FORM/BLOCK = MONTH 9

PAGEID = 156

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 31AUG2007

PAGEID = 157

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)

Contraception

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

Contraception method (females only):	☐ None OR Check all that apply:
SAME AS PAGE 95	☐ Oral contraceptive → Specify OUTCME2 (TYPE 4) _____ 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

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

Natural waist measurement 1: ___ ___ ___ . ___ cm

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

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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)

Pregnancy Test

PREGTEST (TYPE 4)

Complete only for females.

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

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 = 163

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

Doubly Labeled Water (DLW)

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

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

DLWHDR (TYPE 4)

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

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

4 Urine samples:

SAME AS PAGE 114

DLWCHT (TYPE 4)PS

Collection	Sample	Date and Time Collected
Pre dosing *(PD)*	PDa	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	PDb	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 0 (Visit 1)	D0a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D0b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D7b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 14 (Visit 4)	D14a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D14b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

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

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 164

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

Physical Examination

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

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

DATEHDR (TYPE 4)

SAME AS PAGE 32

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 →	

PEXAM (TYPE 4)PS

SAME AS PAGE 32

Physician's Signature

Investigator: _____ (signature) Date: __ __/__ __ __/__ __ __ __ (day/month/year)

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

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

PAGEID = 165

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 35

DXA Scan		**DXA Rescan** OR ☐$_{96}$ NA
Date of scan: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)		Date of rescan: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)
Area Scanned Check all that apply	**If Not Done, Reason** *(Use codelist below)*	**Area Scanned Check all that apply**
☐ Whole body	_____	☐ Whole body
☐ Forearm	_____	☐ Forearm
☐ Spine	_____	☐ Spine
☐ Hip	_____	☐ Hip

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 172

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

SAME AS PAGE 42

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

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 = 173

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

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

PAGEID = 174

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)

SAME AS PAGE 36

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 176

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

PAGEID = 177

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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PAGEID = 178

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.**

DISFEM1 (TYPE 4)PS

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

SAME AS PAGE 48

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

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 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 satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
4.3 The ability to have multiple orgasms *(if typical for you)*	☐0	☐1	☐2	☐3	☐4
4.4 Feelings of closeness and togetherness with your partner	☐0	☐1	☐2	☐3	☐4
4.5 Your sense of control *(timing)* of your orgasm	☐0	☐1	☐2	☐3	☐4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

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

Section 5—Drive and Relationship

SAME AS PAGE 51

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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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

Section 1—Sexual Cognition/Fantasy

SAME AS PAGE 52

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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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 **satisfied** have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
4.3 The length or duration of your orgasm	☐0	☐1	☐2	☐3	☐4
4.4 The amount of seminal liquid that you ejaculate	☐0	☐1	☐2	☐3	☐4
4.5 Your sense of control (timing) of your orgasm	☐0	☐1	☐2	☐3	☐4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

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) (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

DISMALE2 (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				

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): ___ ___

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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.

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

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

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DATEHDR (TYPE 4)

Eating Inventory

TFEQA (TYPE 4)PS

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

SAME AS PAGE 60

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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Eating Inventory (continued)

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TFEQA (TYPE 4)PS

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

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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?	SAME AS PAGE 62 ☐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"

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 191

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)

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.

SAME AS PAGE 63

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 192

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

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

SAME AS PAGE 64

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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)

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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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

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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)

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks... SAME AS PAGE 69	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

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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)*: ~~S~~AME AS PAGE 4

1 Dynometer handle position: _____

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

HANDGRIP (TYPE 4)PS

3 Handgrip strength: SAME AS PAGE 77

Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand
Test 1—peak force	☐0	_____ kg	☐0	_____ kg
Test 2—peak force	☐0	_____ kg	☐0	_____ kg
Test 3—peak force	☐0	_____ kg	☐0	_____ kg

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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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

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes SAME AS PAGE 78 ISOMETRC (TYPE 4)PS

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

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

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

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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 2:	__ __ __ . __ kg
Weight 3:	__ __ __ . __ kg
Weight of gown:	__ __ __ . __ kg

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**

Month 12 Submission ***Visit 2***

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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)*: ___

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 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 202

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

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

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

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

PARQ (TYPE 4)

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 203

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)	Replacement Values: 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

PAGEID = 204

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)*: __ SAME AS PAGE 81

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

3 Rest ECG: **Rhythm** *(check only one)*: ☐ 1 Sinus ☐ 2 Atrial fibrillation ☐ 98 Other
Ventricular conduction *(check only one)*: ☐ 1 Normal ☐ 2 LBBB ☐ 3 RBBB

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

5 **Reason(s) for termination of testing** *(check all that apply)*:
☐ Symptom limited *(dyspnea, fatigue)*
☐ Angina/ischemia → **Complete all that apply:** **HR when true cardiac angina occurred:** _____ bpm OR ☐ 96 NA
HR when ischemic ECG changes occurred: _____ bpm OR ☐ 96 NA
☐ Serious arrhythmias *(VT or SVT)*
☐ Changes in blood pressure
☐ Ventricular ischemia *(schedule stress image study, complete ventricular episode report)*
☐ Orthopedic/extremity complaints *(pains/cramps)*
☐ Other *(specify)*: _____

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

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

8 **Did the participant meet at least 2 of the 3 VO_2 max criteria** *(see box, right)*?
☐ 0 No
☐ 1 Yes → **If Yes: VO_2 max:** _____ mL/kg/min _____ L/min

a Achieve a plateau in VO_2 (change ≤ 150 mL) between the final two stages
b RER ≥ 1.1
c HR max ± 5 bpm of age-predicted maximum

9 **Exercise time:** _____ (minutes) : _____ (seconds)

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

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

12 **Peak RER:** _____

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

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

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

PAGEID = 205

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

Core Temperature

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

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

PAGEID = 206

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

Delayed-type Hypersensitivity (DTH)

DTHADM1 (TYPE 3)

1 Was the DTH worksheet completed?

☐0 No

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

☐1 Yes → STOP. Do not administer test.

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

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

SAME AS PAGE 85

4 Arm injected: ☐1 Right ☐2 Left

5 DTH results:

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

A = Largest diameter

B = Second diameter perpendicular to A

DTHADM2 (TYPE 4)PS

Antigen	24 Hour *(@ Visit 4)*			48 Hour *(@ Visit 5)*		
	A *(diameter)*	B *(diameter)*	Read By:	A *(diameter)*	B *(diameter)*	Read By:
1 Normal saline	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*	___ ___ ___ mm	___ ___ ___ mm	___ ___ ___ (first middle last) *(initials)*
2 Tetanus toxoid *(TT)* *(check only one)*: ☐1 Tetanus toxoid *(Sanofi-Pasteur)* ☐98 Other: _____ Lot #: _____	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
3 Candida *(check only one)*: ☐1 Candin *(AllerMed)* ☐98 Other: _____ Lot #: _____	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
4 Trichophyton *(check only one)*: ☐1 Trichophyton Allergic Extract *(AllerMed)* ☐98 Other: _____ Lot #: _____	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	

Not Done Codelist: 1 Particip[illegible] nt failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 207

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)

MOVED RMR PANEL TO PAGE 207A

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 90

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

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

24-hour Urine Collection

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

URINE24 (TYPE 3)

SAME AS PAGE 90

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 207A

Layout of data entry screen has changes also

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

Sex Hormone

If Not Done → Specify reason *(use codelist below)*: _____ DATEHDR (TYPE 4)

Contraception method *(females only)*: SAME AS PAGE 90A	☐ None OR Check all that apply: OUTCME2 (TYPE 4) ☐ Oral contraceptive → Specify: _____ Record on Concomitant Medications page ☐ Other → Specify *(e.g., barrier, IUD)*: _____

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

Day 2	Date	Time	If Not Done, Reason *(use codelist)*	Staff Initials
~~Date and time of last meal~~				
~~Hormone level blood draw 3 (females only)~~ ~~*Progesterone level*~~				

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason *(Use codelist below)*	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 4	__ __ / __ __ __ / __ __ __ __ (day / month / year)	RMR (TYPE 4)PS SAME AS PAGE 153	__ __ __ (first middle last)

Cart ID

☐ Tufts-003 (623-002) ☐ WASH U-001 (623-003) ☐ PBRC-016 (623-005)
☐ Tufts-006 (623-006) ☐ WASH U-002 (623-004) ☐ PBRC-017 (623-001)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 208

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

SAME AS PAGE 71

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 = 209

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 = 210

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

Biopsy Labs

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

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

SAME AS PAGE 90

BIOPSY (TYPE 4)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

FORM/BLOCK = MONTH 18

PAGEID = 211

Month 18 Submission
Month 17 Visit

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

Clinic Weight

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

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 2: ___ ___ ___ . ___ kg

Weight 3: ___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

Weight of gown: ___ ___ ___ . ___ kg

Pregnancy Test

Complete only for females.

