calerie Phase 2

Phone Screen

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

Phone Screen

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

Verbal consent given by respondent: ☐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 →	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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calerie Phase 2

Phone Screen

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

Medications

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

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

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: _____

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NO DATA <XYES>

calerie Phase 2 Screening Visit 1 Checklist

PROTOCOL = CALERIE_PHASE2
STUDY BOOK = CASE REPORT FORMS
FORM/BLOCK = SCREENING

PAGEID = 3

SUBJNO = INVSITE||-||PATID

Center Number: INVSITE Participant Number: PATID Participant's Initials: INITIALS (first middle last)

Screening Visit 1 Checklist

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

Check completed items:

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

CHECKLST (TYPE 4)

2 ☐ Informed 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? RETVST<XYESNO>

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

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

Item not Displayed this page:
UNABCONT
ADDVISIT<TUADVT>

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

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

PAGEID = 4

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) STUDYDT __ __ : __ __ (00:00 to 23:59) STUDYTM

Staff initials: __ __ __ (first middle last) SINTIALS <V:3>

OR Not done → Specify reason *(use codelist below)*: ____ STUDYND<TUND>

DATEHDR (TYPE 4)

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

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

Weight 2: __ __ __ . __ kg WGHT2

WEIGHT (TYPE 4)

Weight 3: __ __ __ . __ kg WGHT3

Weight of gown: __ __ __ . __ kg GWGHT

Height

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

HEIGHT (TYPE 1)

1 First height: __ __ __ . __ cm HGHT1

2 Second height: __ __ __ . __ cm HGHT2

3 Third height: __ __ __ . __ cm HGHT3

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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: (__ __ __

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 6

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

Demographics

DEMOG (TYPE 1)

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

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

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

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

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

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

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

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

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

EDUCATE<TUEDU>

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

FAMINC<TUFINC>

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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.

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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)*: _____

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

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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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.

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"

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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

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

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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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

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

1	Have you avoided jobs or tasks that involved having to deal with a lot of people?	☐ 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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

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

25	When someone asks you to do something that you don't want to do, do you say "yes" but then work slowly or do a bad job?	☐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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

49	When you are out in public and see people talking, do you often feel that they are talking about you?	☐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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

THIS PAGE NOT ENTERED

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

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

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

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PAGEID = 22

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

Screening Visit 2 Checklist

1 Did participant return for Screening Visit 2?

Display RTNCLINIC<XYESNO>

☐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)

CHECKLST (TYPE 4)

Check completed items:

2 ☐ Fasting blood sample

3 ☐ Urine sample

SAME AS PAGE 3

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

Display UNABCONT

- ☐ Other *(specify)*: _____

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

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

PAGEID = 23

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

Date completed: ___ ___ / Same as page 4 (day / month / year)

No display STUDYND, STUDYTM or SINITIALS

DATEHDR (TYPE 4)

Screening Medical History

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

ASSESS<TUNCHY>

Body System BODYSYS<TUBODY>	Assessments No	Yes	If Yes, Specify Diagnosis
= 1 Head, Ears, Eyes, Nose, Throat	☐0	☐1 →	MEDHIST (TYPE 4)PS
= 2 Dermatologic	☐0	☐1 →	YESEXP<V:100>
= 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 →	

CODELIST TUNCHY
0 = NO/NOCHANGE
1 = YES

Physician's Signature

Signature: _____ NOT DATABASED Date: NOT DATABASED ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 24

THIS IS A REPEATING PAGE

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

Date completed: __ __ / __ __ __ / __ __ __ __ (day / month / year) SAME AS PAGE 23

DATEHDR (TYPE 4)

Medication History

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

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

THIS PAGE NOT ENTERED

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: __ __ / __ __ __ __ (year)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

PAGEID = 26

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)

CHECKLST (TYPE 4)

Check completed items:

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

3 ☐ **Repeated blood sample, if needed**

4 ☐ **14-day food record collected and reviewed**

SAME AS PAGE 22

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

☐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)

Display ADDVISIT<TUADVT>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 27

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)

CHECKLST (TYPE 4)

Check completed items:

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

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

SAME AS PAGE 22

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

☐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)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Informed Consent

1 Did participant present for baseline visit? RTNBL<XYESNO>

CONSENT (TYPE 1)

☐ 0 No → **If No: Specify reason** *(check only one)*:

- ☐ 1 Failed an eligibility criterion (participant no longer meets criteria) FAILELIG ALL<XYES>
- ☐ 2 Lost interest in the study LOSTINT
- ☐ 3 Will take too much time MUCHTIME
- ☐ 4 Scheduling conflicts with work or school SCHEDULE
- ☐ 5 Doesn't like the study's procedures DLKSTDPR
- ☐ 6 Doesn't want to be involved in a research study DWINVSTD
- ☐ 7 Unwilling to be randomized UNWILRAN
- ☐ 8 Lives too far away/transportation problems TRANPROB
- ☐ 9 Needs help with child care *(unable to meet child care needs)* CHLDCARE
- ☐ 10 Refused with no explanation REFEXPLN
- ☐ 11 Unable to contact UNABCONT
- ☐ 98 Other *(specify)*: OTHER OTHERSP<V:50>

☐ 1 Yes

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Informed Consent Detail

Tissue consent:

SUPRESS SEQNO<I:3>

CONSENTD (TYPE 2)
PS

SEQNO<I:3> Sample type SAMPTYPE<TUSAMT>	CNSNTDTL<TUCSTD> 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= 1 Blood archive	☐1 1=	☐2 2=	☐3 3=
2= 2 Urine archive	☐1	☐2	☐3
3= 3 Muscle biopsy archive	☐1	☐2	☐3
4= 4 Fat biopsy archive	☐1	☐2	☐3

<TUSAMT>
1= 1 BLOOD ARCHIVE
2= 2 URINE ARCHIVE
3= 3 MUSCLE BIOPSY ARCHIVE
4= 4 FAT BIOPSY ARCHIVE

<TUCSTD>
1= 1 EXTERNAL INVESTIGATORS
2= 2 CALERIE CONSENT
3= 3 CONSENT NOT GIVEN

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 29

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)

DATEHDR (TYPE 4)

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

SAME AS PAGE 4

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

WEIGHT (TYPE 4)

Weight 1: ___ ___ ___ . ___ kg

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Vital Signs

Assessment date and time: ___ ___ / ___ ___ ___ / VITALDT ___ ___ VITALTM (day / month / year / 00:00 to 23:59)

VITALS (TYPE 3)

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

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

SINTIALS

Staff initials: ___ ___ ___ (first middle last)

Natural waist measurement 1: ___ WMEAS1 cm

Natural waist measurement 2: ___ WMEAS2 cm

Natural waist measurement 3: ___ WMEAS3 cm

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

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

Umbilical point waist measurement 1: ___ UMEAS1 cm

Umbilical point waist measurement 2: ___ UMEAS2 cm

Umbilical point waist measurement 3: ___ UMEAS3 cm

PULSE<I:3>

PULND<TUND>

PINTIAL <V:3>

3 Pulse: ___ ___ ___ bpm OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

TINTIAL <V:3>

TEMP

TMPND<TUND>

4 Temperature: ___ ___ . ___ °C OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

RESP<I:2>

RINTIAL <V:3>

RESPND<TUND>

5 Respirations: ___ ___ per minute OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

BPARM<TUARM>

BPINTIAL <V:3>

6 Blood pressure (check only one): ☐1 Left arm ☐2 Right arm Staff initials: ___ ___ ___ (first middle last)

BPND<TUND>

All Blood Pressures <I:3>

6a Blood pressure 1: BPSYS1 ___ ___ ___ / BPDIA1 ___ ___ ___ (systolic / diastolic) mm Hg Time: BP1TM ___ ___ : ___ ___ (00:00 to 23:59) OR Not done → Specify reason (use codelist below): _____

