

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last**Clinic Weight**Weight date and time: ____/____/____ 00:00 to 23:59
day month yearStaff 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 SignsAssessment date and time: ____/____/____ 00:00 to 23:59
day month year

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

VITALS (TYPE 3)

1 Natural waist measurement

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

Staff initials: _____
first middle last

Natural waist measurement 1: _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ cm

Natural waist measurement 3: _____ cm

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

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**4 Temperature:** _____ °C OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**5 Respirations:** _____ per minute OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**6 Blood pressure** (check only one): ☐₁ Left arm ☐₂ Right armStaff initials: _____
first middle last**6a Blood pressure 1:** _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

OR Not done →

Specify reason (use codelist below): _____

6b Blood pressure 2: _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59**6c Blood pressure 3:** _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

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

12-Lead ECG

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

Safety Labs

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

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____
Urine	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____

SAME AS PAGE 30

Contraception

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

Contraception method (females only): SAME AS PAGE 95	<input type="checkbox"/> None OR Check all that apply: <input type="checkbox"/> Oral contraceptive → Specify OUTCME2 (TYPE 4) Record on Concomitant Medications page <input type="checkbox"/> 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

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

Date completed: ____/____/____
day month year

SAME AS PAGE 36

Specify reason (use codelist below):

DATEHDR (TYPE 4)

BDI-II

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

BDIQ (TYPE 4)

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

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

BDI-II (continued)

8 Self-criticalness:

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

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

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

SAME AS PAGE 40

10 Crying:

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

11 Agitation:

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

12 Loss of interest:

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

13 Indecisiveness:

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

14 Worthlessness:

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

15 Loss of energy:

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

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Participant's Initials: _____
first middle last

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Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last**BDI-II** (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep
- BDIQ (TYPE 4)**
- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time
- SAME AS PAGE 41**
- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time
- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything
- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do
- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012Participant's Initials: _____
first middle last

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last**Clinic Weight**Weight date and time: ____/____/____ 00:00 to 23:59
day month yearStaff 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 SignsAssessment date and time: ____/____/____ 00:00 to 23:59
day month year

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

VITALS (TYPE 3)

1 Natural waist measurement

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

Staff initials: _____
first middle last

Natural waist measurement 1: _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ cm

Natural waist measurement 3: _____ cm

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

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

3 Pulse: _____ bpm OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**4 Temperature:** _____ °C OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**5 Respirations:** _____ per minute OR Not done → Specify reason (use codelist below): _____Staff initials: _____
first middle last**6 Blood pressure** (check only one): ☐₁ Left arm ☐₂ Right armStaff initials: _____
first middle last**6a Blood pressure 1:** _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

OR Not done →

Specify reason (use codelist below): _____

6b Blood pressure 2: _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59**6c Blood pressure 3:** _____ / _____ mm Hg Time: _____
systolic diastolic 00:00 to 23:59

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

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12-Lead ECG

Date and Time	Findings ECG (TYPE 4)	Staff Initials
<p>DATEHDR (TYPE 4)</p> <p>____/____/____ 00:00 to 23:59</p> <p>day month year</p> <p>SAME AS PAGE 30</p> <p>OR Not done → Specify reason (seeodelist below): _____</p>	<p>Is ECG (check only one):</p> <p><input type="checkbox"/> Normal</p> <p><input type="checkbox"/> Abnormal, not clinically significant (specify): _____</p> <p><input type="checkbox"/> Abnormal, clinically significant (specify): _____</p> <p>SAME AS PAGE 30</p>	<p>____</p> <p>first middle last</p>

Safety Labs

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

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

day month year

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	<input type="checkbox"/> No <input type="checkbox"/> Yes	____	<p>SAME AS PAGE 30</p> <p>____</p> <p>first middle last</p>
Urine	<input type="checkbox"/> No <input type="checkbox"/> Yes	____	<p>____</p> <p>first middle last</p>

Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ No

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

day month year

Results: ☐ Negative

☐ Positive

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

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Doubly Labeled Water (DLW)

