up than usual
☐ I am so restless or agitated that it's hard to stay still
☐ I am so restless or agitated that I have to keep moving or doing something

12 Loss of interest:

- ☐ I have not lost interest in other people or activities
☐ I am less interested in other people or things than before
☐ I have lost most of my interest in other people or things
☐ It's hard to get interested in anything

13 Indecisiveness:

- ☐ I make decisions about as well as ever
☐ I find it more difficult to make decisions than usual
☐ I have much greater difficulty in making decisions than I used to
☐ I have trouble making my decisions

14 Worthlessness:

- ☐ I do not feel I am worthless
☐ I don't consider myself as worthwhile and useful as I used to
☐ I feel more worthless as compared to other people
☐ I feel utterly worthless

15 Loss of energy:

- ☐ I have as much energy as ever
☐ I have less energy than I used to have
☐ I don't have enough energy to do very much
☐ I don't have enough energy to do anything

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Participant's Initials: _____
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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

BDI-II (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep

BDIQ (TYPE 4)

- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time

SAME AS PAGE 41

- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time

- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything

- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do

- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

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first middle last

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Date completed: ____/____/____ OR Not done → Specify reason (use codelist below): _____
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Profile of Mood States

Instructions: Please describe **how you feel right now** by checking one box for each of the words listed below.

POMS (TYPE 4) PS

	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1	Friendly	☐ _0	☒ _1 SAME AS PAGE 42	☐ _2	☐ _3	☐ _4
2	Tense	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
3	Angry	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4	Worn out	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
5	Unhappy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
6	Clear-headed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
7	Lively	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
8	Confused	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
9	Sorry for things done	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
10	Shaky	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
11	Listless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
12	Peeved	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
13	Considerate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
14	Sad	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
15	Active	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
16	On edge	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
17	Grouchy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
18	Blue	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
19	Energetic	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
20	Panicky	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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Participant's Initials: _____
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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Profile of Mood States (continued)

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
22 Relaxed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
23 Unworthy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
24 Spiteful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
25 Sympathetic	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
26 Uneasy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
27 Restless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
28 Unable to concentrate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
29 Fatigued	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
30 Helpful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
31 Annoyed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
32 Discouraged	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
33 Resentful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
34 Nervous	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
35 Lonely	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
36 Miserable	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
37 Muddled	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
38 Cheerful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
39 Bitter	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
40 Exhausted	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
41 Anxious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
42 Ready to fight	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
43 Good-natured	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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Profile of Mood States (continued)

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
45 Desperate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
46 Sluggish	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
47 Rebellious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
48 Helpless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
49 Weary	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
50 Bewildered	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
51 Alert	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
52 Deceived	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
53 Furious	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
54 Efficient	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
55 Trusting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
56 Full of pep	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
57 Bad-tempered	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
58 Worthless	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
59 Forgetful	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
60 Carefree	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
61 Terrified	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
62 Guilty	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
63 Vigorous	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
64 Uncertain about things	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
65 Bushed	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

POMS (TYPE 4) PS

SAME AS PAGE 44

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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below):
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Perceived Stress Scale (PSS)

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.

PSS (TYPE 4)

SAME AS PAGE 45

Never Almost Never Some-times Fairly Often Very Often

- 1 In the last month, how often have you felt that you were unable to control the important things in your life? ☐₀ ☐₁ ☐₂ ☐₃ ☐₄
- 2 In the last month, how often have you felt confident about your ability to handle your personal problems? ☐₀ ☐₁ ☐₂ ☐₃ ☐₄
- 3 In the last month, how often have you felt that things were going your way? ☐₀ ☐₁ ☐₂ ☐₃ ☐₄
- 4 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? ☐₀ ☐₁ ☐₂ ☐₃ ☐₄

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day month year SAME AS PAGE 36 DATEHDR (TYPE 4)

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month... SAME AS PAGE 46 PSQI(TYPE 4)