Does participant have reproductive potential?

☐0 No

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

Results: ☐1 Negative ☐2 Positive

PREGTEST (TYPE 4)

Outcomes Labs

SAME AS PAGE 33

Date and time sample collection started: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) ___ ___ : ___ ___ (00:00 to 23:59) OUTCMELB (TYPE 4)PS

Sample *If a sample is not obtained, indicate with a Not Done.*	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐0 No ☐1 Yes SAME AS PAGE 102	___	___ ___ ___ (first middle last)

Vaccine Administration *NOTE: Before any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.*	If Not Done, Reason *(Use codelist below)*	Staff Initials
Vaccine(s) given *(check all that apply)*:	SAME AS PAGE 90	___ ___ ___ (first middle last)

☐ Hepatitis A → Check one: ☐1 Havrix *(GSK)* ☐2 Vaqta *(Merck)* ☐98 Other: ___ HEPA<XYES> HEPVAC<TUHVAC> HEPSPEC V:30

Dose *(check one)*: ☐1 Adult ☐2 Pediatric HEPDOS<TUHDOS>

Lot #: ___ HEPLOT V:20

TD<XYES>

☐ Tetanus/diphtheria → Check one: ☐1 Decovac *(Sanofi-Pasteur)* ☐98 Other: ___ TETVAC<TUTVAC> TETSPEC V:30

Lot #: ___ TETLOT V:20

PV<XYES>

☐ Pneumococcal vaccine → Check one: ☐1 Pneumovax *(Merck)* ☐98 Other: ___ PNEUVAC<TUPVAC> PNEUSPEC V:30

Lot #: ___ PNEULOT V:20

DO NOT DISPLAY LMEALDT LMEALTM

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

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

PAGEID = 212

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

PAGEID = 213

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): 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) 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.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 214

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)*: __

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

SAME AS PAGE 114

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

4 Urine samples:

DLWCHT (TYPE 4)PS

Collection	Sample	Date and Time Collected
Pre dosing *(PD)*	PDa	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	PDb	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 0 (Visit 1)	D0a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D0b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D7b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 14 (Visit 4)	D14a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D14b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

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

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 215

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

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

SAME AS PAGE 33

Results: ☐1 Negative
☐2 Positive

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

DXA Scan		**DXA Rescan** OR ☐96 NA
Date of scan: __ __/__ __ __/__ __ __ __ (day/month/year)		Date of rescan: __ __/__ __ __/__ __ __ __ (day/month/year)
Area Scanned Check all that apply	**If Not Done, Reason** *(Use codelist below)*	**Area Scanned Check all that apply**
☐ Whole body	_____	☐ Whole body
☐ Forearm	_____	☐ Forearm
☐ Spine	_____	☐ Spine
☐ Hip	_____	☐ Hip

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 216

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)*:

SAME AS PAGE 4

Weight 1: __ __ __ . __ kg

Weight 2: __ __ __ . __ kg

WEIGHT (TYPE 4)

Weight 3: __ __ __ . __ kg

Weight of gown: __ __ __ . __ kg

Contraception

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

Contraception method *(females only)*:

SAME AS PAGE 95

☐ None OR Check all that apply:

☐ Oral contraceptive → Specify: _____

Record on Concomitant Medications page

☐ Other → Specify *(e.g., barrier, IUD)*: _____

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGEID = 217

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

Seven-Day Physical Activity Recall (PAR)

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

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

PARHDR (TYPE 4)

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 Clinici

CALERIE PHASE2 ANNOTATION 4.0 12JUN2008

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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

PAGEID = 219

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

PAGEID = 223

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)

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

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

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

SAME AS PAGE 66

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 225

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

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

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

SAME AS PAGE 67

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

Inpatient Admission and Discharge

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

ADMIT (TYPE 3)

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

No Display SINTIALS, CTSTRDT, CTSTPDT, CTSTRTM, CTSTPTM, CTND

Clinic Weight

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

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

Clinic weight *(if the two measurements are more than 0.1 kg apart, measure weight a third time)*: DATEHDR (TYPE 4)

Weight 1:	___ ___ ___ . ___ kg	SAME AS PAGE 4 WEIGHT (TYPE 4)
Weight 2:	___ ___ ___ . ___ kg	
Weight 3:	___ ___ ___ . ___ kg	
Weight of gown:	___ ___ ___ . ___ kg	

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 5	___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SAME AS PAGE 153	_____ RMR (TYPE 4)PS	___ ___ ___ (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)		

ADD CARTID TO RMR PANEL

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 = 227

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

SAME AS PAGE 71

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 = 228

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

FORM/BLOCK = MONTH 24

PAGEID = 229

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 (TYPE 4)

Weight 1:	__ __ __ . __ kg
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)

Results: ☐1 Negative ☐2 Positive

SAME AS PAGE 33

Outcomes Labs

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

OUTCMELB (TYPE 4)PS

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

Vaccine Administration *NOTE: Before any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.*		If Not Done, Reason *(Use codelist below)*	Staff Initials
Vaccine(s) given *(check all that apply)*:	☐ Hepatitis A → Check one: ☐1 Havrix *(GSK)* ☐2 Vaqta *(Merck)* ☐98 Other: _____ Dose *(check one)*: ☐1 Adult ☐2 Pediatric Lot #: _____		__ __ __ (first middle last)

SAME AS PAGE 211

HEPDOS<TUHDOS>

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

Vaccine Display same as page 211 and No Display: TD PV

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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)

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

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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)

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

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

PAGEID = 232

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)*: __

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

SAME AS PAGE 114

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

4 Urine samples:

DLWCHT (TYPE 4)PS

Collection	Sample	Date and Time Collected
Pre dosing *(PD)*	PDa	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	PDb	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 0 (Visit 1)	D0a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D0b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 7 (Visit 2)	D7a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D7b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
Day 14 (Visit 4)	D14a	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)
	D14b	__ __/__ __ __/__ __ __ __ (day / month / year) __ __ : __ __ (00:00 to 23:59)

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

Affix Test Sample Label Here

Affix Retest Sample Label Here

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

CALERIE PHASEE2 ANNOTATION V8.0
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Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Physical Examination

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

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

DATEHDR (TYPE 4)

SAME AS PAGE 32

Body System	Assessments			If Abnormal or Not Done: Explain
	Normal	Abnormal	Not Done	
1 General appearance:	☐1	☐0 →	☐97 →	PEXAM (TYPE 4)PS
2 Head, Ears, Eyes, Nose, Throat:	☐1	☐0 →	☐97 →	SAME AS PAGE 32
3 Neck:	☐1	☐0 →	☐97 →	
4 Heart:	☐1	☐0 →	☐97 →	
5 Lungs:	☐1	☐0 →	☐97 →	
6 Abdomen:	☐1	☐0 →	☐97 →	
7 Lymph nodes:	☐1	☐0 →	☐97 →	
8 Extremities/Skin:	☐1	☐0 →	☐97 →	
9 Neurological:	☐1	☐0 →	☐97 →	
10 Musculoskeletal:	☐1	☐0 →	☐97 →	
	Normal	Abnormal	Not Done*	
11 Genitourinary:	☐1	☐0 →	☐97 →	
12 Breast:	☐1	☐0 →	☐97 →	

Physician's Signature

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

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

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

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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 35

DXA Scan		**DXA Rescan** OR ☐96 NA
Date of scan: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)		Date of rescan: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)
Area Scanned Check all that apply	**If Not Done, Reason** *(Use codelist below)*	**Area Scanned Check all that apply**
☐ Whole body	_____	☐ Whole body
☐ Forearm	_____	☐ Forearm
☐ Spine	_____	☐ Spine
☐ Hip	_____	☐ Hip

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

CALERIE PHASEE2 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

SAME AS PAGE 42

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

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

CALERIE PHASEE2 ANNOTATION V8.0
24FEB2012

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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

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icipant'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

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 PHASEE2 ANNOTATION V8.0
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Participant's Initials: ___ ___ ___ (first middle last)

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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)

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

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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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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)

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

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

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

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

DISFEM1 (TYPE 4)PS

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

SAME AS PAGE 48

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

CALERIE PHASEE2 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 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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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

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

SAME AS PAGE 51

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

PAGEID = 251

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

Section 1—Sexual Cognition/Fantasy

SAME AS PAGE 52

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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

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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 **satisfied** have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely
4.1 Your ability to have an orgasm	☐0	☐1	☐2	☐3	☐4
4.2 The intensity of your orgasm	☐0	☐1	☐2	☐3	☐4
4.3 The length or duration of your orgasm	☐0	☐1	☐2	☐3	☐4
4.4 The amount of seminal liquid that you ejaculate	☐0	☐1	☐2	☐3	☐4
4.5 Your sense of control (timing) of your orgasm	☐0	☐1	☐2	☐3	☐4
4.6 Feeling a sense of relaxation and well-being after orgasm	☐0	☐1	☐2	☐3	☐4

CALERIE PHASEE2 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) (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

DISMALE2 (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				

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): ___ ___

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

PAGEID = 256

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 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.