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

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

DLWHDR (TYPE 4)

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

3 Exact weight of DLW mixture: _____ , _____ grams

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

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Physical Examination

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

Staff initials: _____
first middle last

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

DATEHDR (TYPE 4)

SAME AS PAGE 32

Body System	Assessments			If Abnormal or Not Done: Explain
	Normal	Abnormal	Not Done	
1 General appearance:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
2 Head, Ears, Eyes, Nose, Throat:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	PEXAM (TYPE 4)PS
3 Neck:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	SAME AS PAGE 32
4 Heart:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
5 Lungs:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
6 Abdomen:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
7 Lymph nodes:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
8 Extremities/Skin:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
9 Neurological:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
10 Musculoskeletal:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
	Normal	Abnormal	Not Done *	
11 Genitourinary:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
12 Breast:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	

Physician's Signature

Investigator: _____ Date: ____/____/____
signature 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

1 Has the participant taken a calcium supplement today?

☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.

DXASCAN (TYPE 4)

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

☐ No ☐ Yes

SAME AS PAGE 35

DXA Scan		DXA Rescan OR <input type="checkbox"/> 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
<input type="checkbox"/> Whole body	_____	<input type="checkbox"/> Whole body
<input type="checkbox"/> Forearm	_____	<input type="checkbox"/> Forearm
<input type="checkbox"/> Spine	_____	<input type="checkbox"/> Spine
<input type="checkbox"/> Hip	_____	<input type="checkbox"/> Hip

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

RAND SF-36

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

RANDSF1 (TYPE 3)

SAME AS PAGE 36

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

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

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

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

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

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

5 Lifting or carrying groceries ☐₁ ☐₂ ☐₃

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

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

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

9 Walking more than a mile ☐₁ ☐₂ ☐₃

10 Walking several blocks ☐₁ ☐₂ ☐₃

11 Walking one block ☐₁ ☐₂ ☐₃

12 Bathing or dressing yourself ☐₁ ☐₂ ☐₃

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Participant's Initials: _____
first middle last

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Rand SF-36 (continued)

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

RANDSF2 (TYPE 3)

SAME AS PAGE 37

Yes

No

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

☐₁
☐₂

14 Accomplished less than you would like

☐₁
☐₂

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

☐₁
☐₂

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

☐₁
☐₂

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

Yes

No

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

☐₁
☐₂

18 Accomplished less than you would like

☐₁
☐₂

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

☐₁
☐₂

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

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

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

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

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

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

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Participant's Initials: first middle last _____

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RAND SF-36 (continued)

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

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RANDSF3 (TYPE 3)

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

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

23 Did you feel full of pep?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

24 Have you been a very nervous person?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
---	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

25 Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
--	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

26 Have you felt calm and peaceful?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
-------------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

27 Did you have a lot of energy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
----------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

28 Have you felt downhearted and blue?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
--	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

29 Did you feel worn out?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
---------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

30 Have you been a happy person?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
----------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

31 Did you feel tired?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

32 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

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

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

33 I seem to get sick a little easier than other people.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
--	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

34 I am healthy as anybody I know.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
------------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

35 I expect my health to get worse.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
-------------------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

36 My health is excellent.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
----------------------------	----------------------------	----------------------------	----------------------------	----------------------------	----------------------------

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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PAGEID = 169

Center Number: _____ Participant Number: _____ Participant's Initials: _____
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day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

BDI-II

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

BDIQ (TYPE 4)

1 Sadness:

- ☐ I do not feel sad
☐ I feel sad much of the time
☐ I am sad all of the time
☐ I am so sad or unhappy that I can't stand it

SAME AS PAGE 39

2 Pessimism:

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

3 Past failure:

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

4 Loss of pleasure:

- ☐ I get as much pleasure as I ever did from the things I enjoy
☐ I don't enjoy things as much as I used to
☐ I get very little pleasure from the things I used to enjoy
☐ I can't get any pleasure from the things I used to enjoy