1	When have you usually gone to bed?	____:____ 00:00 to 23:59								
2	How long (in minutes) has it taken you to fall asleep each night?	_____ minutes								
3	When have you usually gotten up in the morning?	____:____ 00:00 to 23:59								
4	How many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) ____ + ____ hours									
5	During the past month, how often have you had trouble sleeping because you... (check only one answer per question)	<table border="0"> <tr> <th>Not during the past month</th> <th>Less than once a week</th> <th>Once or twice a week</th> <th>3 or more times a week</th> </tr> <tr> <td>☐_0</td> <td>☐_1</td> <td>☐_2</td> <td>☐_3</td> </tr> </table>	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week	☐ _0	☐ _1	☐ _2	☐ _3
Not during the past month	Less than once a week	Once or twice a week	3 or more times a week							
☐ _0	☐ _1	☐ _2	☐ _3							
a	Cannot get to sleep within 30 minutes									
b	Wake up in the middle of the night or early morning									
c	Have to get up to use the bathroom									
d	Cannot breathe comfortably									
e	Cough or snore loudly									
f	Feel too cold									
g	Feel too hot									
h	Have bad dreams									
i	Have pain									
j	Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): _____									
6	During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	<table border="0"> <tr> <td>☐_0</td> <td>☐_1</td> <td>☐_2</td> <td>☐_3</td> </tr> </table>	☐ _0	☐ _1	☐ _2	☐ _3				
☐ _0	☐ _1	☐ _2	☐ _3							

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Pittsburgh Sleep Quality Index (PSQI) (continued)

SAME AS PAGE 47

PSQI2 (TYPE 3)

Never

Once or
twice

Once or
twice each
week

3 or more
times each
week

7 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

☐₀

☐₁

☐₂

☐₃

No problem
at all

Only a very
slight
problem

Somewhat
of a
problem

A very big
problem

8 During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

☐₀

☐₁

☐₂

☐₃

Very
good

Fairly
good

Fairly
bad

Very
bad

9 During the past month, how would you rate your sleep quality overall?

☐₀

☐₁

☐₂

☐₃

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SAME AS PAGE 36

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about **sexual fantasies** or daydreams, while another inquires about the kinds of **sexual experiences** that you have. You are also asked about the nature of your **sexual arousal** and the quality of your **orgasm**. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "0 = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. **For each item, please check the scale number that best describes your personal experience.**

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

If you have any questions, please ask the person who gave you the inventory for help.

Section 1—Sexual Cognition/Fantasy

During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.3 Erotic or romantic situations	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.4 Caressing, touching, undressing, or foreplay	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
1.5 Sexual intercourse, oral sex, touching to orgasm	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8

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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 2—Sexual Arousal

SAME AS PAGE 49

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.2 Actively seek sexual satisfaction	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.3 Feel sexually aroused with a partner	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
	Never	Rarely	Sometimes	Usually	Always	DISFEM2 (TYPE 4)PS			
2.4 Have normal lubrication with masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4				
2.5 Have normal lubrication throughout sexual relations	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4				

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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 3—Sexual Behavior/Experiences SAME AS PAGE 50 DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.2 Masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.3 Casual kissing and petting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.4 Sexual foreplay	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.5 Sexual intercourse, oral sex, etc.	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

Section 4—Orgasm DISFEM3 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.2 The intensity of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.3 The ability to have multiple orgasms <i>(if typical for you)</i>	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.4 Feelings of closeness and togetherness with your partner	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.5 Your sense of control <i>(timing)</i> of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)

Section 5—Drive and Relationship

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DISFEM1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
	Not at all	Slightly	Moderately	Highly	Extremely	DISFEM3 (TYPE 4)PS			
5.2 During this period, how interested have you been in sex?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	DISFEM4 (TYPE 4)PS			
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about **sexual fantasies** or daydreams, while another inquires about the kinds of **sexual experiences** that you have. You are also asked about the nature of your **sexual arousal** and the quality of your **orgasm**. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "0 = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. **For each item, please check the scale number that best describes your personal experience.**

If you have any questions, please ask the person who gave you the inventory for help. **DISMALE1 (TYPE 4)PS**

SAME AS PAGE 52

Section 1—Sexual Cognition/Fantasy

During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈
1.3 Erotic or romantic situations	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈
1.4 Caressing, touching, undressing, or foreplay	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈
1.5 Sexual intercourse, oral sex, touching to orgasm	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 2—Sexual Arousal

SAME AS PAGE 53

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.2 A full erection during a sexual fantasy or daydream	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.4 A full erection during masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 3—Sexual Behavior/Experiences SAME AS PAGE 54 DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.2 Masturbation	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.3 Casual kissing and petting	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.4 Sexual foreplay	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8
3.5 Sexual intercourse, oral sex, etc.	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5	☐ _6	☐ _7	☐ _8