6b Blood pressure 2: BPSYS2 ___ ___ ___ / BPDIA2 ___ ___ ___ (systolic / diastolic) mm Hg Time: BP2TM ___ ___ : ___ ___ (00:00 to 23:59)

6c Blood pressure 3: BPSYS3 ___ ___ ___ / BPDIA3 ___ ___ ___ (systolic / diastolic) mm Hg Time: BP3TM ___ ___ : ___ ___ (00:00 to 23:59)

ALL TIMES ASSOCIATED WITH VITALDT

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

PAGEID = 30

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

12-Lead ECG

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

Safety Labs

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

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
	BLSMPCOL<XYESNO>	BLSMPND<TUND>	BLDINIT<V:3>
Blood	☐0 No ☐1 Yes	_____	(first middle last)
	URSMPCOL<XYESNO>	URSMPND<TUND>	URNINIT<V:3>
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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

Abbreviated Medical History

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

Body System	Assessments		
	No Change	Yes	If Yes, Specify Diagnosis
1 Head, Ears, Eyes, Nose, Throat	☐0	☐1 →	MEDHIST (TYPE 4)PS
2 Dermatologic	☐0	☐1 →	
3 Cardiovascular	☐0	☐1 →	SAME AS PAGE 23
4 Respiratory	☐0	☐1 →	
5 Gastrointestinal	☐0	☐1 →	
6 Endocrine/Metabolic	☐0	☐1 →	
7 Genitourinary	☐0	☐1 →	
8 Neurological	☐0	☐1 →	
9 Blood/Lymphatic	☐0	☐1 →	
10 Musculoskeletal	☐0	☐1 →	
11 Hepatic	☐0	☐1 →	
12 Drug Allergies	☐0	☐1 →	
13 Other Allergies	☐0	☐1 →	
14 Psychological/Psychiatric	☐0	☐1 →	
15 Other	☐0	☐1 →	

Physician's Signature

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

PAGEID = 32

Baseline Submission 1
Visit 1

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

Physical Examination

SAME AS PAGE 4
No display STUDYH, STUDYM

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

Staff initials: ___ ___ ___ (first middle last)

DATEHDR (TYPE 4)

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

Body System PEXAM<TUPEXM>	Assessments: Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain
1 General appearance:	☐ 1	☐ 0 →	☐ 97 →	PEXAM (TYPE 4)PS
2 Head, Ears, Eyes, Nose, Throat:	☐ 1	☐ 0 →	☐ 97 →	ABNDSP<V:200>
3 Neck:	☐ 1	☐ 0 →	☐ 97 →	
4 Heart:	☐ 1	☐ 0 →	☐ 97 →	
5 Lungs:	☐ 1	☐ 0 →	☐ 97 →	
6 Abdomen:	☐ 1	☐ 0 →	☐ 97 →	
7 Lymph nodes:	☐ 1	☐ 0 →	☐ 97 →	
8 Extremities/Skin:	☐ 1	☐ 0 →	☐ 97 →	
9 Neurological:	☐ 1	☐ 0 →	☐ 97 →	
10 Musculoskeletal:	☐ 1	☐ 0 →	☐ 97 →	
	Normal	Abnormal	Not Done*	
11 Genitourinary:	☐ 1	☐ 0 →	☐ 97 →	
12 Breast:	☐ 1	☐ 0 →	☐ 97 →	

EXAM<TUASSE>

Physician's Signature

NOT DATABASED

Investigator: _____ (signature)

NOT DATABASED

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Not Done Codelist: 1 Participa... 5 Not required

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59) Staff initials: __ __ __ (first middle last)

DATEHDR (TYPE 4)

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 SAME AS PAGE 4 WEIGHT (TYPE 4)

Weight 2: __ __ __ . __ kg

Weight 3: __ __ __ . __ kg

Weight of gown: __ __ __ . __ kg

Pregnancy Test

Complete only for females.

REPOTEN<XYESNO> PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ 0 No

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

Results: ☐ 1 Negative ☐ 2 Positive PGRSLT<TURSLT>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Doubly Labeled Water (DLW)

DLWHDR (TYPE 4)

1 Date and time of DLW dosing: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) DLWDSEDT ___ ___:___ ___ (00:00 to 23:59) DLWDSETM

Staff initials: ___ ___ ___ (first middle last) SINTIALS

OR Not done → Specify reason *(use codelist below)*: ___ DLWND<TUND>

2 DLW dose mixture ID and bottle number: DLWMAN<V:2> ___ ___ – ___ ___ ___ ___ – ___ ___ ___ – CA DLWBOTNO<I:3>

DLWMIX<I:5>

3 Exact weight of DLW mixture: DLWMIXWT<F:9:3> ___ ___ ___ . ___ ___ grams

4 Urine samples:

DLWCHT (TYPE 4)PS

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

NOTE: INCLUDE THESE ITEMS IN THE DLWHDR PANEL ABOVE

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

Affix Label Here

DLWLBL1<V:15>

Not displayed this page
DLWLBL2<V:15>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

DXA Scan

DXASCAN (TYPE 4)

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.

CALSUP<XYESNO>

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

☐0 No ☐1 Yes BARSTDY<XYESNO>

DXA Scan		**DXA Rescan** OR ☐96 NA RENA<XYES>
Date of scan: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DXADT		Date of rescan: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) REDXADT
Area Scanned Check all that apply	**If Not Done, Reason** *(Use codelist below)*	**Area Scanned Check all that apply**
WBDY ALL<XYES> ☐ Whole body	WBDYND ALL<TUND> _____	REWBDY ALL<XYES> ☐ Whole body
FARM ☐ Forearm	FARMND _____	REFARM ☐ Forearm
SPINE ☐ Spine	SPINEND _____	RESPINE ☐ Spine
HIP ☐ Hip	HIPND _____	REHIP ☐ Hip

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Profile of Mood States

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

POMS (TYPE 4)PS

	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
	POMSQ<TUPOMA>	POMSA<TUPOMB>				
=	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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Send to DCRI [illegible] Durham NC 27705

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

Profile of Mood States (continued)

POMS (TYPE 4)PS

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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)

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

Profile of Mood States (continued)

POMS (TYPE 4)PS

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)

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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)*: ___ ___

SAME AS PAGE 36

DATEHDR (TYPE 4)

Perceived Stress Scale (PSS)

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

PSS (TYPE 4)

ALL<TUPSS>

	Never	Almost Never	Some-times	Fairly Often	Very Often
1 In the last month, how often have you felt that you were unable to control the important things in your life? CTRLTHNG	☐0	☐1	☐2	☐3	☐4
2 In the last month, how often have you felt confident about your ability to handle your personal problems? HANDPROB	☐0	☐1	☐2	☐3	☐4
3 In the last month, how often have you felt that things were going your way? GOYOWAY	☐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? PILEHIGH	☐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 PHASE2 ANNOTATION V8.0 24FEB2012

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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)*: _____

SAME AS PAGE 36

DATEHDR (TYPE 4)

Pittsburgh Sleep Quality Index (PSQI)

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

During the past month...