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

SAME AS PAGE 59

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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

PAGEID = 257

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)

TFEQA (TYPE 4)PS

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

SAME AS PAGE 60

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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

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

Eating Inventory (continued)

SAME AS PAGE 61

TFEQA (TYPE 4)PS

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 PHASEE2 ANNOTATION V8.0 24FEB2012

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

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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?	SAME AS PAGE 62 ☐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"

CALERIE PHASEE2 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)

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.

SAME AS PAGE 63

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

Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

SAME AS PAGE 64

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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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

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

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 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

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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 PHASEE2 ANNOTATION V8.0 24FEB2012

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

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks... SAME AS PAGE 69	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

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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)*: ~~S~~AME AS PAGE 4

1 Dynometer handle position: _____

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

HANDGRIP (TYPE 4)PS

3 Handgrip strength: SAME AS PAGE 77

Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand
Test 1—peak force	☐0	_____ kg	☐0	_____ kg
Test 2—peak force	☐0	_____ kg	☐0	_____ kg
Test 3—peak force	☐0	_____ kg	☐0	_____ kg

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

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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

2 Recent injury or pain—left knee? ☐0 No ☐1 Yes SAME AS PAGE 78 ISOMETRC (TYPE 4)PS

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

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

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

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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 2:	___ ___ ___ . ___ kg
Weight 3:	___ ___ ___ . ___ kg
Weight of gown:	___ ___ ___ . ___ kg

WEIGHT (TYPE 4)

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

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calerie Phase 2

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Month 24 Submission *Visit 2*

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

SAME AS PAGE 71

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 = 271

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

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

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

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

PARQ (TYPE 4)

SAME AS PAGE 72

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

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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

- ☐ 0 No
- ☐ 1 Yes

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PAGEID = 272

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)	Replacement Values: 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 PHASEE2 ANNOTATION V8.0 24FEB2012

PAGEID = 273

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

VO_2 Max

SAME AS PAGE 4

DATEHDR (TYPE 4)

VOMAX (TYPE 3)

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

OR Not done → Specify reason *(use codelist below)*: __ SAME AS PAGE 81

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

3 Rest ECG: **Rhythm** *(check only one)*: ☐ 1 Sinus ☐ 2 Atrial fibrillation ☐ 98 Other
Ventricular conduction *(check only one)*: ☐ 1 Normal ☐ 2 LBBB ☐ 3 RBBB

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

5 **Reason(s) for termination of testing** *(check all that apply)*:
☐ Symptom limited *(dyspnea, fatigue)*
☐ Angina/ischemia++ → **Complete all that apply:** **HR when true cardiac angina occurred:** _____ bpm OR ☐ 96 NA
HR when ischemic ECG changes occurred: _____ bpm OR ☐ 96 NA
☐ Serious arrhythmias *(VT or SVT)*
☐ Changes in blood pressure
☐ Ventricular ischemia *(schedule stress image study, complete ventricular episode report)*
☐ Orthopedic/extremity complaints *(pains/cramps)*
☐ Other *(specify)*: _____

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

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

8 **Did the participant meet at least 2 of the 3 VO_2 max criteria** *(see box, right)*?
☐ 0 No
☐ 1 Yes → **If Yes: VO_2 max:** _____ mL/kg/min _____ L/min

a Achieve a plateau in VO_2 (change ≤ 150 mL) between the final two stages
b RER ≥ 1.1
c HR max ± 5 bpm of age-predicted maximum

9 **Exercise time:** _____ (minutes) : _____ (seconds)

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

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

12 **Peak RER:** _____

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

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

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24FEB2012

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

Outcomes Labs

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

OUTCMELB (TYPE 4)PS

No Display LMEALDT, LMEALTM

Sample *If a sample is not obtained, indicate with a Not Done.*	Sample Complete?	If Not Done, Reason *(Use codelist below)*	Staff Initials
Blood	☐ 0 No ☐ 1 Yes	SAME AS PAGE 102 _____	__ __ __ (first middle last)

Core Temperature

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

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 PHASEE2 ANNOTATION V8.0 24FEB2012

PAGEID = 275

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

Delayed-type Hypersensitivity (DTH)

DTHADM1 (TYPE 3)

1 Was the DTH worksheet completed?

☐ 0 No

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

☐ 1 Yes → STOP. Do not administer test.

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

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

SAME AS PAGE 85

4 Arm injected: ☐ 1 Right ☐ 2 Left

5 DTH results:

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

A = Largest diameter

B = Second diameter perpendicular to A

DTHADM2 (TYPE 4)PS

Antigen	24 Hour *(@ Visit 4)*			48 Hour *(@ Visit 5)*		
	A *(diameter)*	B *(diameter)*	Read By:	A *(diameter)*	B *(diameter)*	Read By:
1 Normal saline	___ ___ ___ mm	___ ___ ___ mm		___ ___ ___ mm	___ ___ ___ mm	
2 Tetanus toxoid *(TT)* *(check only one)*: ☐ 1 Tetanus toxoid *(Sanofi-Pasteur)* ☐ 98 Other: _____ Lot #: _____	___ ___ ___ 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	

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 = 276

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)*:

WEIGHT (TYPE 4)

Weight 1:	__ __ __ . __ kg SAME AS PAGE 4
Weight 2:	__ __ __ . __ kg
Weight 3:	__ __ __ . __ kg
Weight of gown:	__ __ __ . __ kg

MOVED THE RMR PANEL TO PAGE 276A

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 90

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

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

24-hour Urine Collection

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

URINE24 (TYPE 3)

SAME AS PAGE 90

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

PAGEID = 276A

Layout of data entry screen has changes also

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

Sex Hormone

If Not Done → Specify reason *(use codelist below)*: ~~SAME AS PAGE 90A~~ DATEHDR (TYPE 4)

Contraception method *(females only)*: SAME AS PAGE 90A

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

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

Day 2	Date	Time	If Not Done, Reason *(use codelist)*	Staff Initials
~~Date and time of last meal~~				
~~Hormone level blood draw 3 (females only)~~ ~~*Progesterone level*~~				

Metabolic Rate

Sample	Date of Collection	If Not Done, Reason *(Use codelist below)*	Staff Initials
Resting Metabolic Rate *(RMR)*—Visit 4	SAME AS PAGE 153 __ __ / __ __ __ / __ __ __ __ (day / month / year)	RMR (TYPE 4)PS _____	__ __ __ (first middle last)

Cart ID

☐ Tufts-003 (623-002) ☐ WASH U-001 (623-003) ☐ PBRC-016 (623-005)
☐ Tufts-006 (623-006) ☐ WASH U-002 (623-004) ☐ PBRC-017 (623-001)

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

CALERIE PHASEE2 ANNOTATION V8.0
24FEB2012

calerie Phase 2

Month 24 Submission *Visit 4*

PAGEID = 277

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

SAME AS PAGE 71

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

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PAGEID = 278

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 PHASEE2 ANNOTATION V8.0 24FEB2012

PAGEID = 279

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

Biopsy Labs

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

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

SAME AS PAGE 90

BIOPSY (TYPE 4)

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

FORM/BLOCK = ADVERSE EVENTS

Signs, Symptoms and Adverse Events Log

AELOG (TYPE 4)R

PAGEID = 280

THIS IS A REPEATING PAGE

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

Signs, Symptoms and Adverse Events

Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline:
☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