Section 4—Orgasm DISMALE2 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.2 The intensity of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.3 The length or duration of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.4 The amount of seminal liquid that you ejaculate	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.5 Your sense of control (timing) of your orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐ _0	☐ _1	☐ _2	☐ _3	☐ _4

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Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)

Section 5—Drive and Relationship

SAME AS PAGE 55

DISMALE1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈
	Not at all	Slightly	Moderately	Highly	Extremely	DISMALE2 (TYPE 4)PS			
5.2 During this period, how interested have you been in sex?	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	DISMALE3 (TYPE 4)PS			
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐ ₀	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅	☐ ₆	☐ ₇	☐ ₈

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day month year

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DATEHDR (TYPE 4)

Food Cravings Questionnaire—State (FCQ—S)

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment **right now, at this very moment**. Notice that some questions refer to foods in general while others refer to one or more specific foods. Please respond to each item as honestly as possible.

FCQSTATE (TYPE 4)PS

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1 I have an intense desire to eat [one or more specific foods].	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2 I'm craving [one or more specific foods].	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3 I have an urge for [one or more specific foods]	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4 Eating [one or more specific foods] would make things seem just perfect.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5 If I were to eat what I am craving, I am sure my mood would improve.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6 Eating [one or more specific foods] would feel wonderful.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7 If I ate something, I wouldn't feel so sluggish and lethargic.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8 Satisfying my craving would make me feel less grouchy and irritable.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9 I would feel more alert if I could satisfy my craving.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10 If I had [one or more specific foods], I could not stop eating it.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11 My desire to eat [one or more specific foods] seems overpowering.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
13 I am hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14 If I ate right now, my stomach wouldn't feel as empty.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15 I feel weak because of not eating.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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DATEHDR (TYPE 4)

Food Craving Inventory (FCI-II)

For each of the foods listed below, please check the appropriate box.

CRAVE (TYPE 4)PS

Note: A craving is defined as an intense desire to consume a particular food or food type that is difficult to resist.

Over the past month, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
2 Pizza	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
3 Fried chicken	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
4 Gravy	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
5 Sandwich bread	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
6 Sausage	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
7 French fries	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
8 Cinnamon rolls	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
9 Rice	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
10 Hot dog	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
11 Hamburger	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
12 Biscuits	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
13 Ice cream	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
14 Pasta	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
15 Fried fish	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
16 Cookies	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
17 Chocolate	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
18 Pancakes or waffles	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
19 Corn bread	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
20 Chips	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
21 Rolls	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
22 Cereal	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
23 Donuts	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
24 Candy	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
25 Brownies	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
26 Bacon	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
27 Steak	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5
28 Baked potato	☐ _1	☐ _2	☐ _3	☐ _4	☐ _5

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DATEHDR (TYPE 4)

Eating Inventory

1 When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal. TFEQA (TYPE 4) PS
☐ True ☐ False

2 I usually eat too much at social occasions, like parties and picnics. SAME AS PAGE 60
☐ True ☐ False

3 I am usually so hungry that I eat more than three times a day. ☐ True ☐ False

4 When I have eaten my quota of calories, I am usually good about not eating anymore. ☐ True ☐ False

5 Dieting is so hard for me because I just get too hungry. ☐ True ☐ False

6 I deliberately take small helpings as a means of controlling my weight. ☐ True ☐ False

7 Sometimes things just taste so good that I keep on eating even when I am no longer hungry. ☐ True ☐ False

8 Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat. ☐ True ☐ False

9 When I feel anxious, I find myself eating. ☐ True ☐ False

10 Life is too short to worry about dieting. ☐ True ☐ False

11 Since my weight goes up and down, I have gone on reducing diets more than once. ☐ True ☐ False

12 I often feel so hungry that I just have to eat something. ☐ True ☐ False

13 When I am with someone who is overeating, I usually overeat too. ☐ True ☐ False

14 I have a pretty good idea of the number of calories in common food. ☐ True ☐ False

15 Sometimes when I start eating, I just can't seem to stop. ☐ True ☐ False

16 It is not difficult for me to leave something on my plate. ☐ True ☐ False

17 At certain times of the day, I get hungry because I have gotten used to eating then. ☐ True ☐ False

18 While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it. ☐ True ☐ False

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Eating Inventory (continued)