5 Guilty feelings:

- ☐ I don't feel particularly guilty
☐ I feel guilty over many things I have done or should have done
☐ I feel quite guilty most of the time
☐ I feel guilty all of the time

6 Punishment feelings:

- ☐ I don't feel I am being punished
☐ I feel I may be punished
☐ I expect to be punished
☐ I feel I am being punished

7 Self-dislike:

- ☐ I feel the same about myself as ever
☐ I have lost confidence in myself
☐ I am disappointed in myself
☐ I dislike myself

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PAGEID = 170

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

BDI-II (continued)

8 Self-criticalness:

- ☐₀ I don't criticize or blame myself more than usual
☐₁ I am more critical of myself than I used to be
☐₂ I criticize myself for all of my faults
☐₃ I blame myself for everything bad that happens **BDIQ (TYPE 4)**

9 Suicidal thoughts or wishes:

- ☐₀ I don't have any thoughts of killing myself
☐₁ I have thoughts of killing myself but I would not carry them out
☐₂ I would like to kill myself
☐₃ I would kill myself if I had the chance **SAME AS PAGE 40**

10 Crying:

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

11 Agitation:

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

12 Loss of interest:

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

13 Indecisiveness:

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

14 Worthlessness:

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

15 Loss of energy:

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

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BDI-II (continued)

- 16 Changes in sleeping pattern:**
- ☐₀ I have not experienced any change in my sleeping pattern
 - ☐₁ I sleep somewhat more than usual
 - ☐₂ I sleep somewhat less than usual
 - ☐₃ I sleep a lot more than usual
 - ☐₄ I sleep a lot less than usual
 - ☐₅ I sleep most of the day
 - ☐₆ I wake up 1-2 hours early and can't get back to sleep
- BDIQ (TYPE 4)**
- 17 Irritability:**
- ☐₀ I am no more irritable than usual
 - ☐₁ I am more irritable than usual
 - ☐₂ I am much more irritable than usual
 - ☐₃ I am irritable all of the time
- SAME AS PAGE 41**
- 18 Changes in appetite:**
- ☐₀ I have not experienced any change in my appetite
 - ☐₁ My appetite is somewhat less than usual
 - ☐₂ My appetite is somewhat greater than usual
 - ☐₃ My appetite is much less than before
 - ☐₄ My appetite is much greater than usual
 - ☐₅ I have no appetite at all
 - ☐₆ I crave food all of the time
- 19 Concentration difficulty:**
- ☐₀ I can concentrate as well as ever
 - ☐₁ I can't concentrate as well as usual
 - ☐₂ It's hard to keep my mind on anything for very long
 - ☐₃ I find I can't concentrate on anything
- 20 Tiredness or fatigue:**
- ☐₀ I am no more tired or fatigued than usual
 - ☐₁ I get more tired or fatigued more easily than usual
 - ☐₂ I am too tired or fatigued to do a lot of the things I used to do
 - ☐₃ I am too tired or fatigued to do most of the things I used to do
- 21 Loss of interest in sex:**
- ☐₀ I have not noticed any recent change in my interest in sex
 - ☐₁ I am less interested in sex than I used to be
 - ☐₂ I am much less interested in sex now
 - ☐₃ I have lost interest in sex completely

PAGEID = 172

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Profile of Mood States

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

POMS (TYPE 4)PS

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

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

Profile of Mood States (continued)

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

POMS (TYPE 4)PS

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CRF, page 173

PAGEID = 174

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

Profile of Mood States (continued)

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

POMS (TYPE 4) PS

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PAGEID = 175

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first middle last

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

Perceived Stress Scale (PSS)

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

	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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
2 In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
3 In the last month, how often have you felt that things were going your way?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4 In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4

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Participant's Initials: _____
first middle last

PAGEID = 176

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

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

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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
b Wake up in the middle of the night or early morning	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
c Have to get up to use the bathroom	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
d Cannot breathe comfortably	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
e Cough or snore loudly	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
f Feel too cold	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
g Feel too hot	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
h Have bad dreams	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
i Have pain	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): _____	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
6 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3

