calerie Phase 2

Phone Screen

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: ☐0 No ☐1 Yes Interviewer's initials: ___ ___ ___ (first middle last)

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year) Source: ____________ Age: ___ ___

Last name: ____________ First name: ____________ DOB: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

Address: ____________ Zip: ____________

Phone *(home)*: ____________ Phone *(work)*: ____________ E-mail: ____________

Height: ___ ft ___ ___ in Weight: ___ ___ ___ lbs BMI: ________ Gender: ☐1 Male ☐2 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	☐0 No	☐1 Yes →	
Abnormal heart rhythm	☐0 No	☐1 Yes →	
Cancer	☐0 No	☐1 Yes →	
Shortness of breath or other breathing problem	☐0 No	☐1 Yes →	
Diabetes *(meds)*	☐0 No	☐1 Yes →	
High blood pressure *(> 140/90)*	☐0 No	☐1 Yes →	
Anemia or other blood condition	☐0 No	☐1 Yes →	
Thyroid or other metabolic disorder such as phenylketonuria	☐0 No	☐1 Yes →	
Stomach or digestive disorders	☐0 No	☐1 Yes →	
Immunologic disorder or AIDS	☐0 No	☐1 Yes →	
Depression or any other psychiatric or neurologic disease	☐0 No	☐1 Yes →	
Active liver disease and/or gallstones	☐0 No	☐1 Yes →	
Kidney or urologic disorders	☐0 No	☐1 Yes →	
Major abdominal or chest surgery	☐0 No	☐1 Yes →	
Weight loss or gain of > 3 kg over the past 6 months	☐0 No	☐1 Yes →	
Known metallic objects or implants in your body	☐0 No	☐1 Yes →	
Anaphylaxis, severe allergies, or asthma	☐0 No	☐1 Yes →	

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

calerie Phase 2

Phone Screen

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Medications

	Question	Response	
1	Have you received medication for depression or any other psychiatric disease in the past year?	☐0 No ☐1 Yes →	If Yes: Specify medications: ________
2	Have you received more than one episode of medication for depression or any other psychiatric disease ever?	☐0 No ☐1 Yes →	If Yes: Specify medications: ________
3	Have you been treated with steroids in the last six months?	☐0 No ☐1 Yes	
4	Have you been treated with steroids for more than a month in the past five years?	☐0 No ☐1 Yes	
5	Do you currently use regular medications other than birth control pills?	☐0 No ☐1 Yes →	If Yes: Specify medications: ________

Women

	Question	Response	
1	Are you currently pregnant or breast feeding?	☐0 No ☐1 Yes	
2	Do you plan to have children in the next two years?	☐0 No ☐1 Yes	
3	Do you use some form of birth control?	☐0 No ☐1 Yes →	If Yes: Specify: ________

Physical Activity/Lifestyle

	Question	Response	
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.)*	☐0 No ☐1 Yes →	If Yes: Specify type and frequency of activity: ________
2	Have you used drugs recreationally within the past two years?	☐0 No ☐1 Yes	
3	Have you smoked within the past twelve months?	☐0 No ☐1 Yes	
4	Have you given blood in the last 30 days?	☐0 No ☐1 Yes	
5	Are you currently participating in another interventional trial?	☐0 No ☐1 Yes	
6	Are you currently practicing a vegan dietary lifestyle?	☐0 No ☐1 Yes	
7	Do you anticipate difficulties adhering to special diets and clinical visits over a two year period?	☐0 No ☐1 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: ☐0 No → **If No: Reason for not being eligible:** ________

☐1 Yes → **If Yes: Is participant interested in participating?** ☐0 No ☐1 Yes

☐2 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: ________

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first, middle, last)

Screening Visit 1 Checklist

1 Date of initial clinic visit for Screening Visit 1: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Check completed items:

2 ☐ Informed consent

3 ☐ HIPAA authorization

4 ☐ Study video

5 ☐ Study brochure

6 ☐ Weight and height measures, including BMI eligibility

7 ☐ Demographic form

8 ☐ Stanford Activity Assessment

9 ☐ General Dietary Questionnaire

10 ☐ Eating Inventory

11 ☐ MAEDS

12 ☐ SCID-II

13 ☐ BDI-II

14 ☐ Meeting with dietitian

15 ☐ Meeting with study coordinator/manager

16 ☐ Schedule Assessment Calendar

17 ☐ Inclusion/Exclusion criteria review

18 Is the participant expected to return for Screening Visit 2?

☐0 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
- ☐ Other *(specify)*: ______________________________

☐1 Yes → **If Yes: Date of scheduled Screening Visit 2:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Height

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

1 **First height:** ___ ___ ___ . ___ cm

2 **Second height:** ___ ___ ___ . ___ cm

3 **Third height:** ___ ___ ___ . ___ cm

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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (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? ☐0 No ☐1 Yes

Best time to call, and where: ____________

E-mail address: ____________ Cell phone: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Do you use e-mail regularly? ☐0 No ☐1 Yes → If Yes: How often? ____________

Date of birth: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year) Age: ________

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: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___ Fax: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Demographics

1 Date of birth: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

2 Sex:
- ☐1 Male
- ☐2 Female

3 Ethnicity *(check only one)*:
- ☐1 Hispanic or Latino
- ☐2 Not Hispanic or Latino
- ☐3 Unknown *(not reporting ethnicity)*

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

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

6 Living situation: Where do you live *(check only one)*:
- ☐1 House
- ☐2 Apartment
- ☐3 Shelter
- ☐4 Dormitory
- ☐98 Other *(specify)*: ______________________

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.)*

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

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)

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.

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Eating Inventory

#	Item	True	False
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.	☐ 1 True	☐ 0 False
2	I usually eat too much at social occasions, like parties and picnics.	☐ 1 True	☐ 0 False
3	I am usually so hungry that I eat more than three times a day.	☐ 1 True	☐ 0 False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐ 1 True	☐ 0 False
5	Dieting is so hard for me because I just get too hungry.	☐ 1 True	☐ 0 False
6	I deliberately take small helpings as a means of controlling my weight.	☐ 1 True	☐ 0 False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False
9	When I feel anxious, I find myself eating.	☐ 1 True	☐ 0 False
10	Life is too short to worry about dieting.	☐ 1 True	☐ 0 False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐ 1 True	☐ 0 False
12	I often feel so hungry that I just have to eat something.	☐ 1 True	☐ 0 False
13	When I am with someone who is overeating, I usually overeat too.	☐ 1 True	☐ 0 False
14	I have a pretty good idea of the number of calories in common food.	☐ 1 True	☐ 0 False
15	Sometimes when I start eating, I just can't seem to stop.	☐ 1 True	☐ 0 False
16	It is not difficult for me to leave something on my plate.	☐ 1 True	☐ 0 False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False

Participant's Initials: ___ ___ ___ (first middle last)

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

Eating Inventory (continued)

#	Item	True	False
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

Participant's Initials: ___ ___ ___ (first middle last)

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

Eating Inventory (continued)

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

#	Question	Answers
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 ☐1 Slightly difficult ☐2 Moderately difficult ☐3 Very difficult
42	How conscious are you of what you are eating?	☐0 Not at all ☐1 Slightly ☐2 Moderately ☐3 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐0 Almost never ☐1 Seldom ☐2 Usually ☐3 Almost always
44	How likely are you to shop for low calorie foods?	☐0 Unlikely ☐1 Slightly likely ☐2 Moderately 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 ☐1 Slightly likely ☐2 Moderately likely ☐3 Very likely
47	How frequently do you skip dessert because you are no longer hungry?	☐0 Almost never ☐1 Seldom ☐2 At least once a week ☐3 Almost every day
48	How likely are you to consciously eat less than you want?	☐0 Unlikely ☐1 Slightly likely ☐2 Moderately likely ☐3 Very likely
49	Do you go on eating binges though you are not hungry?	☐0 Never ☐1 Rarely ☐2 Sometimes ☐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"

Participant's Initials: ___ ___ ___ (first middle last)

calerie Phase 2

Screening

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

Date completed: ___ ___ /___ ___ ___ /___ ___ ___ ___
day month year

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	Some-times	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

Participant's Initials: ___ ___ ___
first middle last

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

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

Participant's Initials: ___ ___ ___
first middle last

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Date completed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

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

#	Question	No	Yes
1	Have you avoided jobs or tasks that involved having to deal with a lot of people?	☐ 0 No	☐ 1 Yes
2	Do you avoid getting involved with people unless you are certain they will like you?	☐ 0 No	☐ 1 Yes
3	Do you find it hard to be "open" even with people are you close to?	☐ 0 No	☐ 1 Yes
4	Do you often worry about being criticized or rejected in social situations?	☐ 0 No	☐ 1 Yes
5	Are you usually quiet when you meet new people?	☐ 0 No	☐ 1 Yes
6	Do you believe that you're not as good, as smart, or as attractive as most other people?	☐ 0 No	☐ 1 Yes
7	Are you afraid to try new things?	☐ 0 No	☐ 1 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?	☐ 0 No	☐ 1 Yes
9	Do you depend on other people to handle important areas in your life such as finances, child care, or living arrangements?	☐ 0 No	☐ 1 Yes
10	Do you find it hard to disagree with people even when you think they are wrong?	☐ 0 No	☐ 1 Yes
11	Do you find it hard to start or work on tasks when there is no one to help you?	☐ 0 No	☐ 1 Yes
12	Have you often volunteered to do things that are unpleasant?	☐ 0 No	☐ 1 Yes
13	Do you usually feel uncomfortable when you are by yourself?	☐ 0 No	☐ 1 Yes
14	When a close relationship ends, do you feel you immediately have to find someone else to take care of you?	☐ 0 No	☐ 1 Yes
15	Do you worry a lot about being left alone to take care of yourself?	☐ 0 No	☐ 1 Yes
16	Are you the kind of person who focuses on details, order, and organization or likes to make lists and schedules?	☐ 0 No	☐ 1 Yes
17	Do you have trouble finishing jobs because you spend so much time trying to get things exactly right?	☐ 0 No	☐ 1 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?	☐ 0 No	☐ 1 Yes
19	Do you have very high standards about what is right and what is wrong?	☐ 0 No	☐ 1 Yes
20	Do you have trouble throwing things out because they might come in handy some day?	☐ 0 No	☐ 1 Yes
21	Is it hard for you to let other people help you unless they agree to do things exactly the way you want?	☐ 0 No	☐ 1 Yes
22	Is it hard for you to spend money on yourself and other people even when you have enough?	☐ 0 No	☐ 1 Yes
23	Are you often so sure you are right that it doesn't matter what other people say?	☐ 0 No	☐ 1 Yes
24	Have other people told you that you are stubborn or rigid?	☐ 0 No	☐ 1 Yes

Participant's Initials: ___ ___ ___ (first middle last)

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

#	Question	No	Yes
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?	☐0 No	☐1 Yes
26	If you don't want to do something, do you often just "forget" to do it?	☐0 No	☐1 Yes
27	Do you often feel that other people don't understand you, or don't appreciate how much you do?	☐0 No	☐1 Yes
28	Are you often grumpy and likely to get into arguments?	☐0 No	☐1 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?	☐0 No	☐1 Yes
30	Do you often think that it's not fair that other people have more than you do?	☐0 No	☐1 Yes
31	Do you often complain that more than your share of bad things have happened to you?	☐0 No	☐1 Yes
32	Do you often angrily refuse to do what others want and then later feel bad and apologize?	☐0 No	☐1 Yes
33	Do you usually feel unhappy or that life is no fun?	☐0 No	☐1 Yes
34	Do you believe that you are basically an inadequate person and often don't feel good about yourself?	☐0 No	☐1 Yes
35	Do you often put yourself down?	☐0 No	☐1 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?	☐0 No	☐1 Yes
37	Do you often judge others harshly and easily find fault with them?	☐0 No	☐1 Yes
38	Do you think that most people are basically no good?	☐0 No	☐1 Yes
39	Do you almost always expect things to turn out badly?	☐0 No	☐1 Yes
40	Do you often feel guilty about things you have or haven't done?	☐0 No	☐1 Yes
41	Do you often have to keep an eye out to stop people from using you or hurting you?	☐0 No	☐1 Yes
42	Do you spend a lot of time wondering if you can trust your friends or the people you work with?	☐0 No	☐1 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?	☐0 No	☐1 Yes
44	Do you often detect hidden threats or insults in things people say or do?	☐0 No	☐1 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?	☐0 No	☐1 Yes
46	Are there many people you can't forgive because they did or said something to you a long time ago?	☐0 No	☐1 Yes
47	Do you often get angry or lash out when someone criticizes or insults you in some way?	☐0 No	☐1 Yes
48	Have you often suspected that your spouse or partner has been unfaithful?	☐0 No	☐1 Yes