PSQI1(TYPE 4)

BEDHR<I:2>

BEDMIN<I:2>

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 FALLASLP<I:3>

WAKEHR<I:2>

3 When have you usually gotten up in the morning? ___ ___ : ___ ___ (00:00 to 23:59) WAKEMIN<I:2>

4 How many hours of actual sleep did you get at night? ACTSLP<F:9:3>
(This may be different than the number of hours you spend in bed.) ___ . ___ hours

ALL<TUSLP>

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 WITHIN30	☐0	☐1	☐2	☐3
b Wake up in the middle of the night or early morning MIDNGHMG	☐0	☐1	☐2	☐3
c Have to get up to use the bathroom GOBTHRM	☐0	☐1	☐2	☐3
d Cannot breathe comfortably BREATHE	☐0	☐1	☐2	☐3
e Cough or snore loudly SNORE	☐0	☐1	☐2	☐3
f Feel too cold COLD	☐0	☐1	☐2	☐3
g Feel too hot HOT	☐0	☐1	☐2	☐3
h Have bad dreams BADDRM	☐0	☐1	☐2	☐3
i Have pain PAIN	☐0	☐1	☐2	☐3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): _____ OTHER	☐0	☐1	☐2	☐3
6 During the past month, how often have you taken medicine *(prescribed or "over the counter")* to help you sleep? MEDSTKN	☐0	☐1	☐2	☐3

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 47

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

Pittsburgh Sleep Quality Index (PSQI) (continued)

PSQI2 (TYPE 3)

	Never	Once or twice	Once or twice each week	3 or more times each week
7 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? AWKESOC<TUSLPB>	☐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? KPENTHUS<TUSLPC>	☐0	☐1	☐2	☐3

	Very good	Fairly good	Fairly bad	Very bad
9 During the past month, how would you rate your sleep quality overall? SLPQLTY<TUSLPD>	☐0	☐1	☐2	☐3

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 48

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

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

SAME AS PAGE 36

~~DATE~~HDR (TYPE 4)

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.**

DISFEM1 (TYPE 4)PS

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

Section 1—Sexual Cognition/Fantasy

RESPONSE<TUDSFA>

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
FEMALEQ<TUFQUE> 1 ~~1.~~1 A sexually attractive person	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2 ~~1.~~2 Erotic parts of a man's body *(e.g., face, shoulders, legs)*	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3 ~~1.~~3 Erotic or romantic situations	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
4 ~~1.~~4 Caressing, touching, undressing, or foreplay	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
5 ~~1.~~5 Sexual intercourse, oral sex, touching to orgasm	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 49

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

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

Section 2—Sexual Arousal

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
6 = **2.1** Feel sexually aroused while alone	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
7 = **2.2** Actively seek sexual satisfaction	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
8 = **2.3** Feel sexually aroused with a partner	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

FEMALEQ<TUFQUE>

DISFEM2 (TYPE 4)PS

	Never	Rarely	Sometimes	Usually	Always
			RESPONSE<TUDSFB>		
9 = **2.4** Have normal lubrication with masturbation	☐0	☐1	☐2	☐3	☐4
10 = **2.5** Have normal lubrication throughout sexual relations	☐0	☐1	☐2	☐3	☐4

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 50

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

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
11 = 3.1 Reading or viewing romantic or erotic books or stories	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
12 = 3.2 Masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
13 = 3.3 Casual kissing and petting	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
14 = 3.4 Sexual foreplay	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
15 = 3.5 Sexual intercourse, oral sex, etc.	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

Section 4—Orgasm

FEMALEQ<TUFQUE>

DISFEM3 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
		RESPONSE<TUDSFC>			
16 = 4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
17 = 4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
18 = 4.3 The ability to have multiple orgasms *(if typical for you)*	☐0	☐1	☐2	☐3	☐4
19 = 4.4 Feelings of closeness and togetherness with your partner	☐0	☐1	☐2	☐3	☐4
20 = 4.5 Your sense of control *(timing)* of your orgasm	☐0	☐1	☐2	☐3	☐4
21 = 4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 51

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

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22 = **5.1** With the partner of your choice, what would be your **ideal** frequency of sexual intercourse?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

	Not at all	Slightly	Moderately	Highly	Extremely
23 = **5.2** During this period, how interested have you been in sex?	☐0	☐1	☐2	☐3	☐4
24 = **5.3** During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐0	☐1	☐2	☐3	☐4

DISFEM3 (TYPE 4)PS

SAME AS PAGE 50

DISFEM4 (TYPE 4)PS

FEMALEQ<TUFQUE>

RESPONSE<TUDSFD>

	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
25 = **5.4** In general, what would represent the best description of the quality of your sexual functioning?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 52

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

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

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

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "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.

DISMALE1 (TYPE 4)PS

Section 1—Sexual Cognition/Fantasy

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 53

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

SAME AS PAGE 52

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
6 = **2.1** A full erection upon awakening	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
7 = **2.2** A full erection during a sexual fantasy or daydream	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
8 = **2.3** A full erection while looking at a sexually arousing person, movie, or picture	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
9 = **2.4** A full erection during masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
10 = **2.5** A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 54

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

SAME AS PAGE 52

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
11 = 3.1 Reading or viewing romantic or erotic books or stories	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
12 = 3.2 Masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
13 = 3.3 Casual kissing and petting	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
14 = 3.4 Sexual foreplay	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
15 = 3.5 Sexual intercourse, oral sex, etc.	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

Section 4—Orgasm

MALEQ<TUMQUE> RESPONSE<TUDSFC>

DISMALE2 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
16 = 4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
17 = 4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
18 = 4.3 The length or duration of your orgasm	☐0	☐1	☐2	☐3	☐4
19 = 4.4 The amount of seminal liquid that you ejaculate	☐0	☐1	☐2	☐3	☐4
20 = 4.5 Your sense of control (timing) of your orgasm	☐0	☐1	☐2	☐3	☐4
21 = 4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 55

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

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

Section 5—Drive and Relationship

SAME AS PAGE 52

DISMALE1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22 = **5.1** With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

	Not at all	Slightly	Moderately	Highly	Extremely
23 = **5.2** During this period, how interested have you been in sex?	☐0	☐1	☐2	☐3	☐4
24 = **5.3** During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐0	☐1	☐2	☐3	☐4

DISMALE2 (TYPE 4)PS

SAME AS PAGE 54

DISMALE3 (TYPE 4)PS

MALEQ<TUMQUE>

RESPONSE<TUDSFD>

	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
25 = **5.4** In general, what would represent the best description of the quality of your sexual functioning?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

SAME AS PAGE 36 DATEHDR (TYPE 4)

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.