19 Being with someone who is eating often makes me hungry to eat also. ☐ True ☐ False

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TFEOA (TYPE 4) PS

20 When I feel blue, I often overeat. ☐ True ☐ False

21 I enjoy eating too much to spoil it by counting calories or watching my weight. ☐ True ☐ False

22 When I see a real delicacy, I often get so hungry that I have to eat right away. ☐ True ☐ False

23 I often stop eating when I am not really full as a conscious means of limiting the amount I eat. ☐ True ☐ False

24 I get so hungry that my stomach often seems like a bottomless pit. ☐ True ☐ False

25 My weight has hardly changed at all in the last ten years. ☐ True ☐ False

26 I am always hungry so it is hard for me to stop eating before I finish the food on my plate. ☐ True ☐ False

27 When I feel lonely, I console myself by eating. ☐ True ☐ False

28 I consciously hold back at meals in order not to gain weight. ☐ True ☐ False

29 I sometimes get very hungry late in the evening or at night. ☐ True ☐ False

30 I eat anything I want, any time I want. ☐ True ☐ False

31 Without even thinking about it, I take a long time to eat. ☐ True ☐ False

32 I count calories as a conscious means of controlling my weight. ☐ True ☐ False

33 I do not eat some foods because they make me fat. ☐ True ☐ False

34 I am always hungry enough to eat at any time. ☐ True ☐ False

35 I pay a great deal of attention to changes in my figure. ☐ True ☐ False

36 While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. ☐ True ☐ False

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Eating Inventory (continued)

Please check one answer that is most appropriate to you for each question below. **TFEQB (TYPE 3)**

37	How often are you dieting in a conscious effort to control your weight?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always
39	How often do you feel hungry?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	☐ 1 Rarely	☐ 2 Sometimes	☐ 3 Usually	☐ 4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐ 1 Easy ☐ 3 Moderately difficult	☐ 2 Slightly difficult ☐ 4 Very difficult		
42	How conscious are you of what you are eating?	☐ 1 Not at all ☐ 3 Moderately	☐ 2 Slightly ☐ 4 Extremely		
43	How frequently do you avoid "stocking up" on tempting foods?	☐ 1 Almost never ☐ 3 Usually	☐ 2 Seldom ☐ 4 Almost always		
44	How likely are you to shop for low calorie foods?	☐ 1 Unlikely ☐ 3 Moderately likely	☐ 2 Slightly likely ☐ 4 Very likely		
45	Do you eat sensibly in front of others and splurge alone?	☐ 1 Never	☐ 2 Rarely	☐ 3 Often	☐ 4 Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐ 1 Unlikely ☐ 3 Moderately likely	☐ 2 Slightly likely ☐ 4 Very likely		
47	How frequently do you skip dessert because you are no longer hungry?	☐ 1 Almost never ☐ 3 At least once a week	☐ 2 Seldom ☐ 4 Almost every day		
48	How likely are you to consciously eat less than you want?	☐ 1 Unlikely ☐ 3 Moderately likely	☐ 2 Slightly likely ☐ 4 Very likely		
49	Do you go on eating binges though you are not hungry?	☐ 1 Never ☐ 3 Sometimes	☐ 2 Rarely ☐ 4 At least once a week		

50 To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."

☐ 1 Not like me
☐ 2 Little like me
☐ 3 Pretty good description of me
☐ 4 Describes me perfectly

51 On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?

☐ 0 Eat whatever you want, whenever you want it
☐ 1 Usually eat whatever you want, whenever you want it
☐ 2 Often eat whatever you want, whenever you want it
☐ 3 Often limit food intake, but often "give in"
☐ 4 Usually limit food intake, rarely "give in"
☐ 5 Constantly limiting food intake, never "giving in"

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DATEHDR (TYPE 4)

Weight Efficacy Lifestyle Questionnaire (WEL)

This form describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you to identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to **successfully resist** the desire to eat. Check this number for each item.