TIMEPT<TUTMPT> see attached page for codelist

AE #	Adverse Event	Serious	Intensity	Causality (check only one)	Action Taken Due to AE (check all that apply)	Outcome	Start/End Date OR Check if Continuing
AENUM<I:4>			AEINTEN<TUTEN>		ALL<XYES>	AEOUTCME<TUOCME>	
___	AESPEC<V:100>	☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other (specify): _____	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	Start Date: AESTRDT End Date: AESTPDT OR ☐1 Continuing
	AESER<XYESNO>			AECAUSE<TUCAUS>			AECONT<XYES>
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other (specify): _____ ACNONE ACTEMPD ACMEDREQ ACPERMD ACOTHR	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	Start Date: ___/___/___ End Date: ___/___/___ OR ☐1 Continuing
	MEDRA MEDRTEXT<V:100> MEDRCODE<V:8> WORKFLOW<V:5> CODETM<DATETIME> CONFLVL<V:2> MATCHES<V:4> CODER<V:20>						
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other (specify): _____	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	Start Date: ___/___/___ End Date: ___/___/___ OR ☐1 Continuing
___		☐0 No ☐1 Yes*	☐1 Mild ☐2 Moderate ☐3 Severe	☐1 None ☐2 Doubtful ☐3 Possibly ☐4 Probably ☐5 Very likely	☐1 None ☐2 Intervention temporarily discontinued ☐3 Medical therapy required ☐4 Intervention permanently discontinued ☐98 Other (specify): _____	☐1 Still present and unchanged ☐2 Improving ☐3 Resolved ☐4 Resolved with sequelae ☐5 Death	Start Date: ___/___/___ End Date: ___/___/___ OR ☐1 Continuing

ACOTHSP<V:50>

*If Serious is Yes, submit expedited SAE form.

SAE Reporting Criteria: 1 Death 2 Persistent or significant disability/incapacity 5 Congenital anomaly or birth defect
hospitalization 6 Other significant medical event

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

TUTMPT Codelist

1 = Baseline 1

2 = Baseline 2

3 = Month 1

4 = Month 3

5 = Month 6

6 = Month 9

7 = Month 12

8 = Month 18

9 = Month 24

FORM/BLOCK = CONMED LOG

PAGEID = 281

Concomitant Medications Log

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

Concomitant Medications Log

Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box.
Send copies of this form with each submission starting with baseline: TIMEPT<TUTMPT> include on CONMED2 panel

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

	Medication STUDYSUP<TUMED>	Start Date or ☑ if Pre-study	Stop Date or ☑ if Continuing	Indication
1	Study vitamin-mineral supplement	SUPSTRDT __/__/____ (day/month/year) Derivation for CONMED1	SUPSTPDT __/__/____ WHOTERM WHOCODE	CONMED1 (TYPE 4)PS
2	Study calcium supplement	__/__/____	Vitamins ____ 90005301001 Calcium 00751501001	
3	SEE PAGE 281A	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	CONMED2 (TYPE 4)R
4	CMEDNUM<I:2> CMED<V:110>	CMSTRDT __/__/____ OR ☐1 Pre-study	CMSTPDT __/__/____ OR ☐1 Continuing	MEDIND<V:110>
5		CMPSTDY<XYES> __/__/____ OR ☐1 Pre-study	CMEDCONT<XYES> __/__/____ OR ☐1 Continuing	
6	WHODRUG_B2 WHONAME<V:80>	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
7	WHOCODE <V:32> WORKFLOW <V:5> CODER <V:20>	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
8	CODETM<DATETIME> CONFLVL <V:2> MATCHES <V:4>	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
9	WHODRUG_ATC_B2	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
10	ATCTERM<V:110> ATCCODE<V:40> WORKFLO2<V:5>	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
11	CODETM2 <DATETIME> CONFLVL2<V:2> MATCHES2<V:4> CODER2<V:20>	__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	
12		__/__/____ OR ☐1 Pre-study	__/__/____ OR ☐1 Continuing	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

THIS IS A REPEATING PAGE

Concomitant Medications Log

PAGEID = 281+

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

Concomitant Medications Log

Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box.
Send copies of this form with each submission starting with baseline:

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

CONMED2 (TYPE 4)R

Medication	Start Date or ☑ if Pre-study	Stop Date or ☑ if Continuing	Indication
1	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
2	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	SAME AS PAGE 281
3	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
4	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
5	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
6	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
7	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
8	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
9	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
10	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
11	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	
12	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Pre-study	__ __/__ __ __/__ __ __ __ (day/month/year) OR ☐1 Continuing	

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

FORM/BLOCK = CONMED LOG

Concomitant Medications Log

PAGEID = 281

Center Number: __ __ Participant Number: __ __ __ CONMED1 (TYPE 4)PS __
first middle last

Study Calcium Supplement 1000 mg

Medication STUDYSUP<TUMED>	Start Date	Stop Date
3 = Study calcium supplement, 1000 mg	SUPSTRDT __ __/__ __ __/__ __ __ __ day month year	SUPSTPDT __ __/__ __ __/__ __ __ __ day month year

SAME AS PAGE 281

Derivation for CONMED1

WHOTERM	WHOCODE
Calcium	00751501001

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

THIS IS A REPEATING PAGE

Date received at DCRI Safety Surveillance

PAGEID = 282 FORM/BLOCK = ADVERSE EVENTS

Serious Adverse Event Form

Report type: ☐ Initial SAETYPE<TURPTP>
☐ Follow-up #: _____ **Center Number:** __ __ **Participant Number:** __ __ __ __ **Participant's Initials:** __ __ __ (first middle last)

SAE Details:	Participant's Details:
SAE Term *(Medical Diagnosis)*: SAEDIAG<V:100> _____	**Date of birth:** __ __/__ __ __/__ __ __ __ (day/month/year) SAEFORM (TYPE 4)R
SAE Onset Date: __ __/__ __ __/__ __ __ __ (day/month/year) SAESTRDT	**Gender:** ☐ Male ☐ Female
SAE Stop Date: __ __/__ __ __/__ __ __ __ (day/month/year) SAESTPDT	

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

MEDRA
MEDRTEXT<V:100>
MEDRCODE<V:8>
WORKFLOW<V:5>
CODETM<DATETIME>
CONFLVL<V:2>
MATCHES<V:4>
CODER<V:20>

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

☐ None ACNONE
☐ Intervention temporarily discontinued → **Complete and fax the Temporary Discontinuation from CR Intervention form** ACTEMPD
☐ Medical therapy required ACMEDREQ
☐ Intervention permanently discontinued → **Complete and fax the Permanent Discontinuation from CR Intervention form** ACPERMD
☐ Other *(specify)*: ACOTHR _____ ACOTHSP <V:50>

ADDITIONAL PANEL ITEM ON PAGE 284._

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

Fax SAE form to DCRI Safety Surveillance at 1-919-668-7138 or 1-866-668-7138 within 24 hours of initial notification

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie Phase 2

Date received at DCRI Safety Surveillance

Serious Adverse Event Form

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

Medical History *(relevant to event)*:

THIS PAGE NOT ENTERED

Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)
				__ __/__ __ __/__ __ __ __ (day month year)	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ (day month year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		
	__ __/__ __ __/__ __ __ __ (day month year)		

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

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification

Date received at DCRI Safety Surveillance

CONTINUED FROM PAGE 282

Serious Adverse Event Form

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

Please provide a brief summary of the event:	
SAESUMRY<V:150>	
Please describe the sequence of events including action taken, treatment given, hospital dates, etc.:	
NOT DATABASED	
Information Source:	
Date Investigator notified of Event: __ __/__ __ __/__ __ __ __ (day / month / year)	Date of this report: __ __/__ __ __/__ __ __ __ (day / month / year)
Person completing form: _____	Phone number: (__ __ __) __ __ __ – __ __ __ __
PI name: _____	Fax number: (__ __ __) __ __ __ – __ __ __ __
PI signature: _____	Date of signature: __ __/__ __ __/__ __ __ __ (day / month / year)

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

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification

calerie Phase 2

FORM/BLOCK = SURVEILLANCE

THIS IS A REPEATING PAGE

PAGEID = 285

Excessive Weight Loss Episode Report

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

Excessive Weight Loss Episode

Excessive weight loss is defined as a BMI < 18.5 kg/m². This report is completed for each episode of excessive weight loss. Reporting starts when the BMI level is first observed to be < 18.5 kg/m², and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

WGHTLOSS (TYPE 4)

A Identifying information

1 Date of initial report: __ __/__ __ __/__ __ __ __ (day/month/year) REPORTDT

2 Name of person making this report: _____ NOT DATABASED

B BMI below 18.5 kg/m²

3 Date of threshold value: __ __/__ __ __/__ __ __ __ (day/month/year) THRESDT

All measurements <F:9:3>

4 Height: __ __ __ . __ cm *(from original measurement at Screening)* HEIGHT

5 Weight: __ __ __ . __ kg WEIGHT1

6 Calculated BMI: _____ kg/m² CALBMI1

C Temporary Discontinuation

If BMI < 18.5 kg/m², the participant is advised about the risks of excessive weight loss and is prescribed a diet plan with increased number of calories up to the baseline level for up to one month. TMPDIS<XYESNO>

7 Was CR temporarily discontinued and a diet plan prescribed?

☐ 0 No → If No: Indicate the reason why it was not temporarily discontinued: _____ EXPLAIN<V:50>

☐ 1 Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to section D below.