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Pittsburgh Sleep Quality Index (PSQI) (continued)

SAME AS PAGE 47

PSQI2(TYPE 3)

Never

Once or
twice

Once or
twice each
week

3 or more
times each
week

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

☐₀

☐₁

☐₂

☐₃

No problem
at all

Only a very
slight
problem

Somewhat
of a
problem

A very big
problem

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

☐₀

☐₁

☐₂

☐₃

Very
good

Fairly
good

Fairly
bad

Very
bad

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

☐₀

☐₁

☐₂

☐₃

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PAGEID = 178

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first middle last

Date completed: ____/____/____ OR Not done → Specify reason (useodelist 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 "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	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.3 Erotic or romantic situations	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.4 Caressing, touching, undressing, or foreplay	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.5 Sexual intercourse, oral sex, touching to orgasm	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈

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

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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	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
2.2 Actively seek sexual satisfaction	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
2.3 Feel sexually aroused with a partner	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
	Never	Rarely	Sometimes	Usually	Always	DISFEM2 (TYPE 4)PS			
2.4 Have normal lubrication with masturbation	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄				
2.5 Have normal lubrication throughout sexual relations	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄				

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Participant's Initials: first middle last

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

Section 3—Sexual Behavior/Experiences **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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.2 Masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.3 Casual kissing and petting	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.4 Sexual foreplay	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.5 Sexual intercourse, oral sex, etc.	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	
4.2 The intensity of your orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	
4.3 The ability to have multiple orgasms <i>(if typical for you)</i>	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	
4.4 Feelings of closeness and togetherness with your partner	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	
4.5 Your sense of control <i>(timing)</i> of your orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	
4.6 Feeling a sense of relaxation and well-being after orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	

PAGEID = 181

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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
	Not at all	Slightly	Moderately	Highly	Extremely	DISFEM3 (TYPE 4)PS			
5.2 During this period, how interested have you been in sex?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

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PAGEID = 182

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	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.3 Erotic or romantic situations	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.4 Caressing, touching, undressing, or foreplay	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.5 Sexual intercourse, oral sex, touching to orgasm	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈

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

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Participant's Initials: first middle last

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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.2 A full erection during a sexual fantasy or daydream	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.4 A full erection during masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.2 Masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.3 Casual kissing and petting	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.4 Sexual foreplay	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.5 Sexual intercourse, oral sex, etc.	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

Section 4—Orgasm

DISMALE2 (TYPE 4)PS

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

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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	DISMALE2 (TYPE 4)PS			
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

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SAME AS PAGE 36

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

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Food Craving Inventory (FCI-II)

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

CRAVE (TYPE 4)PS

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

Over the past month, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake SAME AS PAGE 59	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
2 Pizza	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
3 Fried chicken	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
4 Gravy	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
5 Sandwich bread	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
6 Sausage	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
7 French fries	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
8 Cinnamon rolls	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
9 Rice	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
10 Hot dog	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
11 Hamburger	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
12 Biscuits	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
13 Ice cream	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
14 Pasta	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
15 Fried fish	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
16 Cookies	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
17 Chocolate	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
18 Pancakes or waffles	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
19 Corn bread	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
20 Chips	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
21 Rolls	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
22 Cereal	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
23 Donuts	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
24 Candy	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
25 Brownies	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
26 Bacon	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
27 Steak	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
28 Baked potato	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _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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Date completed: ____/____/____ OR Not done → Specify reason (use codelist below):
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Eating Inventory

TFEQA (TYPE 4) PS

SAME AS PAGE 60

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

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

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Eating Inventory (continued)

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

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Eating Inventory (continued)