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WELQ (TYPE 4)PS

I am confident that:	Not confident at all that you can resist the desire to eat					Very confident that you can resist the desire to eat				
	0	1	2	3	4	5	6	7	8	9
1 I can resist eating when I am anxious (nervous).	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2 I can control my eating on the weekends.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3 I can resist eating even when I have to say "no" to others.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4 I can resist eating when I feel physically run down.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5 I can resist eating when I am watching TV.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6 I can resist eating when I am depressed (or down).	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7 I can resist eating when there are many different kinds of food available.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8 I can resist eating even when I feel it is impolite to refuse a second helping.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9 I can resist eating even when I have a headache.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

I am confident that:	Not confident at all that you can resist the desire to eat				Very confident that you can resist the desire to eat					
	0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am reading.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11 I can resist eating when I am angry (or irritable).	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12 I can resist eating even when I am at a party.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13 I can resist eating even when others are pressuring me to eat.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14 I can resist eating when I am in pain.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15 I can resist eating just before going to bed.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16 I can resist eating when I have experienced failure.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
17 I can resist eating when high-calorie foods are available.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
18 I can resist eating even when I think others will be upset if I don't eat.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
19 I can resist eating when I feel uncomfortable.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
20 I can resist eating when I am happy.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Date completed: ____/____/____ **SAME AS PAGE 36** **DATEHDR (TYPE 4)**
OR Not done → Specify reason (useodelist below): _____
MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
1 Fasting is a good way to lose weight.	☐	☐	☐	☐	☐	☐	☐
2 My sleep isn't as good as it used to be.	☐	☐	☐	☐	☐	☐	☐
3 I avoid eating for as long as I can.	☐	☐	☐	☐	☐	☐	☐
4 Certain foods are "forbidden" for me to eat.	☐	☐	☐	☐	☐	☐	☐
5 I can't keep certain foods in my house because I will binge on them.	☐	☐	☐	☐	☐	☐	☐
6 I can easily make myself vomit.	☐	☐	☐	☐	☐	☐	☐
7 I can feel that being fat is terrible.	☐	☐	☐	☐	☐	☐	☐
8 I avoid greasy foods.	☐	☐	☐	☐	☐	☐	☐
9 It's okay to binge and purge once in a while.	☐	☐	☐	☐	☐	☐	☐
10 I don't eat certain foods.	☐	☐	☐	☐	☐	☐	☐
11 I think I am a good person.	☐	☐	☐	☐	☐	☐	☐
12 My eating is normal.	☐	☐	☐	☐	☐	☐	☐
13 I can't seem to concentrate lately.	☐	☐	☐	☐	☐	☐	☐
14 I try to diet by fasting.	☐	☐	☐	☐	☐	☐	☐
15 I vomit to control my weight.	☐	☐	☐	☐	☐	☐	☐
16 Lately nothing seems enjoyable anymore.	☐	☐	☐	☐	☐	☐	☐
17 Laxatives help keep you slim.	☐	☐	☐	☐	☐	☐	☐
18 I don't eat red meat.	☐	☐	☐	☐	☐	☐	☐
19 I eat so rapidly I can't even taste my food.	☐	☐	☐	☐	☐	☐	☐

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

SAME AS PAGE 66		Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
20	I do everything I can to avoid being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
21	When I feel bloated, I must do something to rid myself of that feeling.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
22	I overeat too frequently.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
23	It's okay to be overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
24	Recently I have felt that I am a worthless person.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
25	I would be very upset if I gained 2 pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
26	I crave sweets and carbohydrates.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
27	I lose control when I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
28	Being fat would be terrible.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
29	I have thought seriously about suicide lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
30	I don't have any energy anymore.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
31	I eat small portions to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
32	I eat 3 meals a day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
33	Lately I have been easily irritated.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
34	Some foods should be totally avoided.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
35	I use laxatives to control my weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
36	I am terrified by the thought of being overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
37	Purging is a good way to lose weight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
38	I avoid fatty foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

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Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)

SAME AS PAGE 67	MAEDS (TYPE 4) PS						
	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
39 Recently I have felt pretty blue.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
40 I am obsessed with becoming overweight.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
41 I don't eat fried foods.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
42 I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
43 Fat people are unhappy.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
44 People are too concerned with the way I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
45 I feel good when I skip meals.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
46 I avoid foods with sugar.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
47 I hate it when I feel fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
48 I am too fat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
49 I eat until I am completely stuffed.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
50 I hate to eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
51 I feel guilty about a lot of things these days.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
52 I'm very careful of what I eat.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
53 I can "hold off" and not eat even if I am hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
54 I eat even when I am not hungry.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
55 Fat people are disgusting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
56 I wouldn't mind gaining a few pounds.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

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PAGEID = 145

Center Number: _____ Participant Number: _____ Participant's Initials: _____

Date completed: ____/____/____ OR Not done → Specify reason (useodelist below):

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**. BSQ (TYPE 4)PS
Please read each question and check the box for the appropriate choice. Please answer all the questions.