FCQTRAIT (TYPE 4)PS

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

Food Cravings Questionnaire—Trait (continued)

SAME AS PAGE 56

FCQTRAIT (TYPE 4)PS

	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Send to DCRI For[illegible] Durham NC 27705

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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)*: ___ ___

SAME AS PAGE 36

DATEHDR (TYPE 4)

Food Cravings Questionnaire—State (FCQ–S)

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

FCQSTATE (TYPE 4)PS

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

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DATEHDR (TYPE 4)

Food Craving Inventory (FCI–II)

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

CRAVE (TYPE 4)PS

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

Over the past month, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
=1 Cake FCIQ<TUCRVA>	☐1	☐2	☐3	☐4	☐5
=2 Pizza FCIA<TUCRVB>	☐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

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

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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):

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DATEHDR (TYPE 4)

TFEQA (TYPE 4)PS

Eating Inventory

EATINVQ<TUTFEQ>

EATINV<TUTFA>

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

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

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

Eating Inventory (continued)

=19	Being with someone who is eating often makes me hungry to eat also.	☐1 True ☐0 False
	SAME AS PAGE 60 TFEQA (TYPE 4)PS	
=20	When I feel blue, I often overeat.	☐1 True ☐0 False
=21	I enjoy eating too much to spoil it by counting calories or watching my weight.	☐1 True ☐0 False
=22	When I see a real delicacy, I often get so hungry that I have to eat right away.	☐1 True ☐0 False
=23	I often stop eating when I am not really full as a conscious means of limiting the amount I eat.	☐1 True ☐0 False
=24	I get so hungry that my stomach often seems like a bottomless pit.	☐1 True ☐0 False
=25	My weight has hardly changed at all in the last ten years.	☐1 True ☐0 False
=26	I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	☐1 True ☐0 False
=27	When I feel lonely, I console myself by eating.	☐1 True ☐0 False
=28	I consciously hold back at meals in order not to gain weight.	☐1 True ☐0 False
=29	I sometimes get very hungry late in the evening or at night.	☐1 True ☐0 False
=30	I eat anything I want, any time I want.	☐1 True ☐0 False
=31	Without even thinking about it, I take a long time to eat.	☐1 True ☐0 False
=32	I count calories as a conscious means of controlling my weight.	☐1 True ☐0 False
=33	I do not eat some foods because they make me fat.	☐1 True ☐0 False
=34	I am always hungry enough to eat at any time.	☐1 True ☐0 False
=35	I pay a great deal of attention to changes in my figure.	☐1 True ☐0 False
=36	While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods.	☐1 True ☐0 False

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

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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. TFEQB (TYPE 3)

37	How often are you dieting in a conscious effort to control your weight? WTCONTR<TUFREQ>	☐1 Rarely	☐2 Sometimes	☐3 Usually	☐4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life? WTFLUCT<TUFREQ>	☐1 Rarely	☐2 Sometimes	☐3 Usually	☐4 Always
39	How often do you feel hungry? OFTHUNG<TUFREQ>	☐1 Rarely	☐2 Sometimes	☐3 Usually	☐4 Always
40	Do your feelings of guilt about overeating help you to control your food intake? FEELGUIL<TUFREQ>	☐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? EATDIFF<TUDIFF>	☐1 Easy	☐2 Slightly difficult	☐3 Moderately difficult	☐4 Very difficult
42	How conscious are you of what you are eating? CONSEAT<TUCONS>	☐1 Not at all	☐2 Slightly	☐3 Moderately	☐4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods? STOCKING<TUSTOC>	☐1 Almost never	☐2 Seldom	☐3 Usually	☐4 Almost always
44	How likely are you to shop for low calorie foods? LOWCAL<TULIKE>	☐1 Unlikely	☐2 Slightly likely	☐3 Moderately likely	☐4 Very likely
45	Do you eat sensibly in front of others and splurge alone? SPLURG<TUSPLU>	☐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? EATSLOW<TULIKE>	☐1 Unlikely	☐2 Slightly likely	☐3 Moderately likely	☐4 Very likely
47	How frequently do you skip dessert because you are no longer hungry? DESSERT<TUDESS>	☐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? EATLESS<TULIKE>	☐1 Unlikely	☐2 Slightly likely	☐3 Moderately likely	☐4 Very likely
49	Do you go on eating binges though you are not hungry? BINGES<TUBING>	☐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." BEHAVIOR<TUBEHA>	☐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? RESTRAIN<TUSTRN>	☐0 Eat whatever you want, whenever you want it ☐1 Usually eat whatever you want, whenever you want it ☐2 Often eat whatever you want, whenever you want it ☐3 Often limit food intake, but often "give in" ☐4 Usually limit food intake, rarely "give in" ☐5 Constantly limiting food intake, never "giving in"

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DATEHDR (TYPE 4)

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

WELQ (TYPE 4)PS

I am confident that: WELQUES<TUWELQ>	**Not confident** at all that you can resist the desire to eat WELANSW<TUWELA> 0	1	2	3	4	5	6	7	8	**Very confident** that you can resist the desire to eat 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

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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WELQ (TYPE 4)PS

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

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DATEHDR (TYPE 4)

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

MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

MAEDQ<TUMAEY>

MAEDA<TUMAEZ>

	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

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

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

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

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MAEDS (TYPE 4)PS

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

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

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	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 68

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

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

BSQ (TYPE 4)PS

BSQQUES<TUBSQX>

BSQANSW<TUBSQW>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Body Shape Questionnaire (BSQ) (continued)

SAME AS PAGE 68

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 70

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

Staff initials: __ __ __ (first middle last)

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

DATEHDR (TYPE 4)

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

SAME AS PAGE 4

WEIGHT (TYPE 4)

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 PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

Baseline Submission 1 **Visit 3**

PAGEID = 71

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

THIS ITEM NOT DATABASED

PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ___/___/___ (day/month/year) PARDT Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below): ___ PARND<TUND>

Interviewer initials: ___ (first middle last) SINTIALS

1 Were you employed in the last seven days? EMPLOY<XYESNO> ☐ 0 No → Skip to question 3 ☐ 1 Yes

2 If Yes: Which days (check all that apply)? MON1 TUES1 WED1 THURS1 FRI1 SAT1 SUN1

3 Which days do you consider your weekend, or non-work, days? MON2 TUES2 WED2 THURS2 FRI2 SAT2 SUN2

ALL <XYES>

Day #	Day of Week	Date	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7 (yesterday)	PARDAY<TUPDAY>	___/___/___ (day/month/year) SDPARDT	___:___ 00:00 to 23:59	___:___ 00:00 to 23:59	___:___ 00:00 to 23:59	___:___ 00:00 to 23:59									
6			INBED1TM AWAKE1TM INBED2TM AWAKE2TM		WRKSTRTM WRKSTPTM										
5							ALL <I:3> MORMOD MORHARD								
4							MORVHRD			AFTRMOD					
3										AFTRHARD	AFTRVHRD				
2												EVEMOD		EVEHARD	
1 (1 week ago)							EVEVHRD								

PARCHT (TYPE 4)PS

THIS COLUMN NOT DATABASED

SEE NEXT PAGE FOR CALCULATIONS

ALL TIMES DERIVED USING SDPARDT

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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CALCULATIONS FOR 7dPAR

SLEEP TIME

AWAKE1TM AND AWAKE2TM ASSOCIATED WITH SDPARDT +1 when

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

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

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

TOTAL SLEEP TIME

TOTSLEEP = SLP2TM + SLP1TM

TOTAL WORK TIME

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

ALL TIMES DERIVED USING SDPARDT

PAGEID = 72

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

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

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

PARQ (TYPE 4)