D Follow-up BMI Value

The CR intervention is only restarted if the BMI increases to 18.5 kg/m² or higher after one month of treatment.

8 Date of follow-up value: __ __/__ __ __/__ __ __ __ (day/month/year) FLWUPDT

9 Weight: __ __ __ . __ kg WEIGHT2

10 Calculated BMI: _____ kg/m² CALBMI2

E Permanent Discontinuation

If BMI is still < 18.5 kg/m2 after one month of increased calorie intake, CR intervention is permanently discontinued.

11 Was the participant permanently discontinued from the CR intervention? PERMDIS<XYESNO>

☐ 0 No → If No: Indicate the reason CR was not permanently discontinued *(check only one)*:

☐ 1 BMI returned to 18.5 kg/m² or higher PERMRSN<TUBMI>

☐ 98 Other *(specify)*: _____ EXPLNOTH<V:50>

☐ 1 Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

Note that a participant is permanently discontinued from the CR intervention if a BMI < 18.5 kg/m² occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Excessive Weight Loss Episode Report

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

Excessive Weight Loss Episode (continued)

F Please provide a description of this episode including actions taken:

THIS PAGE NOT ENTERED

Study Manager's Signature

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

THIS IS A REPEATING PAGE

Depression Episode Report

PAGEID = 287

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

Depression Episode

Depression is defined as a BDI score ≥ 20. This report is completed for each episode of depression. Reporting starts when the initial BDI is ≥ 20, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

DEPRESS (TYPE 4)

A Identifying information

REPORTDT

1 Date of initial report: __ __/__ __ __/__ __ __ __ (day / month / year)

2 Name of person making this report: _____

NOT DATABASED

B Initial Elevation in BDI Score ≥ 20

INELEVDT

3 Date of initial elevation: __ __/__ __ __/__ __ __ __ (day / month / year)

4 BDI score: _____

INITBDI <I:3>

C Repeat BDI Score

*The questionnaire is repeated in **one week**.*

REPBDIDT

5 Date of follow-up questionnaire: __ __/__ __ __/__ __ __ __ (day / month / year)

6 BDI score: _____

REPBDI <I:3>

D Temporary Discontinuation

If the repeat score is ≥ 20, the CR intervention is temporarily discontinued and a participant is advised to seek medical help outside of the study.

TMPDIS<XYESNO>

7 Was the participant temporarily discontinued from the CR intervention?

☐ 0 No → If No: Indicate the reason CR was not temporarily discontinued *(check only one)*:

TMPRSN<TUBDI>

- ☐ 1 BDI score returned to < 20 → If the BDI score returned to < 20, then stop here; the episode has resolved. Sign the form on the last page and store in participant's binder.
- ☐ 98 Other *(specify)*: _____

EXPLAIN<V:50>

☐ 1 Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

E Follow-up BDI Score

*The questionnaire is repeated in **one month**.*

FLWUPDT

8 Date of follow-up questionnaire: __ __/__ __ __/__ __ __ __ (day / month / year)

9 BDI score: _____

FLWUPBDI<I:3>

ADDITIONAL PANEL ITEMS NEXT PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

CONTINUED FROM PAGE 287

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

Depression Episode (continued)

F Permanent Discontinuation

If BDI score is ≥ 20 after one month of treatment, or a qualified mental health professional indicates that it is unsafe to restart the CR, intervention will be permanently discontinued.

10 Was the participant permanently discontinued from the CR intervention? PERMDIS<XYESNO>

☐ 0 No → **If No: Indicate why CR was not permanently discontinued** *(check only one)*:

- ☐ 1 BDI score returned below 20 PERMRSN<TUDEPR>
- ☐ 2 Mental health professional indicated it is safe to resume
- ☐ 98 Other *(specify)*: _____ EXPLAIN2<V:50>

☐ 1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

Note that a participant is permanently discontinued from the CR intervention if a BDI score ≥ 20 occurs at any point after the CR was restarted. If this happens, please complete the Permanent Discontinuation from CR Intervention form.

G Please provide a description of this episode, including actions taken:

_____

_____

_____

_____

_____ NOT DATABASED

_____

_____

_____

_____

_____

_____

Study Manager's Signature

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax to Safety Surveillance at 1-866-668-7138

THIS IS A REPEATING PAGE

Eating Disorder Episode Report

PAGEID = 289

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

Eating Disorder Episode

*Eating disorders are defined in terms of scores on the Multi-axial Assessment of Eating Disorder Symptoms (MAEDS) and the Body Acceptability Morph (BAM) and Interview for the Diagnosis of Eating Disorders–Fourth Version (IDED-IV). Reporting starts when MAEDS and/or BAM **indicate** that there is an eating disorder, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.*

EDISORD (TYPE 4)

A Identifying information

1 Date of initial report: ___/___/___ (day/month/year) REPORTDT

NOT DATABASED

2 Name of person making this report: _____

Please complete Section B and/or C according to whether the episode was defined in terms of the MAEDS or the BAM, or both.

B Disorder Detected by the MAEDS

A participant who has a t-score of 70 or higher on any subscale of the MAEDS is administered the IDED-IV.

ALL<I:3>

MAEDS Domain	t-score	MAEDS Domain	t-score
3 Binge eating BINEAT	_____	6 Purgative behavior PURGE	_____
4 Restrictive eating RESEAT	_____	7 Avoidance of forbidden foods AVOID	_____
5 Fear of fatness FEARFAT	_____	8 Depression DEPRESN	_____

C Disorder Detected by the BAM

A participant who (a) scores a t-score of 70 or higher on the current body size, (b) scores a t-score lower than 30 on the ideal body size, or (c) shows confirming acceptability of the extreme body size shown in the acceptability phase of the measure is administered the IDED-IV.

ALL<I:3>

ALL 3 <XYESNO>

9 Was an alert issued for the current body size scale? CBSSCALE ☐0 No ☐1 Yes → If Yes: t-score: ____ CBSCORE

10 Was an alert issued for the ideal body size scale? IBSSCALE ☐0 No ☐1 Yes → If Yes: t-score: ____ IBSCORE

11 Was there confirming acceptability of the extreme body size shown? EBSSCALE ☐0 No ☐1 Yes

D Follow-up with IDED-IV

The diagnostic criteria for anorexia nervosa, bulimia nervosa, or binge eating disorder require an IDED-IV rating of "3" or more for each of its diagnostic criteria. A sub threshold eating disorder is defined as an IDED-IV rating of "3" or more on at least 5 of the 8 combined symptoms for bulimia nervosa and anorexia nervosa (only).

12 Did the participant meet the following diagnostic criteria *(check all that apply)*?

Anorexia nervosa	☐0 No	☐1 Yes	ANERVOSA
Bulimia nervosa	☐0 No	☐1 Yes	BNERVOSA
Binge eating	☐0 No	☐1 Yes	BINGE
Sub threshold eating disorder	☐0 No	☐1 Yes	SUBTHRES

ALL <XYESNO>

ADDITIONAL PANEL ITEMS NEXT PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Eating Disorder Episode Report

CONTINUED FROM PAGE 289

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

Eating Disorder Episode (continued)

E Permanent Discontinuation

If a participant meets one or more of these diagnostic criteria, the CR intervention is permanently discontinued and a participant is advised to seek medical help outside of the study.