Participant's Initials: ___ ___ ___ (first middle last)

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

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

#	Question	No	Yes
49	When you are out in public and see people talking, do you often feel that they are talking about you?	☐ 0 No	☐ 1 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?	☐ 0 No	☐ 1 Yes
51	When you are around people, do you often get the feeling that you are being watched or stared at?	☐ 0 No	☐ 1 Yes
52	Have you ever felt that you could make things happen just by making a wish or thinking about them?	☐ 0 No	☐ 1 Yes
53	Have you had personal experiences with the supernatural?	☐ 0 No	☐ 1 Yes
54	Do you believe that you have a "sixth sense" that allows you to know and predict things that others can't?	☐ 0 No	☐ 1 Yes
55	Does it often seem that objects or shadows are really people or animals or that noises are actually people's voices?	☐ 0 No	☐ 1 Yes
56	Have you had the sense that some person or force is around you, even though you cannot see anyone?	☐ 0 No	☐ 1 Yes
57	Do you often see auras or energy fields around people?	☐ 0 No	☐ 1 Yes
58	Are there very few people that you're really close to outside of your immediate family?	☐ 0 No	☐ 1 Yes
59	Do you often feel nervous when you are with other people?	☐ 0 No	☐ 1 Yes
60	Is it NOT important to you whether you have any close relationships?	☐ 0 No	☐ 1 Yes
61	Would you almost always rather do things alone than with other people?	☐ 0 No	☐ 1 Yes
62	Could you be content without ever being sexually involved with anyone?	☐ 0 No	☐ 1 Yes
63	Are there really very few things that give you pleasure?	☐ 0 No	☐ 1 Yes
64	Does it NOT matter to you what people think of you?	☐ 0 No	☐ 1 Yes
65	Do you find that nothing makes you very happy or very sad?	☐ 0 No	☐ 1 Yes
66	Do you like to be the center of attention?	☐ 0 No	☐ 1 Yes
67	Do you flirt a lot?	☐ 0 No	☐ 1 Yes
68	Do you often find yourself "coming on" to people?	☐ 0 No	☐ 1 Yes
69	Do you try to draw attention to yourself by the way you dress or look?	☐ 0 No	☐ 1 Yes
70	Do you often make a point of being dramatic and colorful?	☐ 0 No	☐ 1 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?	☐ 0 No	☐ 1 Yes
72	Do you have lots of friends that you are very close to?	☐ 0 No	☐ 1 Yes

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

#	Question	No	Yes
73	Do people often fail to appreciate your very special talents or accomplishments?	☐0 No	☐1 Yes
74	Have people told you that you have too high an opinion of yourself?	☐0 No	☐1 Yes
75	Do you think a lot about the power, fame, or recognition that will be yours someday?	☐0 No	☐1 Yes
76	Do you think a lot about the perfect romance that will be yours someday?	☐0 No	☐1 Yes
77	When you have a problem, do you almost always insist on seeing the top person?	☐0 No	☐1 Yes
78	Do you feel it is important to spend time with people who are special or influential?	☐0 No	☐1 Yes
79	Is it very important to you that people pay attention to you or admire you in some way?	☐0 No	☐1 Yes
80	Do you think that it's not necessary to follow certain rules or social conventions when they get in your way?	☐0 No	☐1 Yes
81	Do you feel that you are the kind of person who deserves special treatment?	☐0 No	☐1 Yes
82	Do you often find it necessary to step on a few toes to get what you want?	☐0 No	☐1 Yes
83	Do you often have to put your needs above other people's?	☐0 No	☐1 Yes
84	Do you often expect other people to do what you ask without question because of who you are?	☐0 No	☐1 Yes
85	Are you NOT really interested in other people's problems or feelings?	☐0 No	☐1 Yes
86	Have people complained to you that you don't listen to them or care about their feelings?	☐0 No	☐1 Yes
87	Are you often envious of others?	☐0 No	☐1 Yes
88	Do you feel that others are often envious of you?	☐0 No	☐1 Yes
89	Do you find that there are very few people that are worth your time and attention?	☐0 No	☐1 Yes
90	Have you often become frantic when you thought that someone you really cared about was going to leave you?	☐0 No	☐1 Yes
91	Do your relationships with people you really care about have lots of extreme ups and downs?	☐0 No	☐1 Yes
92	Have you all of a sudden changed your sense of who you are and where you are headed?	☐0 No	☐1 Yes
93	Does your sense of who you are often change dramatically?	☐0 No	☐1 Yes
94	Are you different with different people or in different situations, so that you sometimes don't know who you really are?	☐0 No	☐1 Yes
95	Have there been lots of sudden changes in your goals, career plans, religious beliefs, and so on?	☐0 No	☐1 Yes
96	Have you often done things impulsively?	☐0 No	☐1 Yes
97	Have you tried to hurt or kill yourself or threatened to do so?	☐0 No	☐1 Yes
98	Have you ever cut, burned, or scratched yourself on purpose?	☐0 No	☐1 Yes

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

#	Question		
99	Do you have a lot of sudden mood changes?	☐0 No	☐1 Yes
100	Do you often feel empty inside?	☐0 No	☐1 Yes
101	Do you often have temper outbursts or get so angry that you lose control?	☐0 No	☐1 Yes
102	Do you hit people or throw things when you get angry?	☐0 No	☐1 Yes
103	Do even little things get you very angry?	☐0 No	☐1 Yes
104	When you are under a lot of stress, do you get suspicious of other people or feel especially spaced out?	☐0 No	☐1 Yes
105	Before you were 15, would you bully or threaten other kids?	☐0 No	☐1 Yes
106	Before you were 15, would you start fights?	☐0 No	☐1 Yes
107	Before you were 15, did you hurt or threaten someone with a weapon, like a bat, brick, broken bottle, knife, or gun?	☐0 No	☐1 Yes
108	Before you were 15, did you deliberately torture someone or cause someone physical pain and suffering?	☐0 No	☐1 Yes
109	Before you were 15, did you torture or hurt animals on purpose?	☐0 No	☐1 Yes
110	Before you were 15, did you rob, mug, or forcibly take something from someone by threatening him or her?	☐0 No	☐1 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?	☐0 No	☐1 Yes
112	Before you were 15, did you set fires?	☐0 No	☐1 Yes
113	Before you were 15, did you deliberately destroy things that weren't yours?	☐0 No	☐1 Yes
114	Before you were 15, did you break into houses, other buildings, or cars?	☐0 No	☐1 Yes
115	Before you were 15, did you lie a lot or "con" other people?	☐0 No	☐1 Yes
116	Before you were 15, did you sometimes steal or shoplift things or forge someone's signature?	☐0 No	☐1 Yes
117	Before you were 15, did you run away from home and stay away overnight?	☐0 No	☐1 Yes
118	Before you were 13, did you often stay out very late, long after the time you were supposed to be home?	☐0 No	☐1 Yes
119	Before you were 13, did you often skip school?	☐0 No	☐1 Yes

Center Number: __ __ Participant Number: __ __ __ __ Participant's Initials: __ __ __ (first middle last)

Screening Visit 2 Checklist

1 Did participant return for Screening Visit 2?

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

☐ 1 Yes → **If Yes: Date of initial clinic visit for Screening Visit 2:** __ __ / __ __ __ / __ __ __ __ (day / month / year)

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?

☐ 0 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)*: ____________________

☐ 1 Yes → **If Yes: Date of scheduled Screening Visit 3:** __ __ / __ __ __ / __ __ __ __ (day / month / year)

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)

Screening Medical History

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

Body System	Assessments		
	No	**Yes**	**If Yes, Specify Diagnosis**
1 Head, Ears, Eyes, Nose, Throat	☐0	☐1 →	
2 Dermatologic	☐0	☐1 →	
3 Cardiovascular	☐0	☐1 →	
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 *(including contraception methods, females only)*	☐0	☐1 →	

Physician's Signature

Signature: ______________________________ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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

calerie **Phase 2**

Baseline Submission 1
Screening

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Date completed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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
1	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
2	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
3	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
4	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
5	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
6	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
7	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
8	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
9	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
10	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
11	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 Continuing	
12	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) OR ☐1 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 Concomitant Medication Log for Baseline Submission 1.

calerie Phase 2

Screening

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Physical Examination

Date of examination: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) OR Not done → Specify reason *(use codelist below)*: _______

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: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

* *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?

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

☐ 1 Yes → **If Yes: Date of initial clinic visit for Screening Visit 3:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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**

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

☐ 0 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)*: ______________________

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

☐ 1 Screening Visit 4 → **Date of scheduled Screening Visit 4:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

☐ 2 Baseline visit → **Date of scheduled Baseline Visit:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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?

- ☐ 0 No → **If No: Skip to question 4 and provide reason.**
- ☐ 1 Yes → **If Yes: Date of initial clinic visit for Screening Visit 4:** ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

Check completed items:

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

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

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

- ☐ 0 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)*: ______________________________
- ☐ 1 Yes → **If Yes: Date of scheduled Baseline Visit:** ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

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

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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Informed Consent

1 Did participant present for baseline visit?

☐ 0 No → **If No: Specify reason** *(check only one)*:
- ☐ 1 Failed an eligibility criterion *(participant no longer meets criteria)*
- ☐ 2 Lost interest in the study
- ☐ 3 Will take too much time
- ☐ 4 Scheduling conflicts with work or school
- ☐ 5 Doesn't like the study's procedures
- ☐ 6 Doesn't want to be involved in a research study
- ☐ 7 Unwilling to be randomized
- ☐ 8 Lives too far away/transportation problems
- ☐ 9 Needs help with child care *(unanticipated child care needs)*
- ☐ 10 Refused with no explanation
- ☐ 11 Unable to contact
- ☐ 98 Other *(specify)*: ______________________

☐ 1 Yes

2 Date and time study baseline informed consent signed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

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

Informed Consent Detail

Tissue consent:

Sample type	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	☐ 2	☐ 3
2 Urine archive	☐ 1	☐ 2	☐ 3
3 Muscle biopsy archive	☐ 1	☐ 2	☐ 3
4 Fat biopsy archive	☐ 1	☐ 2	☐ 3

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59) 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*): _______________	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (*Use codelist below*)	Staff Initials
Blood	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Date completed: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (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 →	
2 Dermatologic	☐0	☐1 →	
3 Cardiovascular	☐0	☐1 →	
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)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Physical Examination

Date of examination: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Staff initials: ___ ___ ___ (first middle last)

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

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

Investigator: ______________________________ (signature)

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

* *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

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)

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)*: ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐ 0 No

☐ 1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Results: ☐ 1 Negative

☐ 2 Positive

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

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 *(use codelist below)*: ___

2 DLW dose mixture ID and bottle number: ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA

3 Exact weight of DLW mixture: ___ ___ ___ . ___ ___ grams

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 4)	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:

Affix
Label
Here

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

DXA Scan

1 **Has the participant taken a calcium supplement today?**

☐ 0 No ☐ 1 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?**

☐ 0 No ☐ 1 Yes

DXA Scan		**DXA Rescan** OR ☐ 96 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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Profile of Mood States

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

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly	☐0	☐1	☐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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Not Done Codelist: **1** Participant refused **2** Clinician unable to obtain **3** Insufficient time **4** Instrument failure **5** Not required

Participant's Initials: ___ ___ ___ (first middle last)

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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Participant's Initials: ___ ___ ___ (first middle last)

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
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

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Participant's Initials: ___ ___ ___ (first middle last)

calerie **Phase 2**

Baseline Submission 1
Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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...