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

LSTWK<TUPHYS>

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

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

- ☐ 0 No
- ☐ 1 Yes

PARPROB<XYESNO>

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

- ☐ 0 No
- ☐ 1 Yes

PARVLD<XYESNO>

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

- ☐ 0 No
- ☐ 1 Yes

OTHACT<XYESNO>

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 73

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

6-Day Food Record

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

	Day of DLW	Date of Record	Record Quality (check only one)	Replacement Values: Day of DLW	Replacement Values: Date of Record	Replacement Values: Record Quality (check only one)
=	1	DLWDAY<TUFDRD> __ __ / __ __ __ / __ __ __ __ (day / month / year) FDRECDT	RECQUAL<TUQUAL> ☐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 PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 74

FORM/BLOCK = BASELINE2

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)

DATEHDR (TYPE 4)

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

SAME AS PAGE 4

WEIGHT (TYPE 4)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

Baseline Submission 2 *Visit 4*

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

PAGEID = 75

PARHDR (TYPE 4)

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)*: ___

1 Were you employed in the last seven days? ☐0 No → Skip to question 3 ☐1 Yes Interviewer initials: ___ ___ ___ (first middle last)

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									

PARCHT (TYPE 4)PS

SAME AS PAGE 71

Not Done Codelist: 1 Participa... ...ot required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 76

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

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

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

PARQ (TYPE 4)

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

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 77

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)

DATEHDR (TYPE 4)

OR Not done → Specify reason *(use codelist below)*: ___SAME AS PAGE 4

1 Dynometer handle position: _____DYNO<I:2>

HANDGRIP (TYPE 4)PS

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

DOMHND<TUDOMH>

3 Handgrip strength:

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 78

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

Isometric/Isokinetic Knee Extension and Flexion

Date and time of assessment: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) Staff initials: ___ ___ ___ (first middle last)

OR Not done → Specify reason (use codelist below): SAME AS PAGE 4

DATEHDR (TYPE 4)

1 Recent injury or pain—right knee? ☐0 No ☐1 Yes RKIP<XYESNO>

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes LKIP<XYESNO>

ISOMETRC (TYPE 4)PS

3 Specify machine used (PBRC only): ☐0 Cybex ☐1 Biolex MACHINE <TUSED>

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

	All values corrected for gravity effect torque		Right Leg	Left Leg	If Not Done, Specify Reason (use codelist below) GETNR<TUND>
3	60°/sec knee extension	1 =			
		2 = peak torque	_____ N.m	_____ N.m	
		3 = total work	_____ N.m	_____ N.m	_____
		4 = average power	_____ watts	_____ watts	
4	60°/sec knee flexion	5 = peak torque	_____ N.m	_____ N.m	
		6 = total work	_____ N.m	_____ N.m	_____
		7 = average power	_____ watts	_____ watts	
5	180°/sec knee extension	8 = peak torque	_____ N.m	_____ N.m	
		9 = total work	_____ N.m	_____ N.m	_____
		10= average power	_____ watts	_____ watts	
		11= work fatigue index	_____ %	_____ %	
6	180°/sec knee flexion	12= peak torque	_____ N.m	_____ N.m	
		13= total work	_____ N.m	_____ N.m	_____
		14= average power	_____ watts	_____ watts	
		15= work fatigue index	_____ %	_____ %	
7	Isometric knee extension: trial 1	16= peak torque	_____ N.m	_____ N.m	
	trial 2	17= peak torque	_____ N.m	_____ N.m	_____
	trial 3	18= peak torque	_____ N.m	_____ N.m	
8	Isometric knee flexion: trial 1	19= peak torque	_____ N.m	_____ N.m	
	trial 2	20= peak torque	_____ N.m	_____ N.m	_____
	trial 3	peak torque	_____ N.m	_____ N.m	

See next page for TUGRAV codelist

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

TUGRAV

1=KE60PT

2=KE60TW

3=KE60AP

4=KF60PT

5=KF60TW

6=KF60AP

7=KE180PT

8=KE180TW

9=KE180AP

10=KE180WFI

11=KF180PT

12=KF180TW

13=KF180AP

14=KF180WFI

15= IKE1

16= IKE2

17= IKE3

18=IKF1

19=IKF2

20=IKF3

PAGEID = 79

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

Doubly Labeled Water (DLW)

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

DLWHDR (TYPE 4)

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

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

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

DLWCHT (TYPE 4)PS

4 Urine samples:

SAME AS PAGE 34 except
No Display Item 1 and 2 below

DLWSMPNO<TUDLW>

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

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

DLWHDR (TYPE 4)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 80

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

Staff initials: __ __ __ (first middle last)

DATEHDR (TYPE 4)

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

SAME AS PAGE 4

WEIGHT (TYPE 4)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 81

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

VO_2 Max

SAME AS PAGE 4 DATEHDR (TYPE 4)

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

VOMAX (TYPE 3)

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

MEALTM (associated with STUDYDT)

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

RESTRHYM<TURHYT>

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

VCONDUCT<TUVCON>

RESTRATE

4 Heart rate (HR) data: Resting heart rate: _____ bpm

AGERATE

Age-predicted heart rate: _____ bpm

HRATEMAX

Heart rate (max): _____ bpm

5 Reason(s) for termination of testing (check all that apply):

SYMLTD ALL<XYES> CANGINA ANGNA<XYES>

☐ Symptom limited (dyspnea, fatigue)

☐ Angina/ischemia — Complete all that apply: HR when true cardiac angina occurred: _____ bpm OR ☐96 NA

ANGISCHEM

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

EGGCHNG ISCHNA<XYES>

ARRYTHM

☐ Serious arrhythmias (VT or SVT)

☐ Changes in blood pressure CHGBP VENISCH

☐ Ventricular ischemia (schedule stress image study, complete ventricular episode report)

PAINCRMP

☐ Orthopedic/extremity complaints (pains/cramps)

OTHER REASONSP<V:50>

☐ Other (specify): _____

6 Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min, bi/tri-geminy, NSVT [≥ 3 beats])?

ECTOPY<XYESNO>

☐0 No

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

EXERCISE<XYES> RECOVERY<XYES>

PVOMEAS1 PVOMEAS2

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

MEETCRIT<XYESNO>

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

VOMEAS1 VOMEAS2

☐0 No

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

EXERMIN<I:3>

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)

EXERSEC<I:2>

VOSYS VODIA

10 Blood pressure at VO_2 peak/VO_2 max: _____ / _____ (systolic / diastolic) mm Hg

BORG<I:2>

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

PEAKHR

12 Peak RER: _____

VEPEAK

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

VEVOPEAK

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

All BPM <I:3>

Other Measures
(ITEMS 7, 8,12,13,14) <F:9:3>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

PAGEID = 82

Baseline Submission 2 ***Visit 5***

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

PARHDR (TYPE 4)

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	___	___	___	___	___	___	___	___	___

PARCHT (TYPE 4)PS

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Not Done Codelist: 1 Participant refused 2 C... Not required

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PAGEID = 83

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

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

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

PARQ (TYPE 4)

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

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 84

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)

FOODRCD (TYPE 4)PS

SAME AS PAGE 73

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

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

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

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed? WKSHTCMP<XYESNO>

DTHADM1 (TYPE 3)

☐0 No

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

EXCLMET<XYESNO> ☐1 Yes → STOP. Do not administer test.