PERMDIS<XYESNO>

13 Was the participant permanently discontinued from the CR intervention?

☐ 0 No → **If No: Indicate why CR was not permanently discontinued** *(check only one)*:

- ☐ 1 Did not meet diagnostic criteria for these eating disorders PERMRSN<TUDISO>
- ☐ 98 Other *(specify)*: _____ EXPLAIN<V:50>

☐ 1 Yes → **If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.**

F Please provide a description of this episode including actions taken:

_____

_____

_____

_____

_____ NOT DATABASED

_____

_____

_____

_____

_____

Study Manager's Signature

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

THIS IS A REPEATING PAGE

Elevated Potassium Episode Report

PAGEID = 291

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

Elevated Potassium Episode

Hyperkalemia is defined as an initial potassium level greater than 5.5 mEq/L followed by a confirmatory value greater than 5.5 mEq/L. This report is completed for each episode of hyperkalemia. Reporting starts when the initial potassium level is greater than 5.5 mEq/L., and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

ELEVATEK (TYPE 4)

A Identifying information

1 Date of initial report: ___/___/____ (day/month/year) REPORTDT

NOT DATABASED

2 Name of person making this report: _____

B Initial Elevation in Potassium Level

3 Date of initial elevation: ___/___/____ (day/month/year) INELEVDT

4 Potassium level: _____ mEq/L KLEVEL1

All measurements <F:9:3>

C Follow-up Repeat Potassium Level

If the initial potassium level is between 5.5 mEq/L and 6.0 mEq/L (inclusive), the test is repeated in one week; if it is greater than 6.0 mEq/L, it is repeated within 48 hours.

5 Date of follow-up test: ___/___/____ (day/month/year) CONFRMDT

6 Potassium level: _____ mEq/L KLEVEL2

D Temporary Discontinuation

If the follow-up test is > 5.5 mEq/L, the CR intervention is temporarily discontinued from the CR intervention and the participant is advised to seek medical help outside of the study.

7 Was the participant temporarily discontinued from the CR intervention? TMPDIS<XYESNO>

☐0 No → If No: Indicate the reason CR was not temporarily discontinued *(check only one)*: TMPRSN<TUELPM>

☐1 Potassium returned to 5.5 mEq/L or lower → If potassium returned to 5.5 mEq/L or lower, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.

☐98 Other *(specify)*: _____ EXPLAIN<V:50>

☐1 Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section E below.

E Follow-up Potassium Level

The CR intervention will only be restarted if the potassium level decreases to ≤ 5.0 mEq/L within one month of treatment.

8 Date of follow-up test: ___/___/____ (day/month/year) FLWUPDT

9 Potassium level: _____ mEq/L KLEVEL3

ADDITIONAL PANEL ITEMS NEXT PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Elevated Potassium Episode Report

CONTINUED FROM PAGE 291

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

Elevated Potassium Episode (continued)

F Permanent Discontinuation

If potassium level is still elevated above 5.0 mEq/L after one month of treatment, the CR intervention is permanently discontinued.

10 Was the participant permanently discontinued from the CR intervention? PERMDIS<XYESNO>

☐ 0 No → If No: Indicate why CR was not permanently discontinued *(check only one)*: PERMRSN<TUELVN>

☐ 1 Potassium returned to 5.0 mEq/L or lower

☐ 98 Other *(specify)*: _____ EXPLAIN2<V:50>

☐ 1 Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

Note that a participant is permanently discontinued from the CR intervention if a potassium level of 5.5 mEq/L or higher occurs at *any* point *after* the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.

G Please provide a description of this episode including actions taken:

_____

_____

_____

_____ NOT DATABASED

_____

_____

_____

_____

_____

_____

_____

Study Manager's Signature:

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax to Safety Surveillance at 1-866-668-7138

THIS IS A REPEATING PAGE

Anemia Episode Report

PAGEID = 293

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

Anemia Episode

*Anemia is defined as a decrease in hemoglobin and/or hematocrit level below the lower limit of normal (LLN) for the laboratory, followed by a confirmatory value satisfying the same criteria. Reporting starts when the **initial** value is observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.*

ANEMIA1 (TYPE 4)

A Identifying Information

1 Date of initial report: ___/___/___ (day/month/year) REPORTDT

All measurements <F:9:3>

2 Name of person making this report: _____ NOT DATABASED

Please complete Section B according to whether the hemoglobin and/or hematocrit was below the lower limit of normal.

B Value(s) Below the Lower Limit of Normal:

3 Date of lab test: ___/___/___ (day/month/year) LABDT

	Value	Lower Limit of Normal (LLN)	Below LLN? ALL<XYESNO>
4 Hemoglobin:	HGLOB1		☐0 No ☐1 Yes
5 Hematocrit:	HCRIT1	GLOBLLN1	☐0 No ☐1 Yes
6 RBC:	RBC1	CRITLLN1	☐0 No ☐1 Yes
7 Iron level:	IRON1	RBCLLN1	☐0 No ☐1 Yes
		IRONLLN1	

C

BLCRITDT		BLCRIT	
FUCRITDT		FLUPCRIT	NOT DATABASED
		DECREASE	

D Repeat Test:

The hematology panel is repeated in two weeks. The iron level is also repeated.

11 Date of repeat lab test: ___/___/___ (day/month/year)

	Value REPTLBDT	Lower Limit of Normal (LLN)	Below LLN? ALL<XYESNO>
12 Hemoglobin:			☐0 No ☐1 Yes
13 Hematocrit:			☐0 No ☐1 Yes
14 RBC:	HGLOB2	GLOBLLN2	☐0 No ☐1 Yes
15 Iron level:	HCRIT2	CRITLLN2	☐0 No ☐1 Yes
	RBC2	RBCLLN2	
	IRON2	IRONLLN2	

If the repeated test confirms the previous findings, a participant is advised to seek medical help outside of the study. Nevertheless, s/he continues the CR intervention.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax to Safety Surveillance at 1-866-668-7138

Anemia Episode (continued)

ANEMIA2 (TYPE 4)

E Medical Help Outside the Study:

16 Was the participant advised to seek medical help outside the study? MEDHELP<XYESNO>

☐0 No → If No: Indicate the reason why not:

☐1 Hematology panel and iron levels returned to acceptable values → If the hematology and iron levels return to acceptable values, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.

HELPRSN<TUHELP>

☐98 Other (specify): HLPOTHSP<V:50> _____

☐1 Yes → If Yes: Date on which patient was advised: __ __/__ __ __/__ __ __ __ (day / month / year)

F One Month Follow-up Test

*If the hematology and iron levels do **not** return to acceptable values, the hematology panel and iron levels are repeated one month after the treatment was initiated.*

17 Date of one month follow-up lab test: FUMTH1DT __ __/__ __ __/__ __ __ __ (day / month / year)

All measurements <F:9:3>

ALL<XYESNO>

	Value	Lower Limit of Normal (LLN)	Below LLN?
18 Hemoglobin:	HGLOB3	GLOBLLN3	☐0 No ☐1 Yes
19 Hematocrit:	HCRIT3	CRITLLN3	☐0 No ☐1 Yes
20 RBC:	RBC3	RBCLLN3	☐0 No ☐1 Yes
21 Iron level:	IRON3	IRONLLN3	☐0 No ☐1 Yes

G Temporary Discontinuation

If anemia is not improving or worsens, the CR intervention is temporarily discontinued.

22 Was the participant temporarily discontinued from the CR intervention? TMPDIS<XYESNO>

☐0 No → If No: Indicate the reason why CR was not temporarily discontinued (check only one):

☐1 Hemoglobin panel and iron levels returned to acceptable values → If the hemoglobin and iron levels return to acceptable levels, the episode has resolved. Stop here, sign the form on the last page, and forward to the coordinating center with the next batch of data forms.

TMPRSN<TUANEP>

☐98 Other (specify): EXPLAIN<V:50> _____

☐1 Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

Continue to Section H, next page.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Anemia Episode (continued)

ANEMIA3 (TYPE 4)

H Two Month Follow-up Value

If anemia is not improving or is worsening after the CR intervention was temporarily discontinued for one month, the intervention is permanently discontinued.

FUMTH2DT

23 Date of two month follow-up lab test: ___/___/___ (day/month/year)

ALL<XYESNO>

	Value	Lower Limit of Normal (LLN)	Below LLN?
24 Hemoglobin:	HGLOB4	GLOBLLN4	☐0 No ☐1 Yes
25 Hematocrit:	HCRIT4	CRITLLN4	☐0 No ☐1 Yes
26 RBC:	RBC4	RBCLLN4	☐0 No ☐1 Yes
27 Iron level:	IRON4	IRONLLN4	☐0 No ☐1 Yes

All measurements <F:9:3>

I Permanent Discontinuation

28 Was the participant permanently discontinued from the CR intervention? PERMDIS<XYESNO>

☐0 No → If No: Indicate the reason why CR was not permanently discontinued *(check only one)*:

PERMRSN<TUANEQ>

☐1 Hemoglobin panel and iron levels returned to acceptable values

☐98 Other *(specify)*: EXPLAIN2<V:50> _____

☐1 Yes → If Yes: Please complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

J Please provide a description of this episode including actions taken: _____

NOT DATABASED

Study Manager's Signature:

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

THIS IS A REPEATING PAGE

Ventricular Ischemia Episode Report

PAGEID = 296

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

Ventricular Ischemia Episode

ISCHEMIA (TYPE 4)

This report is completed if an episode of ventricular ischemia occurs during the VO_2 max measurement (12 or 24 months). Reporting starts when it is first observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

A Identifying information

1 Date of initial report: ___/___/___ (day/month/year) REPORTDT

2 Name of person making this report: _____ NOT DATABASED

B Date when the ventricular ischemia was observed

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

C Temporary Discontinuation

The CR intervention is temporarily discontinued and a stress imaging study is recommended within two weeks.