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)*	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
a Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h Have bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): ______________________	☐ 0	☐ 1	☐ 2	☐ 3
6 During the past month, how often have you taken medicine *(prescribed or "over the counter")* to help you sleep?	☐ 0	☐ 1	☐ 2	☐ 3

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

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?	☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

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

Section 2—Sexual Arousal

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				
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

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

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
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 *(if typical for you)*	☐ 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 *(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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Section 5—Drive and Relationship

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

Participant's Initials: ___ ___ ___ (first middle last)

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

Section 2—Sexual Arousal

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

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

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
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

	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
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

	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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calerie **Phase 2**

Baseline Submission 1
Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Food Cravings Questionnaire—Trait

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

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Food Cravings Questionnaire—Trait (continued)

	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Food Craving Inventory (FCI–II)

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

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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Date completed: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) 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.	☐1 True	☐0 False
2	I usually eat too much at social occasions, like parties and picnics.	☐1 True	☐0 False
3	I am usually so hungry that I eat more than three times a day.	☐1 True	☐0 False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐1 True	☐0 False
5	Dieting is so hard for me because I just get too hungry.	☐1 True	☐0 False
6	I deliberately take small helpings as a means of controlling my weight.	☐1 True	☐0 False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐1 True	☐0 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.	☐1 True	☐0 False
9	When I feel anxious, I find myself eating.	☐1 True	☐0 False
10	Life is too short to worry about dieting.	☐1 True	☐0 False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐1 True	☐0 False
12	I often feel so hungry that I just have to eat something.	☐1 True	☐0 False
13	When I am with someone who is overeating, I usually overeat too.	☐1 True	☐0 False
14	I have a pretty good idea of the number of calories in common food.	☐1 True	☐0 False
15	Sometimes when I start eating, I just can't seem to stop.	☐1 True	☐0 False
16	It is not difficult for me to leave something on my plate.	☐1 True	☐0 False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐1 True	☐0 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.	☐1 True	☐0 False

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

Participant's Initials: ___ ___ ___ (first middle last)

Eating Inventory (continued)

#	Item	True	False
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

Eating Inventory (continued)

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

#	Question	Responses
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 ☐2 Slightly difficult ☐3 Moderately difficult ☐4 Very difficult
42	How conscious are you of what you are eating?	☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐1 Almost never ☐2 Seldom ☐3 Usually ☐4 Almost always
44	How likely are you to shop for low calorie foods?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately 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 ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
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
48	How likely are you to consciously eat less than you want?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
49	Do you go on eating binges though you are not hungry?	☐1 Never ☐2 Rarely ☐3 Sometimes ☐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"

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

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)*.	☐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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**.
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?	☐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

Participant's Initials: ___ ___ ___ (first middle last)

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks...	Never	Rarely	Some-times	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

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)*: ___

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

Weight 1: ___ ___ ___ . ___ kg

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 Phase 2

Baseline Submission 1 *Visit 3*

Center Number: ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐ 0 No → **Skip to question 3** ☐ 1 Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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 Phase 2

Baseline Submission 1
Visit 3

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

6-Day Food Record

Complete below OR Not done → Specify reason *(use Codelist below)*: ________ Staff initials: ___ ___ ___ (first middle last)

			Replacement Values		
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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

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 Phase 2_CRF_V7.0_26 SEP 2008

Center Number: ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (*first middle last*)

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 codelist below*): ___

Interviewer initials: ___ ___ ___ (*first middle last*)

1 **Were you employed in the last seven days?** ☐$_0$ No → **Skip to question 3** ☐$_1$ Yes

2 **If Yes: Which days** (*check all that apply*)**?** ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 **Which days do you consider your weekend, or non-work, days?** ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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)	__ __ : __ __ (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)	__ __ : __ __ (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)	__ __ : __ __ (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)	__ __ : __ __ (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)	__ __ : __ __ (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)	__ __ : __ __ (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)	__ __ : __ __ (00:00 to 23:59)	__ __ : __ __ (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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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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 *(use codelist below)*: ___

1 Dynometer handle position: __________

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

3 Handgrip strength:

Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand
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

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 *(use codelist below)*: ___

1 Recent injury or pain—right knee? ☐0 No ☐1 Yes

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes

3 Specify machine used *(PBRC only)*: ☐0 Cybex ☐1 Biolex

All values corrected for gravity effect torque		Right Leg	Left Leg	If Not Done, Specify Reason *(Use codelist below)*
3 60°/sec knee extension	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
4 60°/sec knee flexion	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
5 180°/sec knee extension	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
	work fatigue index	________ %	________ %	
6 180°/sec knee flexion	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
	work fatigue index	________ %	________ %	
7 Isometric knee extension: trial 1	peak torque	________ N.m	________ N.m	
trial 2	peak torque	________ N.m	________ N.m	________
trial 3	peak torque	________ N.m	________ N.m	
8 Isometric knee flexion: trial 1	peak torque	________ N.m	________ N.m	
trial 2	peak torque	________ N.m	________ N.m	________
trial 3	peak torque	________ N.m	________ N.m	

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

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 (*use codelist below*): __

2 DLW dose mixture ID and bottle number: __ __ – __ __ __ __ – __ __ __ – CA

3 Exact weight of DLW mixture: __ __ __ . __ __ grams

4 Urine samples:

Collection	Sample	Date and Time Collected
Day 0 (Visit 4)	D0a	__ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D0b	__ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 7 (Visit 5)	D7a	__ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D7b	__ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 14 (Visit 7)	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:

Affix
Label
Here

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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

VO_2 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 *(use codelist 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 ☐98 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 → **Complete all that apply: HR when true cardiac angina occurred:** __________ bpm OR ☐96 NA
  HR when ischemic ECG changes occurred: __________ bpm OR ☐96 NA
- ☐ 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/tri-geminy, NSVT [≥ 3 beats])*?

☐0 No

☐1 Yes → **If Yes: When did it occur** *(check all that apply)*? ☐ During exercise ☐ During recovery

7 Peak VO_2: __________ mL/kg/min __________ L/min

8 Did the participant meet at least 2 of the 3 VO_2 max criteria *(see box,right)*?

☐0 No

☐1 Yes → **If Yes: VO_2 max:** __________ mL/kg/min __________ L/min

> *a Achieve a plateau in VO_2 (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 VO_2 peak/VO_2 max: ___ ___ ___/___ ___ ___ mm Hg (systolic diastolic)

11 Borg RPE score at VO_2 peak/VO_2 max: __________ *(6–20)*

12 Peak RER: __________

13 VE at VO_2 peak/VO_2 max: __________ L/min

14 VE/VO_2 at VO_2 peak/VO_2 max __________ L/min

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

calerie Phase 2

Baseline Submission 2 Visit 5

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐$_0$ No → **Skip to question 3** ☐$_1$ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

6-Day Food Record

Complete below OR Not done → Specify reason *(use Codelist below)*: ________ Staff initials: ___ ___ ___ (first middle last)

			Replacement Values		
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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed?

☐ 0 No

☐ 1 Yes → **If Yes: Were any Exclusion criteria met?** ☐ 0 No → **Proceed with test**

☐ 1 Yes → **STOP. Do not administer test.**

2 Date of injection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **OR Not done → Specify reason** *(use codelist below)*: ___

3 Injection by *(initials)*: ___ ___ ___ (first middle last)

4 Arm injected: ☐ 1 Right ☐ 2 Left

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

B = Second diameter perpendicular to A

Antigen	24 Hour *(@Visit 7)*			48 Hour *(@Visit 8)*		
	A *(diameter)*	B *(diameter)*	Read By:	A *(diameter)*	B *(diameter)*	Read By:
1 Normal saline	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*
2 Tetanus toxoid *(TT)*	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
3 Candida	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
4 Trichophyton	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	

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

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___/___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___ /___ ___ ___/___ ___ ___ ___ (day / month / year)

Results: ☐1 Negative

☐2 Positive

Core Temperature

Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason *(Use codelist below)*
___ ___ ___ (first middle last)	Start Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day / month / year)	Start Time ___ ___ : ___ ___ (00:00 to 23:59)	______
	Stop Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day / month / year)	Stop Time ___ ___ : ___ ___ (00:00 to 23:59)	

Inpatient Admission and Discharge

1 Inpatient admission date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

2 Inpatient discharge date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (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

calerie Phase 2

Baseline Submission 2 *Visit 7*

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐$_0$ No → **Skip to question 3** ☐$_1$ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 00:00 to 23:59	___ ___ : ___ ___ 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

2008 DCRI — Confidential

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

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 Phase 2

Baseline Submission 2
Visit 7

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Outcomes Labs

Date and time of last meal: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Catecholamines	☐ 0 No ☐ 1 Yes	______	___ ___ ___ (first middle last)
Blood	☐ 0 No ☐ 1 Yes	______	___ ___ ___ (first middle last)
Oral glucose tolerance test *(OGTT)*	☐ 0 No ☐ 1 Yes	______	___ ___ ___ (first middle last)

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

Biopsy Labs

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Muscle biopsy	___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	______	___ ___ ___ (first middle last)
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 (Use codelist below)	Staff Initials
___ ___ ___ ___ ___ mL	Start Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) Stop Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	Start Time: ___ ___ : ___ ___ (00:00 to 23:59) Stop Time: ___ ___ : ___ ___ (00:00 to 23:59)	______	___ ___ ___ (first middle last)

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

calerie Phase 2

Baseline Submission 2
Visit 7

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Sex Hormone

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

Contraception method *(females only)*:	☐ None **OR Check all that apply:** ☐ Oral contraceptive → **Specify:** ______________ **Record on Concomitant Medications page** ☐ Other → **Specify** *(e.g., barrier, IUD)*: ______________

Day 1	Date	Time	If Not Done, Reason *(use codelist)*	Staff Initials
~~Day 1 of menses (females only)~~				
Date and time of last meal **(males only)**	___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	___ ___ : ___ ___ (00:00 to 23:59)		
Hormone level blood draw 1 **(males only)**	___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	___ ___ : ___ ___ (00:00 to 23:59)	_______	___ ___ ___ (first middle last)
~~Hormone level blood draw 2 (females only)~~ ~~*Progesterone level*~~				
Day 2	**Date**	**Time**	**If Not Done, Reason** *(use codelist)*	**Staff Initials**
~~Date and time of last meal~~				
~~Hormone level blood draw 3 (females only)~~ ~~*Progesterone level*~~				

DXA Scan

1 Has the participant taken a calcium supplement today?

☐ 0 No ☐ 1 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?

☐ 0 No ☐ 1 Yes

DXA Scan		DXA Rescan OR ☐ 96 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

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
Resting Metabolic Rate *(RMR)*—Visit 7	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	______	___ ___ ___ (first middle last)
Cart ID	☐ 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)		
Sample	**Date of Collection**	**If Not Done, Reason** *(Use codelist below)*	**Staff Initials**
Resting Metabolic Rate *(RMR)*—Visit 8	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	______	___ ___ ___ (first middle last)
Cart ID	☐ 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

Baseline Submission 2
Randomization

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Randomization

Date of randomization: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

Treatment Group

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

- ☐ 1 CR–calorie restricted
- ☐ 2 AL–ab libitum *(control)*

Intervention

Did participant start intervention?