2 Date of injection: ___ ___ / ___ ___ / ___ ___ ___ ___ (day / month / year) OR Not done → Specify reason (use codelist below): ___ DTHADMDT DTHND<TUND>

3 Injection by (initials): ___ ___ ___ (first middle last) DTHINIT<V:3>

4 Arm injected: ☐1 Right ☐2 Left ARM<TUDTHA>

5 DTH results:

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

A = Largest diameter

B = Second diameter perpendicular to A

DTHADM2 (TYPE 4)PS

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

ANTITYPE< TUTYPE>

TUTYPE CODELIST
1 = STANDARD
98 = OTHER

TUANTI CODELIST
1 = NORMAL SALINE 24
2 = TETANUS TOXOID 24
3 = CANDIDA 24
4 = TRICHOPHYTON 24
5 = NORMAL SALINE 48
6 = TETANUS TOXOID 48
7 = CANDIDA 48
8 = TRICHOPHYTON 48

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

Send to D ... 27705

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

Clinic Weight

Weight date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) Staff initials: ___ ___ ___ (first middle last)

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

DATEHDR (TYPE 4)

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

Weight 1: ___ ___ ___ . ___ kg

SAME AS PAGE 4

Weight 2: ___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Vital Signs

Assessment date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

VITALS (TYPE 3)

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

SAME AS PAGE 29

Natural waist measurement 3: ___ ___ ___ . ___ cm

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

Umbilical point waist measurement 1: ___ ___ ___ . ___ cm

Umbilical point waist measurement 2: ___ ___ ___ . ___ cm

Umbilical point waist measurement 3: ___ ___ ___ . ___ cm

3 Pulse: ___ ___ ___ bpm OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

4 Temperature: ___ ___ ___ . ___ °C OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

5 Respirations: ___ ___ per minute OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

6 Blood pressure (check only one): ☐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

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

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐0 No

SAME AS PAGE 33

☐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 (ADMIT (TYPE 3))	If Not Done, Reason (Use codelist below)
SINTIALS __ __ __ (first middle last)	Start Date: CTSTRDT __ __/__ __ __/__ __ __ __ (day / month / year)	Start Time CTSTRTM __:__ (00:00 to 23:59)	CTND<TUND> _____
	CTSTPDT Stop Date: __ __/__ __ __/__ __ __ __ (day / month / year)	Stop Time CTSTPTM __:__ (00:00 to 23:59)	

Inpatient Admission and Discharge

1 Inpatient admission date and time: __ __/__ __ __/ ADMITDT (year) ADMITTM __:__ (00:00 to 23:59)

2 Inpatient discharge date and time: __ __/__ __ __/ DISCHDT (year) DISCHTM __:__ (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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calerie Phase 2

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Baseline Submission 2 *Visit 7*

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

PARHDR (TYPE 4)

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)*: ___

1 Were you employed in the last seven days? ☐0 No → **Skip to question 3** ☐1 Yes **Interviewer initials:** ___ ___ ___ (first middle last)

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									

PARCHT (TYPE 4)PS

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Not Done Codelist: 1 Participant refused 2 Clinician un

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

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

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

PARQ (TYPE 4)

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

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

Outcomes Labs

OUTCMELB (TYPE 4)PS

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

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

Sample OTCMSAMP<TUOTCM>	Sample Complete? SAMPCOL<XYESNO>	If Not Done, Reason (Use codelist below) SAMPND<TUND>	Staff Initials SAMPINIT (first middle last)
1 = Catecholamines	☐0 No ☐1 Yes	_____	
2 = Blood	☐0 No ☐1 Yes	_____	
3 = Oral glucose tolerance test (OGTT)	☐0 No ☐1 Yes	_____	

ADDITIONAL ITEMS ON NEXT SLIDE FOR THE OUTCMELB PANEL

4 = Vaccinations appear on p.211

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

BIOPSY (TYPE 4)PS

Biopsy Labs

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

24-hour Urine Collection

URINE24 (TYPE 3)

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

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

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Panel Items not Displayed here appear on p.211:

HEPA, TD, PV ALL<XYES>

Panel Items not Displayed here appear on p.211:

HEPVAC<TUHVAC>

1= HAVRIX

2= VAQTA

98= OTHER

TETVAC<TUTVAC>

1= DECOVAC

98= OTHER

PNEUVAC<TUPVAC>

1= PNEUMOVAX

98= OTHER

SEE PAGE 211

HEPSPEC V:30

TETSPEC V:30

PNEUSPEC V:30

HEPLOT V:20

TETLOT V:20

PNEULOT V:20

PAGEID = 90A

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

Sex Hormone

If Not Done → Specify reason (use codelist below): ____ STUDYN D DATEHDR (TYPE 4)

No display STUDYDT
STUDYTM or SINITIALS

Contraception method (females only):

☐ None OR Check all that apply: OUTCME2 (TYPE 4)

NONE <XYES>

☐ Oral contraceptive → Specify: _____ ORALSP <V:50>

ORAL <XYES>

Record on Concomitant Medications page

☐ Other → Specify (e.g., barrier, IUD): _____ OTHERSP <V:50>

OTHER <XYES>

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

DXA Scan

DXASCAN (TYPE 4)

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

SAME AS PAGE 35 - -

For the area scanned section (below)

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

Display only WBDY WBDYND REWBDY

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

MOVED DXASCAN PANEL FROM PAGE 91

PAGEID = 91

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

Metabolic Rate

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

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 8 2 = RMR2	__ __/__ __ __/__ __ __ __ (day / month / year)	_____	__ __ __ (first middle last)
Cart ID	☐ Tufts-003 (623-002) ☐ 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

RMR (TYPE 4)PS

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

Randomization

RANDOM (TYPE 1)

Date of randomization: __ __ / __ __ __ / __RANDOMDT (day / month / year)

Treatment Group

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

☐ 1 CR–calorie restricted TGROUP<TUGRP>

☐ 2 AL–ab libitum *(control)*

Intervention

Did participant start intervention? SRTINVEN<XYESNO>

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

☐ 1 Yes → If Yes: Date intervention started: __ __ / __ __ __ / __INVENTDT (day / month / year)

Staff Signature NOTE: Signature of staff that randomized participant

Signature: NOT DATABASED Date: NOT DATABASED (day / month / year)

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FORM/BLOCK = MONTH 1

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

12-Lead ECG

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

Safety Labs (Potassium Surveillance)

Date and time of sample collection: __ __/__ __ __/__ __ __ __ (day / month / year) __ __:__ __ (00:00 to 23:59) SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐0 No ☐1 Yes	Do not display LMEALDT LMEALTM URSMPCOL URSMPND URNINIT	SAME AS PAGE 30 __ __ __ (first middle last)

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

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PAGEID = 94

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

Clinic Weight

Weight date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) Staff initials: ___ ___ ___ (first middle last)

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

DATEHDR (TYPE 4)

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

Weight 1: ___ ___ ___ . ___ kg SAME AS PAGE 4

Weight 2: ___ ___ ___ . ___ kg WEIGHT (TYPE 4)

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Vital Signs

Assessment date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

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

VITALS (TYPE 3)