Over the Past Four Weeks...	Never	Rarely	Sometimes	Often	Very Often	Always
1 Has feeling bored made you brood about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
2 Have you been so worried about your shape that you have been feeling that you ought to diet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
3 Have you thought that your thighs, hips, or bottom are too large for the rest of you?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
4 Have you been afraid that you might become fat (or fatter)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
5 Have you worried about your flesh not being firm enough?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
6 Has feeling full (e.g., after eating a large meal) made you feel fat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
7 Have you felt so bad about your shape that you have cried?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
8 Have you avoided running because your flesh might wobble?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
9 Has being with thin women/men made you feel self-conscious about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10 Have you worried about your thighs spreading out when sitting down?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11 Has eating even a small amount of food made you feel fat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
14 Has being naked, such as when taking a bath, made you feel fat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
15 Have you avoided wearing clothes which make you particularly aware of the shape of your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
16 Have you imagined cutting off fleshy areas of your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____

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Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks...

SAME AS PAGE 69

BSQ (TYPE 4) PS

	Never	Rarely	Sometimes	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19 Have you felt excessively large and rounded?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
20 Have you felt ashamed of your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
21 Has worry about your shape made you diet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
22 Have you felt happiest about your shape when your stomach has been empty?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
23 Have you thought that you are the shape you are because you lack self-control?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
25 Have you felt that it is not fair that other women/men are thinner than you?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
26 Have you vomited in order to feel thinner?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
28 Have you worried about your flesh being dimply?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
30 Have you pinched areas of your body to see how much fat is there?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
32 Have you taken laxatives in order to feel thinner?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
33 Have you been particularly self-conscious about your shape when in the company of other people?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
34 Has worry about your shape made you feel you ought to exercise?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: ____/____/____ : ____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . ____ kg

SAME AS PAGE 4

Weight 2: _____ . ____ kg

WEIGHT (TYPE 4)

Weight 3: _____ . ____ kg

Weight of gown: _____ . ____ kg

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Center Number: _____ Participant Number: _____ Participant's Initials: first middle last
PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____

1 Were you employed in the last seven days? ☐ No → Skip to question 3 ☐ Yes

2 If Yes: Which days (check all that apply)?

☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun
☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days?

Interviewer initials: first middle last

Day #	Day of Week	Date ____/____/____ day month year	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	(yesterday)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
6		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
5		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
4		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
3		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
2		____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____
1	(1 week ago)	____/____/____ day month year	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____:____ 00:00 to 23:59	____	____	____	____	____	____	____	____	____

PARCHT (TYPE 4)PS

SAME AS PAGE 71

Not Done Code list: 1 Participant refused

required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 149

Center Number: ____ Participant Number: ____ Participant's Initials: first middle last ____

Seven-Day Physical Activity Recall (PAR) (continued)

- 4** Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

PARQ (TYPE 4)

- ☐ ₁ More
☐ ₂ Less
☐ ₃ About the same

SAME AS PAGE 72

Interviewer: Please answer questions below and note any comments on interview.

- 5** Were there any problems with the Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 6** Do you think this was a valid Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 7** Were there any activities reported by the participant that you don't know how to classify?

- ☐ ₀ No
☐ ₁ Yes

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PAGEID = 150

Center Number: _____ Participant Number: _____ Participant's Initials:

6-Day Food Record

Complete below OR Not done → Specify reason (use Codelist below): _____

Staff initials:

SAME AS PAGE 73

Replacement Values

FOODRCD (TYPE 4)PS

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	8	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
2	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	9	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
3	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	10	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
4	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	11	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
5	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	12	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing
6	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing	13	____/____/____ day month year	☐ 1 Reliable ☐ 2 Unreliable ☐ 3 Missing

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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Outcomes Labs

Date and time of last meal: _____ / _____ / _____ 00:00 to 23:59 **OUTCMELB (TYPE 4)PS**

Date and time sample collection started: _____ / _____ / _____ 00:00 to 23:59 **SAME AS PAGE 102**

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ No ☐ Yes	_____	_____

If a sample is not obtained, indicate with a Not Done.