- ☐ 0 No → **Complete the Study completion/Early Discontinuation of Study Evaluation**
- ☐ 1 Yes → **If Yes: Date intervention started:** ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

Staff Signature NOTE: Signature of staff that randomized participant

Signature: ________________________________ **Date:** ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) 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)*: ______	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Contraception

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

Contraception method *(females only)*:	☐ None **OR Check all that apply:** ☐ 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 Phase 2

Month 3 Submission

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

1 Natural waist measurement **Staff initials:** ___ ___ ___ (first middle last)
(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Natural waist measurement 1: ___ ___ ___ . ___ cm

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: ___ ___ ___/___ ___ ___ (systolic/diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___/___ ___ ___ (systolic/diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___/___ ___ ___ (systolic/diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59) 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*): ______	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (*Use codelist below*)	Staff Initials
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Outcomes Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (*Use codelist below*)	Staff Initials
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

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

Contraception

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

Contraception method (*females only*):

☐ None **OR Check all that apply:**

☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Participant's Initials: ___ ___ ___ (first middle last)

Month 6 Submission
CR Visit 1/Control Visit 2

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___ /___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ /___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ /___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59) 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)*: ____________	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)

Contraception

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

Contraception method *(females only)*:	☐ None **OR Check all that apply:** ☐ 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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

Results: ☐1 Negative
☐2 Positive

DXA Scan

1 **Has the participant taken a calcium supplement today?**

☐0 No ☐1 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?**

☐0 No ☐1 Yes

DXA Scan		**DXA Rescan** OR ☐96 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

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

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 *(use codelist below)*: ___

2 DLW dose mixture ID and bottle number: ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA

3 Exact weight of DLW mixture: ___ ___ ___ . ___ ___ grams

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:

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

calerie **Phase 2**

Month 6 Submission
CR Visit 2/Control Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Profile of Mood States

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

	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1	Friendly	☐ 0	☐ 1	☐ 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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Not Done Codelist: **1** Participant refused **2** Clinician unable to obtain **3** Insufficient time **4** Instrument failure **5** Not required

Participant's Initials: ___ ___ ___ (first middle last)

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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Participant's Initials: ___ ___ ___ (first middle last)

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
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

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Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

calerie Phase 2

Month 6 Submission
CR Visit 2/Control Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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...

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)*	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
a Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h Have bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): ______________________	☐ 0	☐ 1	☐ 2	☐ 3
6 During the past month, how often have you taken medicine *(prescribed or "over the counter")* to help you sleep?	☐ 0	☐ 1	☐ 2	☐ 3

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

Participant's Initials: ___ ___ ___ (first middle last)

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?	☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

Participant's Initials: ___ ___ ___ (first middle last)

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

Section 2—Sexual Arousal

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				
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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Section 3—Sexual Behavior/Experiences

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

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
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 *(if typical for you)*	☐ 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 *(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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Participant's Initials: ___ ___ ___ (first middle last)

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

Section 5—Drive and Relationship

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Section 2—Sexual Arousal

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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Participant's Initials: ___ ___ ___ (first middle last)

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

Section 3—Sexual Behavior/Experiences

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

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
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

	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
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

	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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calerie Phase 2

Month 6 Submission
CR Visit 2/Control Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Food Craving Inventory (FCI–II)

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

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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first, middle, last)

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

Eating Inventory

#	Statement	True	False
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.	☐ 1 True	☐ 0 False
2	I usually eat too much at social occasions, like parties and picnics.	☐ 1 True	☐ 0 False
3	I am usually so hungry that I eat more than three times a day.	☐ 1 True	☐ 0 False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐ 1 True	☐ 0 False
5	Dieting is so hard for me because I just get too hungry.	☐ 1 True	☐ 0 False
6	I deliberately take small helpings as a means of controlling my weight.	☐ 1 True	☐ 0 False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False
9	When I feel anxious, I find myself eating.	☐ 1 True	☐ 0 False
10	Life is too short to worry about dieting.	☐ 1 True	☐ 0 False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐ 1 True	☐ 0 False
12	I often feel so hungry that I just have to eat something.	☐ 1 True	☐ 0 False
13	When I am with someone who is overeating, I usually overeat too.	☐ 1 True	☐ 0 False
14	I have a pretty good idea of the number of calories in common food.	☐ 1 True	☐ 0 False
15	Sometimes when I start eating, I just can't seem to stop.	☐ 1 True	☐ 0 False
16	It is not difficult for me to leave something on my plate.	☐ 1 True	☐ 0 False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False

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

Participant's Initials: ___ ___ ___ (first, middle, last)

Eating Inventory (continued)

No.	Item	True	False
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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Eating Inventory (continued)

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

#	Question	Responses
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 ☐2 Slightly difficult ☐3 Moderately difficult ☐4 Very difficult
42	How conscious are you of what you are eating?	☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐1 Almost never ☐2 Seldom ☐3 Usually ☐4 Almost always
44	How likely are you to shop for low calorie foods?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately 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 ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
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
48	How likely are you to consciously eat less than you want?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
49	Do you go on eating binges though you are not hungry?	☐1 Never ☐2 Rarely ☐3 Sometimes ☐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"

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

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)*.	☐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

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

Participant's Initials: ___ ___ ___ (first middle last)

2008 DCRI — Confidential

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

calerie Phase 2

Month 6 Submission
CR Visit 2/Control Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**.
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?	☐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

Participant's Initials: ___ ___ ___ (first middle last)

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks...	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

Participant's Initials: ___ ___ ___ (first middle last)

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):* _______

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

Weight 1: ___ ___ ___ . ___ kg

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

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calerie Phase 2

Month 6 Submission — CR Visit 3

Center Number: ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐$_0$ No → **Skip to question 3** ☐$_1$ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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 Phase 2

Month 6 Submission
CR Visit 3

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

6-Day Food Record

Complete below OR Not done → Specify reason *(use Codelist below)*: ________ Staff initials: ___ ___ ___ (first middle last)

			Replacement Values		
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

calerie Phase 2

Month 6 Submission
CR Visit 5/Control Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Outcomes Labs

Date and time of last meal: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

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)*
___ ___ ___ (first middle last)	Start Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	Start Time ___ ___ : ___ ___ (00:00 to 23:59)	______
	Stop Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	Stop Time ___ ___ : ___ ___ (00:00 to 23:59)	

Inpatient Admission and Discharge

1 Inpatient admission date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

2 Inpatient discharge date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Results: ☐1 Negative

☐2 Positive

calerie Phase 2

Month 6 Submission
CR Visit 5

Center Number: __ __ Participant Number: __ __ __ __ Participant's Initials: __ __ __ (first middle last)

DXA Scan

1 Has the participant taken a calcium supplement today?

☐ 0 No ☐ 1 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?

☐ 0 No ☐ 1 Yes

DXA Scan		DXA Rescan OR ☐ 96 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)
Cart ID	☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐0 No → **Skip to question 3** ☐1 Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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 Phase 2

Month 9 Submission

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59) 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): ______	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Contraception

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

Contraception method (*females only*):	☐ None **OR Check all that apply:** ☐ 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

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) 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)*: _______	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐$_0$ No ☐$_1$ Yes	_______	___ ___ ___ (first middle last)
Urine	☐$_0$ No ☐$_1$ Yes	_______	___ ___ ___ (first middle last)

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐$_0$ No

☐$_1$ Yes → **If Yes: Date urine pregnancy test performed:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Results: ☐$_1$ Negative

☐$_2$ Positive

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

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 *(use codelist below)*: ___

2 DLW dose mixture ID and bottle number: ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA

3 Exact weight of DLW mixture: ___ ___ ___ . ___ ___ grams

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 1)	D0a	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)
	D0b	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)
	D7b	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day/month/year) ___ ___ : ___ ___ (00:00 to 23:59)
Day 14 (Visit 4)	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:

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

Physical Examination

Date of examination: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year) Staff initials: ___ ___ ___ (first middle last)

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

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

Investigator: ______________________________ (signature) Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

* *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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

DXA Scan

1 Has the participant taken a calcium supplement today?

☐0 No ☐1 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?

☐0 No ☐1 Yes

DXA Scan		DXA Rescan OR ☐96 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

calerie Phase 2

Month 12 Submission Visit 1

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Profile of Mood States

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

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly	☐ 0	☐ 1	☐ 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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Not Done Codelist: **1** Participant refused **2** Clinician unable to obtain **3** Insufficient time **4** Instrument failure **5** Not required

Participant's Initials: ___ ___ ___ (first middle last)

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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Participant's Initials: ___ ___ ___ (first middle last)

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
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

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Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

		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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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...

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)*

	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
a Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h Have bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): ____________________	☐ 0	☐ 1	☐ 2	☐ 3
6 During the past month, how often have you taken medicine *(prescribed or "over the counter")* to help you sleep?	☐ 0	☐ 1	☐ 2	☐ 3

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

Participant's Initials: ___ ___ ___ (first middle last)

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?	☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

Participant's Initials: ___ ___ ___ (first middle last)

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

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				
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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Participant's Initials: ___ ___ ___ (first middle last)

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

Section 3—Sexual Behavior/Experiences

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

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 *(if typical for you)*	☐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 *(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) (F) Female Version (continued)

Section 5—Drive and Relationship

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

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

Section 2—Sexual Arousal

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

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

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
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

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

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Month 12 Submission
Visit 1

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Food Craving Inventory (FCI–II)

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

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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Eating Inventory

#	Item	True	False
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.	☐ 1 True	☐ 0 False
2	I usually eat too much at social occasions, like parties and picnics.	☐ 1 True	☐ 0 False
3	I am usually so hungry that I eat more than three times a day.	☐ 1 True	☐ 0 False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐ 1 True	☐ 0 False
5	Dieting is so hard for me because I just get too hungry.	☐ 1 True	☐ 0 False
6	I deliberately take small helpings as a means of controlling my weight.	☐ 1 True	☐ 0 False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False
9	When I feel anxious, I find myself eating.	☐ 1 True	☐ 0 False
10	Life is too short to worry about dieting.	☐ 1 True	☐ 0 False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐ 1 True	☐ 0 False
12	I often feel so hungry that I just have to eat something.	☐ 1 True	☐ 0 False
13	When I am with someone who is overeating, I usually overeat too.	☐ 1 True	☐ 0 False
14	I have a pretty good idea of the number of calories in common food.	☐ 1 True	☐ 0 False
15	Sometimes when I start eating, I just can't seem to stop.	☐ 1 True	☐ 0 False
16	It is not difficult for me to leave something on my plate.	☐ 1 True	☐ 0 False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐ 1 True	☐ 0 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.	☐ 1 True	☐ 0 False

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

Eating Inventory (continued)

#	Item	True	False
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

Participant's Initials: ___ ___ ___ (first middle last)

Eating Inventory (continued)

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

#	Question	Answers
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 ☐2 Slightly difficult ☐3 Moderately difficult ☐4 Very difficult
42	How conscious are you of what you are eating?	☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐1 Almost never ☐2 Seldom ☐3 Usually ☐4 Almost always
44	How likely are you to shop for low calorie foods?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately 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 ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
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
48	How likely are you to consciously eat less than you want?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
49	Do you go on eating binges though you are not hungry?	☐1 Never ☐2 Rarely ☐3 Sometimes ☐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"

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

I am confident that:	0	1	2	3	4	5	6	7	8	9
	Not confident at all that you can resist the desire to eat									**Very confident** that you can resist the desire to eat
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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

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

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

Participant's Initials: ___ ___ ___
first middle last

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**.
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?	☐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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks...	Never	Rarely	Some-times	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 *(use codelist below)*: ___

1 Dynometer handle position: __________

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

3 Handgrip strength:

Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand
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

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 *(use codelist below)*: ___

1 Recent injury or pain—right knee? ☐0 No ☐1 Yes

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes

3 Specify machine used *(PBRC only)*: ☐0 Cybex ☐1 Biolex

All values corrected for gravity effect torque			Right Leg	Left Leg	If Not Done, Specify Reason *(Use codelist below)*
3 60°/sec knee extension		peak torque	______ N.m	______ N.m	
		total work	______ N.m	______ N.m	______
		average power	______ watts	______ watts	
4 60°/sec knee flexion		peak torque	______ N.m	______ N.m	
		total work	______ N.m	______ N.m	______
		average power	______ watts	______ watts	
5 180°/sec knee extension		peak torque	______ N.m	______ N.m	
		total work	______ N.m	______ N.m	______
		average power	______ watts	______ watts	
		work fatigue index	______ %	______ %	
6 180°/sec knee flexion		peak torque	______ N.m	______ N.m	
		total work	______ N.m	______ N.m	______
		average power	______ watts	______ watts	
		work fatigue index	______ %	______ %	
7 Isometric knee extension:	trial 1	peak torque	______ N.m	______ N.m	
	trial 2	peak torque	______ N.m	______ N.m	______
	trial 3	peak torque	______ N.m	______ N.m	
8 Isometric knee flexion:	trial 1	peak torque	______ N.m	______ N.m	
	trial 2	peak torque	______ N.m	______ N.m	______
	trial 3	peak torque	______ N.m	______ N.m	

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

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):* ___

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

Weight 1:	___ ___ ___ . ___ kg
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

Phase 2

Month 12 Submission *Visit 2*

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐0 No → **Skip to question 3** ☐1 Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 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	___ ___ : ___ ___ 00:00 to 23:59	___ ___ : ___ ___ 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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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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (*first middle last*)

6-Day Food Record

Complete below OR Not done → Specify reason (*use Codelist below*): ________ **Staff initials:** ___ ___ ___ (*first middle last*)

			Replacement Values		
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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

VO_2 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 *(use codelist 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 ☐98 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 → **Complete all that apply: HR when true cardiac angina occurred:** __________ bpm OR ☐96 NA
  HR when ischemic ECG changes occurred: __________ bpm OR ☐96 NA
- ☐ 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/tri-geminy, NSVT [≥ 3 beats])*?