4 Was CR temporarily discontinued and a stress imaging study ordered? TMPDIS<XYESNO>

☐ 0 No → If No: Indicate the reason CR was not temporarily discontinued: _____

_____ EXPLAIN<V:50>

☐ 1 Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section D below.

D Stress Imaging Study

If a stress imaging study confirms presence of ventricular ischemia, the CR intervention will be permanently discontinued and a participant will follow all other study procedures to the study end.

5 Date of study: ___/___/___ (day/month/year) STRESSDT

6 Did the study confirm the presence of ventricular ischemia?

☐ 0 No

☐ 1 Yes ISCHEMIA<XYESNO>

E Permanent Discontinuation

7 Was the participant permanently discontinued from the CR intervention? PERMDIS<XYESNO>

☐ 0 No → If No: Indicate the reason CR was not permanently discontinued:

☐ 1 The study did not confirm the presence of ventricular ischemia. PERMRSN<TUVENT>

☐ 98 Other (specify): _____ EXPLAIN2<V:150>

☐ 1 Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Ventricular Ischemia Episode Report

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

Ventricular Ischemia Episode (continued)

F Please provide details of ECG findings including actions taken:

THIS PAGE NOT ENTERED

Study Manager's Signature:

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

FORM/BLOCK = DISCONTINUATION

calerie **Phase 2**

Temporary Discontinuation from CR Intervention

THIS IS A REPEATING PAGE
PAGEID = 298

DISCTYPE<TURPTP>

Check one: ☐ Initial ☐ Follow-up

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

Temporary Discontinuation

Note: Complete one form per reason for discontinuation.

1 Date of temporary discontinuation: __ __/__ __ __/__ __ __ __ (day / month / year)

TMPDISDT

TEMPDISC (TYPE 4)

2 Reason for discontinuation *(check only one)*:

TEMPRSN<TUTEMP>

- ☐ 1 Persistent potassium level > 5.5 mEq/L and < 6.0 mEq/L at any point during study, confirmed by repeat testing at 1 week
- ☐ 2 Persistent potassium level ≥ 6.1 mEq/L at any point during study, confirmed by repeat testing at 48 hours if second level is above 5.5 mEq/L
- ☐ 3 Treatment resistant anemia *(anemia has not improved after one month of treatment)*
- ☐ 4 Ventricular ischemia observed with exercise *(stress image performed in 2 weeks)*
- ☐ 5 Decrease in BMI to <18.5 at any time
- ☐ 6 Moderate depression *(BDI ≥ 20)*
- ☐ 7 Personal reasons *(specify)*: _____

PERSONAL<V:50>

- ☐ 8 Other *(includes any other disease or condition that requires temporary discontinuation from intervention such as recovery from trauma, surgery, or severe infections) (specify)*: _____

TEMPOTHR<V:50>

Participant's Details:

Date of birth: __ __/__ __ __/__ __ __ __ (day / month / year)

Gender: ☐ Male ☐ Female

Height: __ __ __ . __ cm

Weight: __ __ __ . __ kg

BMI *(if applicable)*: _____

Relevant Medical History:

Relevant Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				__ __/__ __ __/__ __ __ __ (day / month / year)	☐ 0 No ☐ 1 Yes	__ __/__ __ __/__ __ __ __ (day / month / year)
				__ __/__ __ __/__ __ __ __ (day / month / year)	☐ 0 No ☐ 1 Yes	__ __/__ __ __/__ __ __ __ (day / month / year)
				__ __/__ __ __/__ __ __ __ (day / month / year)	☐ 0 No ☐ 1 Yes	__ __/__ __ __/__ __ __ __ (day / month / year)

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ (day / month / year)		
	__ __/__ __ __/__ __ __ __ (day / month / year)		
	__ __/__ __ __/__ __ __ __ (day / month / year)		
	__ __/__ __ __/__ __ __ __ (day / month / year)		

ADDITIONAL PANEL ITEM NEXT PAGE

Fax to Safety Surveillance at 1-866-668-7138

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Temporary Discontinuation from CR Intervention

CONTINUED FROM PAGE 298

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

Temporary Discontinuation (continued)

Please describe any additional action taken *(e.g., observation or seek medical attention outside study)*:

NOT DATABASED

Intervention Resumption

Was intervention resumed? If No: Fill out Permanent Discontinuation from CR Intervention form

If Yes: Date intervention was resumed: __ __/__ __ __/__ __ __ __ (day/month/year) RESUMEDT

Investigator's Signature

Investigator: _____ (signature) Date: __ __/__ __ __/__ __ __ __ (day/month/year)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Permanent Discontinuation from CR Intervention

PAGEID = 300

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

Permanent Discontinuation

PERMDISC (TYPE 1)

1 Date of permanent discontinuation: ___/___/___ (day/month/year) PRMDISDT

2 Reason(s) for discontinuation *(check only one)*: PERMRSN<TUPERM>

- ☐ 1 Persistent potassium level > 5.0 mEq/L resistant to one month of treatment
- ☐ 2 Persistent potassium level ≥ 5.5 mEq/L after CR was temporarily discontinued and restarted
- ☐ 3 Persistent anemia *(anemia still not improving or worsening one month after temporary discontinuation)*
- ☐ 4 Ventricular ischemia confirmed by stress image
- ☐ 5 Decrease in BMD at the hip or spine of 5% or greater from baseline at any time during first 12 months of CR
- ☐ 6 Decrease in BMD at the hip or spine of 10% or greater from baseline at any time during months 12–24 of CR
- ☐ 7 BMD t-score at any site *(hip, femoral neck, or total spine)* of less than –2.5 at any time during study
- ☐ 8 Eating disorder *(including anorexia nervosa, bulimia nervosa or binge eating* OR *experiencing a sub-threshold eating disorder)*
- ☐ 9 Further decrease in BMI after 1 month of increase calorie intake OR temporary discontinuation of CR intervention OR persistent decrease in BMI *(< 18.5)* after CR intervention restarted
- ☐ 10 Psychiatric disorder *(including severe depression)*
- ☐ 11 Reoccurrence of moderate depression *(BDI still > 20)* after CR intervention restarted OR moderate depression that is not improving or is worsening *(BDI ≥ 30)* after temporary discontinuation of CR intervention
- ☐ 12 Major illness or disease *(e.g., cancer)*
- ☐ 13 Trauma requiring prolonged hospitalization or bed rest for more than one month
- ☐ 14 Menstrual irregularities or acyclicity for more than one year *(women only)*
- ☐ 15 Pregnancy *(women only)*
- ☐ 16 Participant withdrew consent
- ☐ 17 Personal reasons *(specify)*: _____ PERSONAL<V:50>
- ☐ 98 Other: _____ PERMOTHR<V:50>

Participant's Details:

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

Gender: ☐ Male ☐ Female

Height: ___ ___ ___ . ___ cm

Weight: ___ ___ ___ . ___ kg

BMI *(if applicable)*: _____

Relevant Medical History:

NOT DATABASED

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Permanent Discontinuation (continued)

Relevant Concomitant Medication *(do not list medication administered to treat this event)*:

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)
				___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)
				___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)	☐0 No ☐1 Yes	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

Relevant Lab Tests:

THIS PAGE NOT ENTERED

Test	Date	Value/Results	Normal Range
	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)		
	___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)		

Please describe any additional action taken *(e.g., observation or seek medical attention outside study)*:

Investigator's Signature

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

CALERIE PHASE2 ANNOTATION V4.012JUN2008

FORM/BLOCK = STUDY COMPLETION

calerie Phase 2

Study Completion/ Early Discontinuation of Study Evaluation

PAGEID = 302

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

Completion/Early Discontinuation

1 Date of study completion or early discontinuation of study: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) STENDDT