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

Natural waist measurement 1: ___ ___ ___ . ___ cm SAME AS PAGE 29

Natural waist measurement 2: ___ ___ ___ . ___ cm

Natural waist measurement 3: ___ ___ ___ . ___ cm

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

Umbilical point waist measurement 1: ___ ___ ___ . ___ cm

Umbilical point waist measurement 2: ___ ___ ___ . ___ cm

Umbilical point waist measurement 3: ___ ___ ___ . ___ cm

3 Pulse: ___ ___ ___ bpm OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

4 Temperature: ___ ___ ___ . ___ °C OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

5 Respirations: ___ ___ per minute OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

6 Blood pressure (check only one): ☐1 Left arm ☐2 Right arm Staff initials: ___ ___ ___ (first middle last)

6a Blood pressure 1: ___ ___ ___ / ___ ___ ___ mm Hg (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 PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 95

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

12-Lead ECG

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

SAFETYLB (TYPE 4)

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

Contraception

If Not Done → Specify reason (use codelist below): ~~CNTRAND<TUND>~~

Contraception method (females only):

No display STUDYDT, STUDYTM or SINITIALS

☐ None OR Check all that apply: OUTCME2 (TYPE 4)

NONE <XYES>

☐ Oral contraceptive → Specify: ~~ORALSP <V:50>~~ _____
Record on Concomitant Medications page

ORAL <XYES>

☐ Other → Specify (e.g., barrier, IUD): ~~OTHERSP <V:50>~~

OTHER <XYES>

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

12-Lead ECG

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

Safety Labs (Potassium Surveillance)

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

SAFETYLB (TYPE 4)

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

SAME AS PAGE 93

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

12-Lead ECG

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

Safety Labs (Potassium Surveillance)

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	_____	SAME AS PAGE 93 ___ ___ ___ (first middle last)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 101

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59) Staff initials: __ __ __ (first middle last)

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

DATEHDR (TYPE 4)

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

Weight 1: __ __ __ . __ kg

SAME AS PAGE 4

Weight 2: __ __ __ . __ kg

WEIGHT (TYPE 4)

Weight 3: __ __ __ . __ kg

Weight of gown: __ __ __ . __ kg

Vital Signs

Assessment date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

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

VITALS (TYPE 3)

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

Staff initials: __ __ __ (first middle last)

Natural waist measurement 1: __ __ __ . __ cm

SAME AS PAGE 29

Natural waist measurement 2: __ __ __ . __ cm

Natural waist measurement 3: __ __ __ . __ cm

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

Umbilical point waist measurement 1: __ __ __ . __ cm

Umbilical point waist measurement 2: __ __ __ . __ cm

Umbilical point waist measurement 3: __ __ __ . __ cm

3 Pulse: __ __ __ bpm OR Not done → Specify reason *(use codelist below)*: _____ Staff initials: __ __ __ (first middle last)

4 Temperature: __ __ __ . __ °C OR Not done → Specify reason *(use codelist below)*: _____ Staff initials: __ __ __ (first middle last)

5 Respirations: __ __ per minute OR Not done → Specify reason *(use codelist below)*: _____ Staff initials: __ __ __ (first middle last)

6 Blood pressure *(check only one)*: ☐1 Left arm ☐2 Right arm Staff initials: __ __ __ (first middle last)

6a Blood pressure 1: __ __ __ / __ __ __ mm Hg (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 PHASE2 ANNOTATION V8.0 24FEB2012

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

12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
DATEHDR (TYPE 4) __ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59) SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): _____	Is ECG (check only one): SAME AS PAGE 30 ☐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)

SAFETYLB (TYPE 4)

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

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)

OUTCMELB (TYPE 4)PS

SAME AS PAGE 90

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
OTCMSAMP<TUOTCM> Blood Display only item 2= Blood	☐0 No ☐1 Yes	_____	__ __ __ (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:
SAME AS PAGE 95	OUTCME2 (TYPE 4) ☐ Oral contraceptive → Specify: _____ Record on Concomitant Medications page ☐ Other → Specify (e.g., barrier, IUD): _____

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 106

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

SAME AS PAGE 36

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

DATEHDR (TYPE 4)

MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

SAME AS PAGE 65

	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

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

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MAEDS (TYPE 4)PS

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

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

SAME AS PAGE 66

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

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

PAGEID = 108

MAEDS (TYPE 4)PS

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

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

SAME AS PAGE 67

	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

12-Lead ECG

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

Safety Labs (Potassium Surveillance)

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	_____	SAME AS PAGE 93 __ __ __ (first middle last)

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

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

12-Lead ECG

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

Safety Labs (Potassium Surveillance)

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	_____	SAME AS PAGE 93 __ __ __ (first middle last)

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

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

Clinic Weight

Weight date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) Staff initials: ___ ___ ___ (first middle last)

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

DATEHDR (TYPE 4)

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

Weight 1: ___ ___ ___ . ___ kg

SAME AS PAGE 4

Weight 2: ___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Vital Signs

Assessment date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59)

VITALS (TYPE 3)

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

SAME AS PAGE 29

Natural waist measurement 2: ___ ___ ___ . ___ cm

Natural waist measurement 3: ___ ___ ___ . ___ cm

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

Umbilical point waist measurement 1: ___ ___ ___ . ___ cm

Umbilical point waist measurement 2: ___ ___ ___ . ___ cm

Umbilical point waist measurement 3: ___ ___ ___ . ___ cm

3 Pulse: ___ ___ ___ bpm OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

4 Temperature: ___ ___ ___ . ___ °C OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

5 Respirations: ___ ___ per minute OR Not done → Specify reason (use codelist below): _____ Staff initials: ___ ___ ___ (first middle last)

6 Blood pressure (check only one): ☐1 Left arm ☐2 Right arm Staff initials: ___ ___ ___ (first middle last)

6a Blood pressure 1: ___ ___ ___ / ___ ___ ___ mm Hg (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 PHASE2 ANNOTATION V8.0 24FEB2012

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

12-Lead ECG

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

Safety Labs

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

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

SAFETYLB (TYPE 4)

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

Contraception

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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)

DATEHDR (TYPE 4)

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)*:

SAME AS PAGE 4

Weight 1: ___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ 0 No

SAME AS PAGE 33

☐ 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?

DXASCAN (TYPE 4)

☐ 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?

SAME AS PAGE 35

☐ 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

PAGEID = 114

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

Doubly Labeled Water (DLW)

DLWHDR (TYPE 4)

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)*: __

SAME AS PAGE 34

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

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

4 Urine samples:

DLWCHT (TYPE 4)PS

Collection	Sample	Date and Time Collected
Pre dosing *(PD)*	PDa	SAME AS PAGE 34 __ __/__ __ __/__ __ __ __ (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)

DISPLAY DLWLBL2

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 PHASE2 ANNOTATION V8.0 24FEB2012

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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): _____

SAME AS PAGE 36

DATEHDR (TYPE 4)

Profile of Mood States

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

POMS (TYPE 4)PS

Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly	☐0	☐1	☐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

SAME AS PAGE 42

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 122

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

Profile of Mood States (continued)

POMS (TYPE 4)PS

SAME AS PAGE 43

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 123

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

Profile of Mood States (continued)

POMS (TYPE 4)PS

SAME AS PAGE 44

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Perceived Stress Scale (PSS)

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

PSS (TYPE 4)

SAME AS PAGE 45

	Never	Almost Never	Some-times	Fairly Often	Very Often
1 In the last month, how often have you felt that you were unable to control the important things in your life?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2 In the last month, how often have you felt confident about your ability to handle your personal problems?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3 In the last month, how often have you felt that things were going your way?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

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

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Pittsburgh Sleep Quality Index (PSQI)

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

During the past month...