☐0 No

☐1 Yes → **If Yes: When did it occur** *(check all that apply)*? ☐ During exercise ☐ During recovery

7 Peak VO_2: __________ mL/kg/min __________ L/min

8 Did the participant meet at least 2 of the 3 VO_2 max criteria *(see box, right)*?

☐0 No

☐1 Yes → **If Yes: VO_2 max:** __________ mL/kg/min __________ L/min

> *a Achieve a plateau in VO_2 (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 VO_2 peak/VO_2 max: ___ ___ ___ /___ ___ ___ (systolic / diastolic) mm Hg

11 Borg RPE score at VO_2 peak/VO_2 max: __________ *(6–20)*

12 Peak RER: __________

13 VE at VO_2 peak/VO_2 max: __________ L/min

14 VE/VO_2 at VO_2 peak/VO_2 max __________ L/min

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Core Temperature

Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason *(Use codelist below)*
___ ___ ___ (first middle last)	Start Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	Start Time ___ ___ : ___ ___ (00:00 to 23:59)	______
	Stop Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	Stop Time ___ ___ : ___ ___ (00:00 to 23:59)	

Inpatient Admission and Discharge

1. Inpatient admission date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)
2. Inpatient discharge date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed?

☐0 No

☐1 Yes → **If Yes: Were any Exclusion criteria met?** ☐0 No → **Proceed with test**

☐1 Yes → **STOP. Do not administer test.**

2 Date of injection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **OR Not done → Specify reason** *(use codelist below)*: ___

3 Injection by *(initials)*: ___ ___ ___ (first middle last)

4 Arm injected: ☐1 Right ☐2 Left

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

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	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*
2 Tetanus toxoid *(TT)*	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
3 Candida	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
4 Trichophyton	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	

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

calerie Phase 2

Month 12 Submission
Visit 4

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)*: ______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Outcomes Labs

Date and time of last meal: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Catecholamines	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Oral glucose tolerance test *(OGTT)*	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

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

24-hour Urine Collection

Total Volume Collected	Date of Sample Collection	Time of Sample Collection	If Not Done, Reason (Use codelist below)	Staff Initials
___ ___ ___ ___ ___ mL	Start Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) Stop Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	Start Time: ___ ___ : ___ ___ (00:00 to 23:59) Stop Time: ___ ___ : ___ ___ (00:00 to 23:59)	______	___ ___ ___ (first middle last)

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

calerie **Phase 2**

Month 12 Submission
Visit 4

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Sex Hormone

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

Contraception method *(females only)*:	☐ None **OR Check all that apply:** ☐ Oral contraceptive → **Specify:** ________________ Record on Concomitant Medications page ☐ Other → **Specify** *(e.g., barrier, IUD)*: ________________

Day 1	Date	Time	If Not Done, Reason (use codelist)	Staff Initials
~~Day 1 of menses **(females only)**~~				
Date and time of last meal **(males only)**	__ __/__ __ __/__ __ __ __ (day month year)	__ __ : __ __ (00:00 to 23:59)		
Hormone level blood draw 1 **(males only)**	__ __/__ __ __/__ __ __ __ (day month year)	__ __ : __ __ (00:00 to 23:59)	_______	___ ___ ___ (first middle last)
~~Hormone level blood draw 2 **(females only)**~~ ~~*Progesterone level*~~				
Day 2	**Date**	**Time**	**If Not Done, Reason** (use codelist)	**Staff Initials**
~~Date and time of last meal~~				
~~Hormone level blood draw 3 **(females only)**~~ ~~*Progesterone level*~~				

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 4	__ __/__ __ __/__ __ __ __ (day month year)	_______	___ ___ ___ (first middle last)
Cart ID	☐ 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

calerie Phase 2

Month 12 Submission ***Visit 4***

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐ $_0$ No → **Skip to question 3** ☐ $_1$ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__ __ : __ __ 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	__ __ : __ __ 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	__ __ : __ __ 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	__ __ : __ __ 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	__ __ : __ __ 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	__ __ : __ __ 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	__ __ : __ __ 00:00 to 23:59	__ __ : __ __ 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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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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Biopsy Labs

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Muscle biopsy	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	______	___ ___ ___ (first middle last)
Fat biopsy	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)	______	___ ___ ___ (first middle last)

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

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)*: ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

Results: ☐1 Negative ☐2 Positive

Outcomes Labs

Date and time sample collection started: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Sample *If a sample is not obtained, indicate with a Not Done.*	**Sample Complete?**	**If Not Done, Reason** *(Use codelist below)*	**Staff Initials**
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Vaccine Administration *NOTE: Before any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.*		**If Not Done, Reason** *(Use codelist below)*	**Staff Initials**
Vaccine(s) given *(check all that apply)***:**	☐ Hepatitis A ☐ Tetanus/diphtheria ☐ Pneumococcal vaccine	______	___ ___ ___ (first middle last)

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

calerie Phase 2

Month 18 Submission
CR Visit 1/Control Visit

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

1 Natural waist measurement **Staff initials:** ___ ___ ___ (first middle last)
(if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Natural waist measurement 1: ___ ___ ___ . ___ cm

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: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ / ___ ___ ___ (systolic / diastolic) mm Hg **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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59) 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*): ___________	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (*Use codelist below*)	Staff Initials
Blood	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)

Outcomes Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason (*Use codelist below*)	Staff Initials
Blood	☐0 No ☐1 Yes	_______	___ ___ ___ (first middle last)

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

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

calerie Phase 2

Month 18 Submission
CR Visit 1

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 (*use codelist below*): ___

2 DLW dose mixture ID and bottle number: ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA

3 Exact weight of DLW mixture: ___ ___ ___ . ___ ___ grams

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 1)	D0a	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)
	D0b	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)
	D7b	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)
Day 14 (Visit 4)	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:

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Results: ☐1 Negative
☐2 Positive

DXA Scan

1 Has the participant taken a calcium supplement today?

☐0 No ☐1 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?

☐0 No ☐1 Yes

DXA Scan		**DXA Rescan** OR ☐96 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

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

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Contraception

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

Contraception method *(females only)***:**

☐ None **OR Check all that apply:**

☐ 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 Phase 2

Month 18 Submission CR Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐₀ No → **Skip to question 3** ☐₁ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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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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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

6-Day Food Record

Complete below OR Not done → Specify reason *(use Codelist below)*: ________ Staff initials: ___ ___ ___ (first middle last)

			Replacement Values		
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

calerie Phase 2

Month 18 Submission
CR Visit 2/Control Visit

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Participant's Initials: ___ ___ ___ (first middle last)

calerie Phase 2

Month 18 Submission
CR Visit 4

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Inpatient Admission and Discharge

1 Inpatient admission date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

2 Inpatient discharge date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

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)*: ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

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)
Cart ID	☐ 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

Month 18 Submission CR Visit 4

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐ 0 No → **Skip to question 3** ☐ 1 Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → **If Yes: Date urine pregnancy test performed:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Results: ☐1 Negative

☐2 Positive

Outcomes Labs

Date and time sample collection started: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample *If a sample is not obtained, indicate with a Not Done.*	**Sample Complete?**	**If Not Done, Reason** (Use codelist below)	**Staff Initials**
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Vaccine Administration *NOTE: Before any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.*		**If Not Done, Reason** (Use codelist below)	**Staff Initials**
Vaccine(s) given:	☐ Hepatitis A	______	___ ___ ___ (first middle last)

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

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)*: _______

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

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)*: _______

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

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 (systolic / diastolic) **Time:** ___ ___ : ___ ___ (00:00 to 23:59) **OR Not done → Specify reason** *(use codelist below)*: _______

6b Blood pressure 2: ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic) **Time:** ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic) **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 Phase 2

Month 24 Submission
Visit 1

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

12-Lead ECG

Date and Time	Findings	Staff Initials
___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59) 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)*: ________	___ ___ ___ (first middle last)

Safety Labs

Date and time of last meal: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Date and time of sample collection: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year) ___ ___:___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐0 No ☐1 Yes	________	___ ___ ___ (first middle last)
Urine	☐0 No ☐1 Yes	________	___ ___ ___ (first middle last)

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

☐1 Yes → If Yes: Date urine pregnancy test performed: ___ ___/___ ___ ___/___ ___ ___ ___ (day/month/year)

Results: ☐1 Negative
☐2 Positive

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

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 (*use codelist below*): ___

2 DLW dose mixture ID and bottle number: ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA

3 Exact weight of DLW mixture: ___ ___ ___ . ___ ___ grams

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 1)	D0a	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)
	D0b	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)
	D7b	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) ___ ___:___ ___ (00:00 to 23:59)
Day 14 (Visit 4)	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:

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Physical Examination

Date of examination: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Staff initials: ___ ___ ___ (first middle last)

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

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

Investigator: ______________________________ (signature)

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

* *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

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2008 DCRI — Confidential

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

DXA Scan

1 Has the participant taken a calcium supplement today?

☐$_0$ No ☐$_1$ 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?

☐$_0$ No ☐$_1$ Yes

DXA Scan		**DXA Rescan** OR ☐$_{96}$ 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

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

calerie Phase 2

Month 24 Submission
Visit 1

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Profile of Mood States

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

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly	☐ 0	☐ 1	☐ 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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Not Done Codelist: **1** Participant refused **2** Clinician unable to obtain **3** Insufficient time **4** Instrument failure **5** Not required

Participant's Initials: ___ ___ ___ (first middle last)

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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Participant's Initials: ___ ___ ___ (first middle last)

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
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

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Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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...

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)*	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
a Cannot get to sleep within 30 minutes	☐ 0	☐ 1	☐ 2	☐ 3
b Wake up in the middle of the night or early morning	☐ 0	☐ 1	☐ 2	☐ 3
c Have to get up to use the bathroom	☐ 0	☐ 1	☐ 2	☐ 3
d Cannot breathe comfortably	☐ 0	☐ 1	☐ 2	☐ 3
e Cough or snore loudly	☐ 0	☐ 1	☐ 2	☐ 3
f Feel too cold	☐ 0	☐ 1	☐ 2	☐ 3
g Feel too hot	☐ 0	☐ 1	☐ 2	☐ 3
h Have bad dreams	☐ 0	☐ 1	☐ 2	☐ 3
i Have pain	☐ 0	☐ 1	☐ 2	☐ 3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): ______________________	☐ 0	☐ 1	☐ 2	☐ 3
6 During the past month, how often have you taken medicine *(prescribed or "over the counter")* to help you sleep?	☐ 0	☐ 1	☐ 2	☐ 3

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

Participant's Initials: ___ ___ ___ (first middle last)

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?	☐ 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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

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

Section 2—Sexual Arousal

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
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

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

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
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 *(if typical for you)*	☐ 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 *(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) (F) Female Version (continued)

Section 5—Drive and Relationship

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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 "O = 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.