2 Did the participant complete the study through Month 24? STDCOMP<XYESNO>

☐ 0 No → If No: Date of last contact: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) LSTCONDT

Indicate the primary reason for discontinuation *(check only one)*: STDYCOMP (TYPE 1)

☐ 1 Consent withdrawn REASON<TUEND>

☐ 2 Lost to follow-up

☐ 3 Adverse event → Complete Signs, Symptoms and Adverse Events Log
- If serious adverse event, complete Serious Adverse Event (SAE) form

☐ 4 Death → Date of death: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DEATHDT
- Complete Signs, Symptoms and Adverse Events Log
- Complete Serious Adverse Events form
- Report cause of death as a Serious Adverse Event

☐ 98 Other *(specify)*: _____ NOCOMPSP<V:50>

☐ 1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

HWGHLOG1 (TYPE 4)

FORM/BLOCK = HOME WEIGHT LOG

THIS IS A REPEATING PAGE

PAGEID = 303

calerie **Phase 2**

Completed by Calerie staff:
☐ Baseline 1 ☐ Baseline 2 ☐ 6 Months ☐ 12 Months ☐ 18 Months ☐ 24 Months

TIMEPT<TUTMPT>

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

Daily Home Weight Log

Were you issued a new scale? ☐0 No ☐1 Yes → If Yes: Date first used: ISSUEDT ___/___/___ (month/day/year) Serial no.: SERIALNO<V:30>

Please complete this log in either blue or black ink. NEWSCALE<XYESNO>

HWGHLOG2 (TYPE 4)R

Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year) HWLOGDT	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)
Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)
Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb HWEIGHT <F:9:3>	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb **Check scale memory**
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)	Date: ___/___/___ (month/day/year)
Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)	Time: ☐1 AM ☐2 PM ___:___ (00:00 to 11:59)
Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb	Weight: ___ ___ ___ . ___ lb **Check scale memory**

NOT DATABASED

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

During DLW Periods

FORM/BLOCK = PROTOCOL DEVIATION

calerie Phase 2

Protocol Deviation

THIS IS A REPEATING PAGE

PAGEID = 304

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

Protocol Deviation

Please indicate below any deviations from the Calerie Protocol taken for this participant. PDEVIATE (TYPE 4)R
Check all that apply *(one participant per form)*:

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

Date of deviation: __ __ / __ __ __ / __ __ __ __ (day / month / year) DEVDT TIMEPT<TUTMPT>

ALL<XYES>

☐ Informed Consent CONSENT
☐ Inclusion/Exclusion criteria INEXCL
☐ Randomization/treatment assignment RANDOM
☐ Concomitant Medications CONMED

STUDYLAB
☐ Study/laboratory procedures *(specify)*: _____ LABEXPLN<V:50>
☐ Participant non-fasting NONFAST
☐ Participant safety *(specify)*: SAFETY SAFEXPLN<V:50>
☐ Other *(specify)*: OTHER OTHEREXP<V:50>

Brief explanation of deviation: DEVEXPLN<V:150>

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

Date of deviation: __ __ / __ __ __ / __ __ __ __ (day / month / year)

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications

☐ Study/laboratory procedures *(specify)*: _____
☐ Participant non-fasting
☐ Participant safety *(specify)*: _____
☐ Other *(specify)*: _____

Brief explanation of deviation: _____

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

Date of deviation: __ __ / __ __ __ / __ __ __ __ (day / month / year)

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications

☐ Study/laboratory procedures *(specify)*: _____
☐ Participant non-fasting
☐ Participant safety *(specify)*: _____
☐ Other *(specify)*: _____

Brief explanation of deviation: _____

Submission date: __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ / __ __ __ / __ __ __ __ (day / month / year) __ __ / __ __ __ / __ __ __ __ (day / month / year)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PROTOCOL = CALERIE_PHASE2

STUDYBOOK = END OF CR SURVEY

FORM = SURVEY

Center Number __ __ Participant Number __ __ __ __

End of CR Survey

CALSRVY (TYPE 1)

I was helped in following my CR prescription by...	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
1. ...feeling prepared by what I was told about the intervention requirements before I started the study. PREREQ	1	2	3	4	5	6	7	0
2. ...being provided my meals during the in-feeding period MEALS	1	2	3	4	5	6	7	0
3. ...trying the Mediterranean diet during the in-feeding period. MEDDIET	1	2	3	4	5	6	7	0
4. ...trying the Low Glycemic diet during the in-feeding period. LOWGLYC	1	2	3	4	5	6	7	0
5. ...trying the Low-fat High fiber diet during the in-feeding period. LOWFAT	1	2	3	4	5	6	7	0
6. ...being trained on portion sizes during the first few weeks of the study. PORTION	1	2	3	4	5	6	7	0
7. ... using a system (like HMR) to memorize estimated calories. HMRSYS	1	2	3	4	5	6	7	0

ALL<TUTOOL>

calerie

Center Number __ __ Participant Number __ __ __ __

I was helped in following my CR prescription by...	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
8. ...being provided recipes by the staff. RECIPES	1	2	3	4	5	6	7	0
9. ...being provided meal plans by the staff. STAFMEA	1	2	3	4	5	6	7	0
10. ...changing which food groups I include in my meals and snacks. FOODCHG	1	2	3	4	5	6	7	0
11. ...changing my eating patterns (how many times I eat a day). EATPATT	1	2	3	4	5	6	7	0
12. ...trying to use a Volumetrics approach (i.e., eating low-calorie foods of high volume), in order to feel fuller on my calorie prescription. VOLUMET	1	2	3	4	5	6	7	0
13. ...weighing in at my sessions. WEIGHIN	1	2	3	4	5	6	7	0
14. ...weighing myself at home. HOMEWGT	1	2	3	4	5	6	7	0

calerie

Center Number __ __ Participant Number __ __ __ __

I was helped in following my CR prescription by...	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
15. ...using the weight zone graph. WGTGRPH	1	2	3	4	5	6	7	0
16. ...self-monitoring my calorie intake using a PDA. USEPDA	1	2	3	4	5	6	7	0
17. ...self-monitoring my calorie intake using a computer program. COMPUTR	1	2	3	4	5	6	7	0
18. ...self-monitoring my calorie intake using a paper record. PAPEREC	1	2	3	4	5	6	7	0
19. ...individual sessions with my counselors. COUNSLR	1	2	3	4	5	6	7	0
20. ...written materials and handouts I received during individual sessions. HANDOUT	1	2	3	4	5	6	7	0
21. ...having extra contacts by phone with my counselors. XTRPHON	1	2	3	4	5	6	7	0
22. ...having extra contacts by email with my counselors. XTREMAI	1	2	3	4	5	6	7	0

calerie

Center Number __ __ Participant Number __ __ __ __

I was helped in following my CR prescription by...	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
23. ... having extra contacts in-person with my counselors INPRSON	1	2	3	4	5	6	7	0
24. ...attending group sessions. GRPSESS	1	2	3	4	5	6	7	0
25. ...written materials and handouts I received at group sessions. GRPHAND	1	2	3	4	5	6	7	0
26. ...using behavioral contracts with my counselors. BEHAVE	1	2	3	4	5	6	7	0
27. ...seeking social support of family or friends. SOCSUPP	1	2	3	4	5	6	7	0
28. ...being provided meal replacements. REPLACE	1	2	3	4	5	6	7	0
29. ...decreasing the frequency of eating out. EATOUT	1	2	3	4	5	6	7	0
30. ...increasing fiber in my diet. HIGHFIB	1	2	3	4	5	6	7	0

calerie

Center Number __ __ Participant Number __ __ __ __

I was helped in following my CR prescription by...	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
31. ...returning to in-feeding later in the study (after the first in-feeding) INFEED	1	2	3	4	5	6	7	0
32. ...having flexible options and strategies to assist my CR (instead of one structured program for everyone). FLEXOPT	1	2	3	4	5	6	7	0
33. ...being given some of my results during the 2 years, such as my total calories expended and how it related to my CR goal. CRGOAL	1	2	3	4	5	6	7	0

Center Number __ __ Participant Number __ __ __ __

Now that you have finished the CALERIE trial, you may or may not choose to continue to follow a CR diet on your own.

Based on how you feel now, please answer these questions about your diet behavior after you finish CALERIE.

	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree
34. After leaving CALERIE, I will continue to follow a CR diet.	1	2	3	4	5	6	7

POSTCR

	To A Great Extent	Somewhat	Undecided	Very Little	Not At All
35. I plan to continue to follow my current level of CR ...	1	2	3	4	5

CRLEVEL<TULEV>