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

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)

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)

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

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.

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)

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
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.

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

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

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
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

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
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)

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

BDI-II

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

1 Sadness:
- ☐ 0 I do not feel sad
- ☐ 1 I feel sad much of the time
- ☐ 2 I am sad all of the time
- ☐ 3 I am so sad or unhappy that I can't stand it

2 Pessimism:
- ☐ 0 I am not discouraged about my future
- ☐ 1 I feel more discouraged about my future than I used to be
- ☐ 2 I do not expect things to work out for me
- ☐ 3 I feel my future is hopeless and will only get worse

3 Past failure:
- ☐ 0 I do not feel like a failure
- ☐ 1 I have failed more than I should have
- ☐ 2 As I look back, I see a lot of failures
- ☐ 3 I feel I am a total failure as a person

4 Loss of pleasure:
- ☐ 0 I get as much pleasure as I ever did from the things I enjoy
- ☐ 1 I don't enjoy things as much as I used to
- ☐ 2 I get very little pleasure from the things I used to enjoy
- ☐ 3 I can't get any pleasure from the things I used to enjoy

5 Guilty feelings:
- ☐ 0 I don't feel particularly guilty
- ☐ 1 I feel guilty over many things I have done or should have done
- ☐ 2 I feel quite guilty most of the time
- ☐ 3 I feel guilty all of the time

6 Punishment feelings:
- ☐ 0 I don't feel I am being punished
- ☐ 1 I feel I may be punished
- ☐ 2 I expect to be punished
- ☐ 3 I feel I am being punished

7 Self-dislike:
- ☐ 0 I feel the same about myself as ever
- ☐ 1 I have lost confidence in myself
- ☐ 2 I am disappointed in myself
- ☐ 3 I dislike myself

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

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

BDI-II (continued)

8 Self-criticalness:

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

9 Suicidal thoughts or wishes:

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

10 Crying:

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

11 Agitation:

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

12 Loss of interest:

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

13 Indecisiveness:

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

14 Worthlessness:

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

15 Loss of energy:

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

BDI-II (continued)

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

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

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

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

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

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

calerie Phase 2

Screening Visit 2 Checklist

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.

Screening Visit 3 Checklist

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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