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

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

Section 2—Sexual Arousal

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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Section 3—Sexual Behavior/Experiences

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

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
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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Participant's Initials: ___ ___ ___ (first middle last)

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

Section 5—Drive and Relationship

	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
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

	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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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

	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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Food Craving Inventory (FCI–II)

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

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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

Eating Inventory

#	Item	True	False
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.	☐1 True	☐0 False
2	I usually eat too much at social occasions, like parties and picnics.	☐1 True	☐0 False
3	I am usually so hungry that I eat more than three times a day.	☐1 True	☐0 False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐1 True	☐0 False
5	Dieting is so hard for me because I just get too hungry.	☐1 True	☐0 False
6	I deliberately take small helpings as a means of controlling my weight.	☐1 True	☐0 False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐1 True	☐0 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.	☐1 True	☐0 False
9	When I feel anxious, I find myself eating.	☐1 True	☐0 False
10	Life is too short to worry about dieting.	☐1 True	☐0 False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐1 True	☐0 False
12	I often feel so hungry that I just have to eat something.	☐1 True	☐0 False
13	When I am with someone who is overeating, I usually overeat too.	☐1 True	☐0 False
14	I have a pretty good idea of the number of calories in common food.	☐1 True	☐0 False
15	Sometimes when I start eating, I just can't seem to stop.	☐1 True	☐0 False
16	It is not difficult for me to leave something on my plate.	☐1 True	☐0 False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	☐1 True	☐0 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.	☐1 True	☐0 False

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

Participant's Initials: ___ ___ ___ (first middle last)

Eating Inventory (continued)

#	Item	True	False
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

Eating Inventory (continued)

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

#	Question	Answers
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 ☐2 Slightly difficult ☐3 Moderately difficult ☐4 Very difficult
42	How conscious are you of what you are eating?	☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐1 Almost never ☐2 Seldom ☐3 Usually ☐4 Almost always
44	How likely are you to shop for low calorie foods?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately 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 ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
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
48	How likely are you to consciously eat less than you want?	☐1 Unlikely ☐2 Slightly likely ☐3 Moderately likely ☐4 Very likely
49	Do you go on eating binges though you are not hungry?	☐1 Never ☐2 Rarely ☐3 Sometimes ☐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"

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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.

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)*.	☐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

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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

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	Some-times	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

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

Participant's Initials: ___ ___ ___ (first middle last)

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

	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

Participant's Initials: ___ ___ ___
first middle last

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

Center Number: __ __ Participant Number: __ __ __ __ Participant's Initials: __ __ __ (first middle last)

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

Body Shape Questionnaire (BSQ)

We would like to know how you have been feeling about your appearance over the **past four weeks**.
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?	☐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

Participant's Initials: __ __ __ (first middle last)

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks...	Never	Rarely	Some-times	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

Participant's Initials: ___ ___ ___ (first middle last)

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 *(use codelist below)*: ___

1 **Dynometer handle position:** __________

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

3 **Handgrip strength:**

Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand
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

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 *(use codelist below)*: ___

1 Recent injury or pain—right knee? ☐0 No ☐1 Yes

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes

3 Specify machine used *(PBRC only)*: ☐0 Cybex ☐1 Biolex

All values corrected for gravity effect torque		Right Leg	Left Leg	If Not Done, Specify Reason *(Use codelist below)*
3 60°/sec knee extension	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
4 60°/sec knee flexion	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
5 180°/sec knee extension	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
	work fatigue index	________ %	________ %	
6 180°/sec knee flexion	peak torque	________ N.m	________ N.m	
	total work	________ N.m	________ N.m	________
	average power	________ watts	________ watts	
	work fatigue index	________ %	________ %	
7 Isometric knee extension: trial 1	peak torque	________ N.m	________ N.m	
trial 2	peak torque	________ N.m	________ N.m	________
trial 3	peak torque	________ N.m	________ N.m	
8 Isometric knee flexion: trial 1	peak torque	________ N.m	________ N.m	
trial 2	peak torque	________ N.m	________ N.m	________
trial 3	peak torque	________ N.m	________ N.m	

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

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):* ___

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

Weight 1: ___ ___ ___ . ___ kg

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 **Phase 2**

Month 24 Submission *Visit 2*

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐ 0 No → **Skip to question 3** ☐ 1 Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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 Phase 2

Month 24 Submission
Visit 2

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

6-Day Food Record

Complete below OR Not done → Specify reason *(use Codelist below)*: ________ **Staff initials:** ___ ___ ___ (first middle last)

			Replacement Values		
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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

VO_2 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 *(use codelist 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 ☐98 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 → **Complete all that apply: HR when true cardiac angina occurred:** __________ bpm OR ☐96 NA

HR when ischemic ECG changes occurred: __________ bpm OR ☐96 NA

☐ 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/tri-geminy, NSVT [≥ 3 beats])*?

☐0 No

☐1 Yes → **If Yes: When did it occur** *(check all that apply)*? ☐ During exercise ☐ During recovery

7 Peak VO_2: __________ mL/kg/min __________ L/min

8 Did the participant meet at least 2 of the 3 VO_2 max criteria *(see box, right)*?

☐0 No

☐1 Yes → **If Yes: VO_2 max:** __________ mL/kg/min __________ L/min

> *a Achieve a plateau in VO_2 (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 VO_2 peak/VO_2 max: ___ ___ ___ /___ ___ ___ (systolic / diastolic) mm Hg

11 Borg RPE score at VO_2 peak/VO_2 max: __________ *(6–20)*

12 Peak RER: __________

13 VE at VO_2 peak/VO_2 max: __________ L/min

14 VE/VO_2 at VO_2 peak/VO_2 max __________ L/min

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

calerie Phase 2

Month 24 Submission
Visit 3

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Outcomes Labs

Date and time sample collection started: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample *If a sample is not obtained, indicate with a Not Done.*	**Sample Complete?**	**If Not Done, Reason** *(Use codelist below)*	**Staff Initials**
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

Core Temperature

Staff Initials	**Provide Date of Sample Collection/Procedure**	**Time of Sample Collection/Procedure**	**If Not Done, Reason** *(Use codelist below)*
___ ___ ___ (first middle last)	Start Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	Start Time ___ ___ : ___ ___ (00:00 to 23:59)	______
	Stop Date: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year)	Stop Time ___ ___ : ___ ___ (00:00 to 23:59)	

Inpatient Admission and Discharge

1 Inpatient admission date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

2 Inpatient discharge date and time: ___ ___ /___ ___ ___/___ ___ ___ ___ (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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed?
☐0 No
☐1 Yes → **If Yes: Were any Exclusion criteria met?** ☐0 No → **Proceed with test**
☐1 Yes → **STOP. Do not administer test.**

2 Date of injection: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) **OR Not done → Specify reason** *(use codelist below)*: ___

3 Injection by *(initials)*: ___ ___ ___ (first middle last)

4 Arm injected: ☐1 Right ☐2 Left

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
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	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*
2 Tetanus toxoid *(TT)*	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
3 Candida	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
4 Trichophyton	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	

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

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)*: ___

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

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Outcomes Labs

Date and time of last meal: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Date and time sample collection started: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year) ___ ___ : ___ ___ (00:00 to 23:59)

Sample	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Catecholamines	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Blood	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)
Oral glucose tolerance test *(OGTT)*	☐0 No ☐1 Yes	______	___ ___ ___ (first middle last)

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

24-hour Urine Collection

Total Volume Collected	Date of Sample Collection	Time of Sample Collection	If Not Done, Reason *(Use codelist below)*	Staff Initials
___ ___ ___ ___ ___ mL	Start Date: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year) Stop Date: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year)	Start Time: ___ ___ : ___ ___ (00:00 to 23:59) Stop Time: ___ ___ : ___ ___ (00:00 to 23:59)	______	___ ___ ___ (first middle last)

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Sex Hormone

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

Contraception method *(females only)*:

☐ None **OR Check all that apply:**
☐ Oral contraceptive → **Specify:** ____________________
Record on Concomitant Medications page
☐ Other → **Specify** *(e.g., barrier, IUD)*: ____________________

Day 1	Date	Time	If Not Done, Reason *(use codelist)*	Staff Initials
~~Day 1 of menses **(females only)**~~				
Date and time of last meal **(males only)**	__ __/__ __ __/__ __ __ __ (day month year)	__ __ : __ __ (00:00 to 23:59)		
Hormone level blood draw 1 **(males only)**	__ __/__ __ __/__ __ __ __ (day month year)	__ __ : __ __ (00:00 to 23:59)	________	___ ___ ___ (first middle last)
~~Hormone level blood draw 2 **(females only)**~~ ~~*Progesterone level*~~				
Day 2	**Date**	**Time**	**If Not Done, Reason** *(use codelist)*	**Staff Initials**
~~Date and time of last meal~~				
~~Hormone level blood draw 3 **(females only)**~~ ~~*Progesterone level*~~				

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason *(Use codelist below)*	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 4	__ __/__ __ __/__ __ __ __ (day month year)	________	___ ___ ___ (first middle last)
Cart ID	☐ 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

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Month 24 Submission Visit 4

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

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 codelist below)*: ___

Interviewer initials: ___ ___ ___ (first middle last)

1 Were you employed in the last seven days? ☐$_0$ No → **Skip to question 3** ☐$_1$ Yes

2 If Yes: Which days *(check all that apply)*? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

3 Which days do you consider your weekend, or non-work, days? ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun

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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 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	__:__ 00:00 to 23:59	__:__ 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

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

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

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Biopsy Labs

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Muscle biopsy	___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year)	_______	___ ___ ___ (first middle last)
Fat biopsy	___ ___ /___ ___ ___ /___ ___ ___ ___ (day month year)	_______	___ ___ ___ (first middle last)

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

Signs, Symptoms and Adverse Events Log

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Signs, Symptoms and Adverse Events

Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline:

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

AE #	Adverse Event	Serious	Intensity	Causality *(check only one)*	Action Taken Due to AE *(check all that apply)*	Outcome	Start/End Date OR Check if Continuing
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other *(specify)*: ________	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	**Start Date:** __ __/__ __ __/__ __ __ __ (day month year) **End Date:** __ __/__ __ __/__ __ __ __ (day month year) **OR** ☐1 Continuing
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other *(specify)*: ________	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	**Start Date:** __ __/__ __ __/__ __ __ __ (day month year) **End Date:** __ __/__ __ __/__ __ __ __ (day month year) **OR** ☐1 Continuing
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other *(specify)*: ________	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	**Start Date:** __ __/__ __ __/__ __ __ __ (day month year) **End Date:** __ __/__ __ __/__ __ __ __ (day month year) **OR** ☐1 Continuing
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other *(specify)*: ________	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	**Start Date:** __ __/__ __ __/__ __ __ __ (day month year) **End Date:** __ __/__ __ __/__ __ __ __ (day month year) **OR** ☐1 Continuing

*If Serious is Yes, submit expedited SAE form.