SAME AS PAGE 46

PSQI1(TYPE 4)

1 When have you usually gone to bed? ___ ___ : ___ ___ (00:00 to 23:59)

2 How long (in minutes) has it taken you to fall asleep each night? _____ minutes

3 When have you usually gotten up in the morning? ___ ___ : ___ ___ (00:00 to 23:59)

4 How many hours of actual sleep did you get at night?
(This may be different than the number of hours you spend in bed.) ___ . ___ hours

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

Pittsburgh Sleep Quality Index (PSQI) (continued)

SAME AS PAGE 47

PSQI2 (TYPE 3)

	Never	Once or twice	Once or twice each week	3 or more times each week
7 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	☐0	☐1	☐2	☐3

	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8 During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?	☐0	☐1	☐2	☐3

	Very good	Fairly good	Fairly bad	Very bad
9 During the past month, how would you rate your sleep quality overall?	☐0	☐1	☐2	☐3

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

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

DATEHDR (TYPE 4)

SAME AS PAGE 36

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

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

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "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.**

SAME AS PAGE 48

DISFEM1 (TYPE 4)PS

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

Section 1—Sexual Cognition/Fantasy

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

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

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

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

Section 2—Sexual Arousal

SAME AS PAGE 49

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.2 Actively seek sexual satisfaction	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.3 Feel sexually aroused with a partner	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

DISFEM2 (TYPE 4)PS

	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

SAME AS PAGE 50

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.2 Masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.3 Casual kissing and petting	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.4 Sexual foreplay	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.5 Sexual intercourse, oral sex, etc.	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

Section 4—Orgasm

DISFEM3 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
4.3 The ability to have multiple orgasms *(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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

Section 5—Drive and Relationship

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DISFEM1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your **ideal** frequency of sexual intercourse?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

	Not at all	Slightly	Moderately	Highly	Extremely
5.2 During this period, how interested have you been in sex?	☐0	☐1	☐2	☐3	☐4

DISFEM3 (TYPE 4)PS

5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	☐0	☐1	☐2	☐3	☐4

DISFEM4 (TYPE 4)PS

	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

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

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

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

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

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

DISMALE1 (TYPE 4)PS

SAME AS PAGE 52

Section 1—Sexual Cognition/Fantasy

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

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

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

Section 2—Sexual Arousal

SAME AS PAGE 53

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.2 A full erection during a sexual fantasy or daydream	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.4 A full erection during masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

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

Section 3—Sexual Behavior/Experiences SAME AS PAGE 54

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.2 Masturbation	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.3 Casual kissing and petting	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.4 Sexual foreplay	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8
3.5 Sexual intercourse, oral sex, etc.	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

Section 4—Orgasm

DISMALE2 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
4.3 The length or duration of your orgasm	☐0	☐1	☐2	☐3	☐4
4.4 The amount of seminal liquid that you ejaculate	☐0	☐1	☐2	☐3	☐4
4.5 Your sense of control (timing) of your orgasm	☐0	☐1	☐2	☐3	☐4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

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

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

Section 5—Drive and Relationship

SAME AS PAGE 55

DISMALE1 (TYPE 4)PS

	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

	Not at all	Slightly	Moderately	Highly	Extremely
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

DISMALE2 (TYPE 4)PS

DISMALE3 (TYPE 4)PS

	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	☐0	☐1	☐2	☐3	☐4	☐5	☐6	☐7	☐8

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

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DATEHDR (TYPE 4)

Food Cravings Questionnaire—State (FCQ–S)

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

FCQSTATE (TYPE 4)PS

SAME AS PAGE 58

	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

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DATEHDR (TYPE 4)

Food Craving Inventory (FCI–II)

CRAVE (TYPE 4)PS

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.

SAME AS PAGE 59

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

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DATEHDR (TYPE 4)

Eating Inventory

TFEQA (TYPE 4)PS

SAME AS PAGE 60

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

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Eating Inventory (continued)

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

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TFEQA (TYPE 4)PS

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Eating Inventory (continued)

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

TFEQB (TYPE 3)

37	How often are you dieting in a conscious effort to control your weight?	☐1 Rarely ☐2 Sometimes ☐3 Usually ☐4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	☐1 Rarely ☐2 Sometimes ☐3 Usually ☐4 Always
39	How often do you feel hungry?	☐1 Rarely ☐2 Sometimes ☐3 Usually ☐4 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	☐1 Rarely ☐2 Sometimes ☐3 Usually ☐4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐1 Easy ☐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"

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

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DATEHDR (TYPE 4)

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

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WELQ (TYPE 4)PS

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

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

WELQ (TYPE 4)PS

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 142

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

SAME AS PAGE 36

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

DATEHDR (TYPE 4)

MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

SAME AS PAGE 65

	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 143

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

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

SAME AS PAGE 66

MAEDS (TYPE 4)PS

	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 144

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

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

SAME AS PAGE 67

MAEDS (TYPE 4)PS

	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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

BSQ (TYPE 4)PS

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.

SAME AS PAGE 68

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 146

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

Body Shape Questionnaire (BSQ) (continued)

SAME AS PAGE 69

BSQ (TYPE 4)PS

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 147

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

Staff initials: __ __ __ (first middle last)

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

DATEHDR (TYPE 4)

Clinic weight *(if the 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

SAME AS PAGE 4

WEIGHT (TYPE 4)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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PARHDR (TYPE 4)

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): ___

1 Were you employed in the last seven days? ☐0 No → Skip to question 3 ☐1 Yes Interviewer initials: ___ ___ ___ (first middle last)

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									

PARCHT (TYPE 4)PS

SAME AS PAGE 71

Not Done Codelist: 1 Participant refused 2 required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

PARQ (TYPE 4)

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

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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)

SAME AS PAGE 73

FOODRCD (TYPE 4)PS

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Replacement Values: Date of Record	Replacement Values: 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 PHASE2 ANNOTATION V8.0 24FEB2012

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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) OUTCMELB (TYPE 4)PS

Date and time sample collection started: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) SAME AS PAGE 102

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)	

ADMIT (TYPE 3)

SAME AS PAGE 87

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 PHASE2 ANNOTATION V8.0 24FEB2012

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

Clinic Weight

Weight date and time: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59) Staff initials: __ __ __ (first middle last)

DATEHDR (TYPE 4)

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)*:

SAME AS PAGE 4

Weight 1: ___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

Weight 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ 0 No

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

SAME AS PAGE 33

Results: ☐ 1 Negative
☐ 2 Positive

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

DXA Scan

DXASCAN (TYPE 4)

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

SAME AS PAGE 90A

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

RMR (TYPE 4)PS

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 5	__ __/__ __ __/__ __ __ __ (day / month / year)	_____	__ __ __ (first middle last)
No Display 2 = RMR2			
Cart ID RMRVISIT<TURMR>	☐ Tufts-003 (623-002) ☐ WASH U-001 (623-003) ☐ PBRC-016 (623-005) ☐ Tufts-006 (623-006) ☐ WASH U-002 (623-004) ☐ PBRC-017 (623-001)		

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

ADD CARTID TO EXISTING RMR PANEL

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

PARHDR (TYPE 4)

Seven-Day Physical Activity Recall (PAR)

Today's date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / 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)									

PARCHT (TYPE 4)PS

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

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

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

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

PARQ (TYPE 4)

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

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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