Core Temperature

Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason (Use codelist below)
_____	Start Date: _____ / _____ / _____	Start Time _____ 00:00 to 23:59	_____
	Stop Date: _____ / _____ / _____	Stop Time _____ 00:00 to 23:59	

Inpatient Admission and Discharge

1 Inpatient admission date and time: _____ / _____ / _____ 00:00 to 23:59

2 Inpatient discharge date and time: _____ / _____ / _____ 00:00 to 23:59

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 152

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Clinic Weight

Weight date and time: ____/____/____ : ____
day month year 00:00 to 23:59

Staff initials: _____
first middle last

OR Not done → Specify reason (useodelist below): _____

DATEHDR (TYPE 4)

Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: _____ . ____ kg

SAME AS PAGE 4

Weight 2: _____ . ____ kg

WEIGHT (TYPE 4)

Weight 3: _____ . ____ kg

Weight of gown: _____ . ____ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

PREGTEST (TYPE 4)

☐ No

☐ Yes → If Yes: Date urine pregnancy test performed: ____/____/____
day month year

SAME AS PAGE 33

Results: ☐ Negative

☐ Positive

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 153

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

DXA Scan

- 1** Has the participant taken a calcium supplement today? DXASCAN (TYPE 4)
☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.
- 2** Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?
☐ No ☐ Yes

SAME AS PAGE 90A

DXA Scan		DXA Rescan OR ☐ NA
Date of scan: ____/____/____ day month year		Date of rescan: ____/____/____ day month year
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply
☐ Whole body	_____	☐ Whole body

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 5	____/____/____ day month year	_____	_____ first middle last
No Display 2 = RMR2 RMR (TYPE 4)PS SAME AS PAGE 91			
Cart ID RMRVISIT<TURMR> ☐ Tufts-003 (623-002) ☐ WASH U-001 (623-003) ☐ PBRC-016 (623-005) ☐ Tufts-006 (623-006) ☐ WASH U-002 (623-004) ☐ PBRC-017 (623-001)			

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

ADD CARTID TO EXISTING RMR PANEL

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Seven-Day Physical Activity Recall (PAR)

Today's date: ____ / ____ / ____
 day month year

Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

OR Not done → Specify reason (use code(s) below): _____

1 Were you employed in the last seven days?

2 If Yes: Which days (check all that apply)?

3 Which days do you consider your weekend, or non-work, days?

		Sleep Time	Work Time	Morning (in minutes)	Afternoon (in minutes)	Evening (in minutes)
Day						

#	Day or Week	Date						
		In Bed	Up	Start	Stop	Mod.	Hard	Very Hard
						Mod.	Hard	Very Hard

[illegible]

7

_____ / _____ / _____
 day month year
 00:00 to 23:59 : : 00:00 to 23:59
 PARCHT (TYPE 4)PS

day)

	-
	-

[illegible]

day	month	year
00:00 to 23:59	00:00 to 23:59	00:00 to 23:59

[illegible]

00.00 to 23.59	00.00 to 23.59
----------------	----------------

[illegible][illegible][illegible][illegible]

day	month	year
00:00 to 23:59	00:00 to 23:59	00:00 to 23:59

[illegible][illegible][illegible][illegible][illegible][illegible][illegible]

	/	00.00 to 23.59	+	00.00 to 23.59	
	/	00.00 to 23.59	+	00.00 to 23.59	
	/	00.00 to 23.59	+	00.00 to 23.59	

[illegible]

ago)	00.00 to 23.59	00.00 to 23.59

[illegible]

Not Done Code list:	1 Participant refused	2 Clinician unable to obtain	3 Insufficient time	4 Instrument failure	5 Not required

[illegible]

CALERIE PHASE2 ANNOIATION V8.0 24FEB2012

PAGEID = 155

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Seven-Day Physical Activity Recall (PAR) (continued)

- 4** Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?

PARQ (TYPE 4)

- ☐ ₁ More
☐ ₂ Less
☐ ₃ About the same

SAME AS PAGE 72

Interviewer: Please answer questions below and note any comments on interview.

- 5** Were there any problems with the Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 6** Do you think this was a valid Seven-Day PAR interview?

- ☐ ₀ No
☐ ₁ Yes

- 7** Were there any activities reported by the participant that you don't know how to classify?

- ☐ ₀ No
☐ ₁ Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012