SAE Reporting Criteria: **1** Death **2** Life threatening **3** Persistent or significant disability/incapacity **4** Prolonged or required hospitalization **5** Congenital anomaly or birth defect **6** Other significant medical event

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Concomitant Medications Log

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Concomitant Medications Log

Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box.
Send copies of this form with each submission starting with baseline:
☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Medication	Start Date or ✓ if Pre-study	Stop Date or ✓ if Continuing	Indication
1 Study vitamin-mineral supplement	___/___/___ day month year	___/___/___ day month year	
2 Study calcium supplement	___/___/___ day month year	___/___/___ day month year	
3	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
4	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
5	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
6	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
7	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
8	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
9	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
10	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
11	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	
12	___/___/___ day month year OR ☐1 Pre-study	___/___/___ day month year OR ☐1 Continuing	

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Concomitant Medications Log

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Concomitant Medications Log

Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box.
Send copies of this form with each submission starting with baseline:
☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Medication	Start Date or ✓ if Pre-study	Stop Date or ✓ if Continuing	Indication
1	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
2	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
3	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
4	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
5	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
6	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
7	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
8	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
9	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
10	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
11	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	
12	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day month year) OR ☐1 Continuing	

Page Numbering: *Sequentially number each page in the right hand corner, i.e. 281+.1, 281+.2, 281+.3. Insert additional pages as needed.*

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Date received at DCRI Safety Surveillance

Serious Adverse Event Form

Report type: ☐ Initial
☐ Follow-up **#:** ________ **Center Number:** __ __ **Participant Number:** __ __ __ __ **Participant's Initials:** __ __ __ (first middle last)

SAE Details:	Participant's Details:
SAE Term *(Medical Diagnosis)*: ________________	**Date of birth:** __ __/__ __ __/__ __ __ __ (day / month / year)
SAE Onset Date: __ __/__ __ __/__ __ __ __ (day / month / year)	**Gender:** ☐ Male ☐ Female
SAE Stop Date: __ __/__ __ __/__ __ __ __ (day / month / year)	

Serious Reporting Criteria: *(check all that apply)*	Causality & Intensity: *(check only one)*	Outcome *(at time of report)*: *(check only one)*
☐ Death ☐ Life-threatening ☐ Persistent or significant disability or incapacity ☐ Prolonged or required hospitalization ☐ Congenital anomaly or birth defect ☐ Other significant event requiring medical and/or surgical intervention	**Causality:** ☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely **Intensity:** ☐1 Mild ☐2 Moderate ☐3 Severe	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death → **If Death: Date of death:** __ __/__ __ __/__ __ __ __ (day / month / year)

Action Taken with Study Intervention: *(check all that apply)*

☐ None
☐ Intervention temporarily discontinued → **Complete and fax the Temporary Discontinuation from CR Intervention form**
☐ Medical therapy required
☐ Intervention permanently discontinued → **Complete and fax the Permanent Discontinuation from CR Intervention form**
☐ Other *(specify)*: ______________________________

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at 1-919-668-7138 or 1-866-668-7138 within 24 hours of initial notification

calerie Phase 2

Date received at DCRI Safety Surveillance

Serious Adverse Event Form

Report type: ☐ Initial
☐ Follow-up **#:** ________ **Center Number:** __ __ **Participant Number:** __ __ __ __ **Participant's Initials:** __ __ __ (first middle last)

Medical History *(relevant to event)*:

Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification

calerie **Phase 2**

Date received at DCRI Safety Surveillance

Serious Adverse Event Form

Report type: ☐ Initial
☐ Follow-up **#:** __________ **Center Number:** ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (*first middle last*)

Please provide a brief summary of the event:	
Please describe the sequence of events including action taken, treatment given, hospital dates, etc.:	
Information Source:	
Date Investigator notified of Event: ___ ___/___ ___ ___/___ ___ ___ ___ (*day month year*)	**Date of this report:** ___ ___/___ ___ ___/___ ___ ___ ___ (*day month year*)
Person completing form: ______________________________ **PI name**: ______________________________	**Phone number:** (___ ___ ___) ___ ___ ___ – ___ ___ ___ ___ **Fax number:** (___ ___ ___) ___ ___ ___ – ___ ___ ___ ___
PI signature: ______________________________	**Date of signature:** ___ ___/___ ___ ___/___ ___ ___ ___ (*day month year*)

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification

calerie Phase 2

Excessive Weight Loss Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Excessive Weight Loss Episode

Excessive weight loss is defined as a BMI < 18.5 kg/m². This report is completed for each episode of excessive weight loss. Reporting starts when the BMI level is first observed to be < 18.5 kg/m², and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

A Identifying information

1 Date of initial report: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

2 Name of person making this report: ____________________

B BMI below 18.5 kg/m²

3 Date of threshold value: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

4 Height: ___ ___ ___ . ___ cm *(from original measurement at Screening)*

5 Weight: ___ ___ ___ . ___ kg

6 Calculated BMI: ____________ kg/m²

C Temporary Discontinuation

If BMI < 18.5 kg/m², the participant is advised about the risks of excessive weight loss and is prescribed a diet plan with increased number of calories up to the baseline level for up to one month.

7 Was CR temporarily discontinued and a diet plan prescribed?

☐0 No → **If No: Indicate the reason why it was not temporarily discontinued:** ____________________

☐1 Yes → **If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to section D below.**

D Follow-up BMI Value

The CR intervention is only restarted if the BMI increases to 18.5 kg/m² or higher after one month of treatment.

8 Date of follow-up value: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

9 Weight: ___ ___ ___ . ___ kg

10 Calculated BMI: ____________ kg/m²

E Permanent Discontinuation

If BMI is still < 18.5 kg/m2 after one month of increased calorie intake, CR intervention is permanently discontinued.

11 Was the participant permanently discontinued from the CR intervention?

☐0 No → **If No: Indicate the reason CR was not permanently discontinued** *(check only one)*:

☐1 BMI returned to 18.5 kg/m² or higher

☐98 Other *(specify)*: ____________________

☐1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

Note that a participant is permanently discontinued from the CR intervention if a BMI < 18.5 kg/m² occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.

Fax to Safety Surveillance at 1-866-668-7138

calerie Phase 2

Excessive Weight Loss Episode Report

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

Excessive Weight Loss Episode (continued)

F Please provide a description of this episode including actions taken:

____

____

____

____

____

____

____

____

____

____

____

____

Study Manager's Signature

Signature: ______________________________ Date: ___ ___ /___ ___ ___/___ ___ ___ ___
day month year

Fax to Safety Surveillance at 1-866-668-7138

Depression Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Depression Episode

Depression is defined as a BDI score ≥ 20. This report is completed for each episode of depression. Reporting starts when the initial BDI is ≥ 20, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

A Identifying information

1 Date of initial report: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

2 Name of person making this report: ______________________________

B Initial Elevation in BDI Score ≥ 20

3 Date of initial elevation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

4 BDI score: __________

C Repeat BDI Score

The questionnaire is repeated in ***one week****.*

5 Date of follow-up questionnaire: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

6 BDI score: __________

D Temporary Discontinuation

If the repeat score is ≥ 20, the CR intervention is temporarily discontinued and a participant is advised to seek medical help outside of the study.

7 Was the participant temporarily discontinued from the CR intervention?

☐ 0 No → **If No: Indicate the reason CR was not temporarily discontinued** *(check only one)***:**

- ☐ 1 BDI score returned to < 20 → **If the BDI score returned to < 20, then stop here; the episode has resolved. Sign the form on the last page and store in participant's binder.**
- ☐ 98 Other *(specify)*: ______________________________

☐ 1 Yes → **If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

E Follow-up BDI Score

The questionnaire is repeated in ***one month****.*

8 Date of follow-up questionnaire: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

9 BDI score: __________

Depression Episode (continued)

F Permanent Discontinuation

If BDI score is ≥ 20 after one month of treatment, or a qualified mental health professional indicates that it is unsafe to restart the CR, intervention will be permanently discontinued.

10 Was the participant permanently discontinued from the CR intervention?

- ☐ 0 No → **If No: Indicate why CR was not permanently discontinued** *(check only one)*:
  - ☐ 1 BDI score returned below 20
  - ☐ 2 Mental health professional indicated it is safe to resume
  - ☐ 98 Other *(specify)*: ______________________________
- ☐ 1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

Note that a participant is permanently discontinued from the CR intervention if a BDI score ≥ 20 occurs at any point after the CR was restarted. If this happens, please complete the Permanent Discontinuation from CR Intervention form.

G Please provide a description of this episode, including actions taken:

____

____

____

____

____

____

____

____

____

____

Study Manager's Signature

Signature: ______________________________ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

Eating Disorder Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Eating Disorder Episode

Eating disorders are defined in terms of scores on the Multi-axial Assessment of Eating Disorder Symptoms (MAEDS) and the Body Acceptability Morph (BAM) and Interview for the Diagnosis of Eating Disorders—Fourth Version (IDED-IV). Reporting starts when MAEDS and/or BAM ***indicate*** *that there is an eating disorder, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.*

A Identifying information

1 Date of initial report: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

2 Name of person making this report: ______________________________

Please complete Section B and/or C according to whether the episode was defined in terms of the MAEDS or the BAM, or both.

B Disorder Detected by the MAEDS

A participant who has a t-score of 70 or higher on any subscale of the MAEDS is administered the IDED-IV.

MAEDS Domain	t-score	MAEDS Domain	t-score
3 Binge eating	________	**6** Purgative behavior	________
4 Restrictive eating	________	**7** Avoidance of forbidden foods	________
5 Fear of fatness	________	**8** Depression	________

C Disorder Detected by the BAM

A participant who (a) scores a t-score of 70 or higher on the current body size, (b) scores a t-score lower than 30 on the ideal body size, or (c) shows confirming acceptability of the extreme body size shown in the acceptability phase of the measure is administered the IDED-IV.

9 Was an alert issued for the current body size scale? .... ☐0 No ☐1 Yes → **If Yes: t-score:** _____

10 Was an alert issued for the ideal body size scale? .... ☐0 No ☐1 Yes → **If Yes: t-score:** _____

11 Was there confirming acceptability of the extreme body size shown? .... ☐0 No ☐1 Yes

D Follow-up with IDED-IV

The diagnostic criteria for anorexia nervosa, bulimia nervosa, or binge eating disorder require an IDED-IV rating of "3" or more for each of its diagnostic criteria. A sub threshold eating disorder is defined as an IDED-IV rating of "3" or more on at least 5 of the 8 combined symptoms for bulimia nervosa and anorexia nervosa (only).

12 Did the participant meet the following diagnostic criteria *(check all that apply)*?

- Anorexia nervosa .... ☐0 No ☐1 Yes
- Bulimia nervosa .... ☐0 No ☐1 Yes
- Binge eating .... ☐0 No ☐1 Yes
- Sub threshold eating disorder .... ☐0 No ☐1 Yes

Fax to Safety Surveillance at 1-866-668-7138

Eating Disorder Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Eating Disorder Episode (continued)

E Permanent Discontinuation

If a participant meets one or more of these diagnostic criteria, the CR intervention is permanently discontinued and a participant is advised to seek medical help outside of the study.

13 Was the participant permanently discontinued from the CR intervention?

- ☐ 0 No → **If No: Indicate why CR was not permanently discontinued** *(check only one)*:
  - ☐ 1 Did not meet diagnostic criteria for these eating disorders
  - ☐ 98 Other *(specify)*: ______________________
- ☐ 1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

F Please provide a description of this episode including actions taken:

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Study Manager's Signature

Signature: ______________________ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

calerie Phase 2

Elevated Potassium Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Elevated Potassium Episode

Hyperkalemia is defined as an initial potassium level greater than 5.5 mEq/L followed by a confirmatory value greater than 5.5 mEq/L. This report is completed for each episode of hyperkalemia. Reporting starts when the initial potassium level is greater than 5.5 mEq/L., and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

A Identifying information

1 Date of initial report: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

2 Name of person making this report: ______________________________

B Initial Elevation in Potassium Level

3 Date of initial elevation: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

4 Potassium level: __________ mEq/L

C Follow-up Repeat Potassium Level

If the initial potassium level is between 5.5 mEq/L and 6.0 mEq/L (inclusive), the test is repeated in one week; if it is greater than 6.0 mEq/L, it is repeated within 48 hours.

5 Date of follow-up test: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

6 Potassium level: __________ mEq/L

D Temporary Discontinuation

If the follow-up test is > 5.5 mEq/L, the CR intervention is temporarily discontinued from the CR intervention and the participant is advised to seek medical help outside of the study.

7 Was the participant temporarily discontinued from the CR intervention?

☐ 0 No → **If No: Indicate the reason CR was not temporarily discontinued** *(check only one)*:

- ☐ 1 Potassium returned to 5.5 mEq/L or lower → **If potassium returned to 5.5 mEq/L or lower, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.**
- ☐ 98 Other *(specify)*: ______________________________

☐ 1 Yes → **If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section E below.**

E Follow-up Potassium Level

The CR intervention will only be restarted if the potassium level decreases to ≤ 5.0 mEq/L within one month of treatment.

8 Date of follow-up test: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

9 Potassium level: __________ mEq/L

Fax to Safety Surveillance at 1-866-668-7138

Elevated Potassium Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Elevated Potassium Episode (continued)

F Permanent Discontinuation

If potassium level is still elevated above 5.0 mEq/L after one month of treatment, the CR intervention is permanently discontinued.

10 Was the participant permanently discontinued from the CR intervention?

☐0 No → **If No: Indicate why CR was not permanently discontinued** *(check only one)*:

- ☐1 Potassium returned to 5.0 mEq/L or lower
- ☐98 Other *(specify)*: ____________________

☐1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

Note that a participant is permanently discontinued from the CR intervention if a potassium level of 5.5 mEq/L or higher occurs at *any* point *after* the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.

G Please provide a description of this episode including actions taken:

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Study Manager's Signature:

Signature: ______________________ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day month year)

Fax to Safety Surveillance at 1-866-668-7138

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Anemia Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Anemia Episode

Anemia is defined as a decrease in hemoglobin and/or hematocrit level below the lower limit of normal (LLN) for the laboratory, followed by a confirmatory value satisfying the same criteria. Reporting starts when the ***initial*** *value is observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.*

A Identifying Information

1 Date of initial report: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

2 Name of person making this report: ______________________________

Please complete Section B according to whether the hemoglobin and/or hematocrit was below the lower limit of normal.

B Value(s) Below the Lower Limit of Normal:

3 Date of lab test: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

	Value	Lower Limit of Normal (LLN)	Below LLN?
4 Hemoglobin:			☐0 No ☐1 Yes
5 Hematocrit:			☐0 No ☐1 Yes
6 RBC:			☐0 No ☐1 Yes
7 Iron level:			☐0 No ☐1 Yes

C

D Repeat Test:

The hematology panel is repeated in two weeks. The iron level is also repeated.

11 Date of repeat lab test: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

	Value	Lower Limit of Normal (LLN)	Below LLN?
12 Hemoglobin:			☐0 No ☐1 Yes
13 Hematocrit:			☐0 No ☐1 Yes
14 RBC:			☐0 No ☐1 Yes
15 Iron level:			☐0 No ☐1 Yes

If the repeated test confirms the previous findings, a participant is advised to seek medical help outside of the study. Nevertheless, s/he continues the CR intervention.

Fax to Safety Surveillance at 1-866-668-7138

Anemia Episode (continued)

E Medical Help Outside the Study:

16 Was the participant advised to seek medical help outside the study?

☐$_0$ No → **If No: Indicate the reason why not:**

☐$_1$ Hematology panel and iron levels returned to acceptable values → **If the hematology and iron levels return to acceptable values, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.**

☐$_{98}$ Other *(specify)*: ______________________

☐$_1$ Yes → **If Yes: Date on which patient was advised:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

F One Month Follow-up Test

If the hematology and iron levels do ***not*** *return to acceptable values, the hematology panel and iron levels are repeated one month after the treatment was initiated.*

17 Date of one month follow-up lab test: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

	Value	Lower Limit of Normal (LLN)	Below LLN?
18 Hemoglobin:			☐$_0$ No ☐$_1$ Yes
19 Hematocrit:			☐$_0$ No ☐$_1$ Yes
20 RBC:			☐$_0$ No ☐$_1$ Yes
21 Iron level:			☐$_0$ No ☐$_1$ Yes

G Temporary Discontinuation

If anemia is not improving or worsens, the CR intervention is temporarily discontinued.

22 Was the participant temporarily discontinued from the CR intervention?

☐$_0$ No → **If No: Indicate the reason why CR was not temporarily discontinued** *(check only one)*:

☐$_1$ Hemoglobin panel and iron levels returned to acceptable values → **If the hemoglobin and iron levels return to acceptable levels, the episode has resolved. Stop here, sign the form on the last page, and forward to the coordinating center with the next batch of data forms.**

☐$_{98}$ Other *(specify)*: ______________________

☐$_1$ Yes → **If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

Continue to Section H, next page.

calerie Phase 2

Anemia Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Anemia Episode (continued)

H Two Month Follow-up Value

If anemia is not improving or is worsening after the CR intervention was temporarily discontinued for one month, the intervention is permanently discontinued.

23 Date of two month follow-up lab test: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

	Value	Lower Limit of Normal (LLN)	Below LLN?
24 Hemoglobin:			☐0 No ☐1 Yes
25 Hematocrit:			☐0 No ☐1 Yes
26 RBC:			☐0 No ☐1 Yes
27 Iron level:			☐0 No ☐1 Yes

I Permanent Discontinuation

28 Was the participant permanently discontinued from the CR intervention?

☐0 No → **If No: Indicate the reason why CR was not permanently discontinued** *(check only one)*:

☐1 Hemoglobin panel and iron levels returned to acceptable values

☐98 Other *(specify)*: ______________________________

☐1 Yes → **If Yes: Please complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

J Please provide a description of this episode including actions taken: ______________________________

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Study Manager's Signature:

Signature: ______________________________ Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

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Ventricular Ischemia Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Ventricular Ischemia Episode

This report is completed if an episode of ventricular ischemia occurs during the VO_2 max measurement (12 or 24 months). Reporting starts when it is first observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

A Identifying information

1 **Date of initial report:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

2 **Name of person making this report:** ______________________________

B Date when the ventricular ischemia was observed

3 **Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

C Temporary Discontinuation

The CR intervention is temporarily discontinued and a stress imaging study is recommended within two weeks.

4 **Was CR temporarily discontinued and a stress imaging study ordered?**

☐0 No → **If No: Indicate the reason CR was not temporarily discontinued:** ______________________________

____

☐1 Yes → **If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section D below.**

D Stress Imaging Study

If a stress imaging study confirms presence of ventricular ischemia, the CR intervention will be permanently discontinued and a participant will follow all other study procedures to the study end.

5 **Date of study:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

6 **Did the study confirm the presence of ventricular ischemia?**

☐0 No

☐1 Yes

E Permanent Discontinuation

7 **Was the participant permanently discontinued from the CR intervention?**

☐0 No → **If No: Indicate the reason CR was not permanently discontinued:**

☐1 The study did not confirm the presence of ventricular ischemia.

☐98 Other *(specify)*: ______________________________

☐1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

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Ventricular Ischemia Episode Report

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Ventricular Ischemia Episode (continued)

F Please provide details of ECG findings including actions taken:

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Study Manager's Signature:

Signature: ______________________________ Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)

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calerie Phase 2

Temporary Discontinuation from CR Intervention

Check one: ☐ Initial ☐ Follow-up

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Temporary Discontinuation

Note: Complete *one* form per reason for discontinuation.

1 Date of temporary discontinuation: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

2 Reason for discontinuation *(check only one)*:

- ☐1 Persistent potassium level > 5.5 mEq/L and < 6.0 mEq/L at any point during study, confirmed by repeat testing at 1 week
- ☐2 Persistent potassium level ≥ 6.1 mEq/L at any point during study, confirmed by repeat testing at 48 hours if second level is above 5.5 mEq/L
- ☐3 Treatment resistant anemia *(anemia has not improved after one month of treatment)*
- ☐4 Ventricular ischemia observed with exercise *(stress image performed in 2 weeks)*
- ☐5 Decrease in BMI to <18.5 at any time
- ☐6 Moderate depression *(BDI ≥ 20)*
- ☐7 Personal reasons *(specify)*: ______________________________
- ☐8 Other *(includes any other disease or condition that requires temporary discontinuation from intervention such as recovery from trauma, surgery, or severe infections) (specify)*: ______________________________

Participant's Details:

Date of birth: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Height: ___ ___ ___ . ___ cm

Gender: ☐ Male ☐ Female

Weight: ___ ___ ___ . ___ kg

BMI *(if applicable)*: __________

Relevant Medical History:

Relevant Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
				___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
				___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day month year)		

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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Temporary Discontinuation (continued)

Please describe any additional action taken *(e.g., observation or seek medical attention outside study)*:

Intervention Resumption

Was intervention resumed? If No: Fill out Permanent Discontinuation from CR Intervention form

If Yes: Date intervention was resumed: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Investigator's Signature

Investigator: ______________________________ (signature) Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

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Permanent Discontinuation from CR Intervention

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Permanent Discontinuation

1 Date of permanent discontinuation: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)

2 Reason(s) for discontinuation *(check only one)*:

☐1 Persistent potassium level > 5.0 mEq/L resistant to one month of treatment
☐2 Persistent potassium level ≥ 5.5 mEq/L after CR was temporarily discontinued and restarted
☐3 Persistent anemia *(anemia still not improving or worsening one month after temporary discontinuation)*
☐4 Ventricular ischemia confirmed by stress image
☐5 Decrease in BMD at the hip or spine of 5% or greater from baseline at any time during first 12 months of CR
☐6 Decrease in BMD at the hip or spine of 10% or greater from baseline at any time during months 12–24 of CR
☐7 BMD t-score at any site *(hip, femoral neck, or total spine)* of less than –2.5 at any time during study
☐8 Eating disorder *(including anorexia nervosa, bulimia nervosa or binge eating* **OR** *experiencing a sub-threshold eating disorder)*
☐9 Further decrease in BMI after 1 month of increase calorie intake **OR** temporary discontinuation of CR intervention **OR** persistent decrease in BMI *(< 18.5)* after CR intervention restarted
☐10 Psychiatric disorder *(including severe depression)*
☐11 Reoccurrence of moderate depression *(BDI still > 20)* after CR intervention restarted **OR** moderate depression that is not improving or is worsening *(BDI ≥ 30)* after temporary discontinuation of CR intervention
☐12 Major illness or disease *(e.g., cancer)*
☐13 Trauma requiring prolonged hospitalization or bed rest for more than one month
☐14 Menstrual irregularities or acyclicity for more than one year *(women only)*
☐15 Pregnancy *(women only)*
☐16 Participant withdrew consent
☐17 Personal reasons *(specify)*: ____________________
☐98 Other: ____________________

Participant's Details:

Date of birth: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)

Gender: ☐ Male ☐ Female

Height: ___ ___ ___ . ___ cm

Weight: ___ ___ ___ . ___ kg

BMI *(if applicable)*: __________

Relevant Medical History:

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Permanent Discontinuation from CR Intervention

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Permanent Discontinuation (continued)

Relevant Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		

Please describe any additional action taken *(e.g., observation or seek medical attention outside study)*:

Investigator's Signature

Investigator: ______________________________ (signature) Date: __ __/__ __ __/__ __ __ __ (day month year)

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Study Completion/ Early Discontinuation of Study Evaluation

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Completion/Early Discontinuation

1 Date of study completion or early discontinuation of study: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

2 Did the participant complete the study through Month 24?

☐0 No → **If No: Date of last contact:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Indicate the primary reason for discontinuation *(check only one)*:

☐1 Consent withdrawn

☐2 Lost to follow-up

☐3 Adverse event → **Complete Signs, Symptoms and Adverse Events Log**

- **If serious adverse event, complete Serious Adverse Event (SAE) form**

☐4 Death → **Date of death:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

- **Complete Signs, Symptoms and Adverse Events Log**
- **Complete Serious Adverse Events form**
- **Report cause of death as a Serious Adverse Event**

☐98 Other *(specify)*: ________________________________

☐1 Yes

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Completed by Calerie staff:

☐ Baseline 1 ☐ 6 Months ☐ 18 Months
☐ Baseline 2 ☐ 12 Months ☐ 24 Months

Center Number: ___ ___ **Participant Number:** ___ ___ ___ ___ **Participant's Initials:** ___ ___ ___ (first middle last)

Daily Home Weight Log

Were you issued a new scale? ☐0 No ☐1 Yes → **If Yes: Date first used:** ___ ___/___ ___/___ ___ ___ ___ (month / day / year) **Serial no.:** __________

Please complete this log in either blue or black ink.

Day of week: ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______
Date: __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)
Time: ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)
Weight: __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb **Check scale memory**

Day of week: ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______	**Day of week:** ______
Date: __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)	**Date:** __ __/__ __/__ __ __ __ (month day year)
Time: ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)	**Time:** ☐1 AM ☐2 PM __ __ : __ __ (00:00 to 11:59)
Weight: __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb	**Weight:** __ __ __ . __ lb **Check scale memory**

Send Completed Logs to DCRI Only If Completed During DLW Periods

calerie Phase 2

Protocol Deviation

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Protocol Deviation

Please indicate below any deviations from the Calerie Protocol taken for this participant.
Check all that apply *(one participant per form)*:

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications
☐ Study/laboratory procedures *(specify)*: ____________________
☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________

____

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications
☐ Study/laboratory procedures *(specify)*: ____________________
☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________

____

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications
☐ Study/laboratory procedures *(specify)*: ____________________
☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________

____

Submission date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)   ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)   ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

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