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

37	How often are you dieting in a conscious effort to control your weight?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
39	How often do you feel hungry?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	<input type="checkbox"/> 1 Easy <input type="checkbox"/> 3 Moderately difficult	<input type="checkbox"/> 2 Slightly difficult <input type="checkbox"/> 4 Very difficult		
42	How conscious are you of what you are eating?	<input type="checkbox"/> 1 Not at all <input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 2 Slightly <input type="checkbox"/> 4 Extremely		
43	How frequently do you avoid "stocking up" on tempting foods?	<input type="checkbox"/> 1 Almost never <input type="checkbox"/> 3 Usually	<input type="checkbox"/> 2 Seldom <input type="checkbox"/> 4 Almost always		
44	How likely are you to shop for low calorie foods?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
45	Do you eat sensibly in front of others and splurge alone?	<input type="checkbox"/> 1 Never	<input type="checkbox"/> 2 Rarely	<input type="checkbox"/> 3 Often	<input type="checkbox"/> 4 Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
47	How frequently do you skip dessert because you are no longer hungry?	<input type="checkbox"/> 1 Almost never <input type="checkbox"/> 3 At least once a week	<input type="checkbox"/> 2 Seldom <input type="checkbox"/> 4 Almost every day		
48	How likely are you to consciously eat less than you want?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
49	Do you go on eating binges though you are not hungry?	<input type="checkbox"/> 1 Never <input type="checkbox"/> 3 Sometimes	<input type="checkbox"/> 2 Rarely <input type="checkbox"/> 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."	<input type="checkbox"/> 1 Not like me <input type="checkbox"/> 2 Little like me <input type="checkbox"/> 3 Pretty good description of me <input type="checkbox"/> 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?	<input type="checkbox"/> 0 Eat whatever you want, whenever you want it <input type="checkbox"/> 1 Usually eat whatever you want, whenever you want it <input type="checkbox"/> 2 Often eat whatever you want, whenever you want it <input type="checkbox"/> 3 Often limit food intake, but often "give in" <input type="checkbox"/> 4 Usually limit food intake, rarely "give in" <input type="checkbox"/> 5 Constantly limiting food intake, never "giving in"
----	---	--

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day month year

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					Very confident that you can resist the desire to eat				
	0	1	2	3	4	5	6	7	8	9
1 I can resist eating when I am anxious (nervous).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 I can control my eating on the weekends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 I can resist eating even when I have to say "no" to others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 I can resist eating when I feel physically run down.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 I can resist eating when I am watching TV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 I can resist eating when I am depressed (or down).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 I can resist eating when there are many different kinds of food available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 I can resist eating even when I feel it is impolite to refuse a second helping.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 I can resist eating even when I have a headache.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

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

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

SAME AS PAGE 65	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
1 Fasting is a good way to lose weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
2 My sleep isn't as good as it used to be.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
3 I avoid eating for as long as I can.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
4 Certain foods are "forbidden" for me to eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
5 I can't keep certain foods in my house because I will binge on them.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
6 I can easily make myself vomit.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
7 I can feel that being fat is terrible.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
8 I avoid greasy foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
9 It's okay to binge and purge once in a while.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
10 I don't eat certain foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
11 I think I am a good person.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
12 My eating is normal.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
13 I can't seem to concentrate lately.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
14 I try to diet by fasting.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
15 I vomit to control my weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
16 Lately nothing seems enjoyable anymore.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
17 Laxatives help keep you slim.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
18 I don't eat red meat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
19 I eat so rapidly I can't even taste my food.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7

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

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

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

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Participant's Initials: first middle last

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

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

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Participant's Initials: first middle last

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PAGEID = 196

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

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

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

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: _____

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Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks... SAME AS PAGE 69	Never	Rarely	Sometimes	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
19 Have you felt excessively large and rounded?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
20 Have you felt ashamed of your body?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
21 Has worry about your shape made you diet?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
22 Have you felt happiest about your shape when your stomach has been empty?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
23 Have you thought that you are the shape you are because you lack self-control?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
25 Have you felt that it is not fair that other women/men are thinner than you?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
26 Have you vomited in order to feel thinner?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
28 Have you worried about your flesh being dimply?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
30 Have you pinched areas of your body to see how much fat is there?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
32 Have you taken laxatives in order to feel thinner?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
33 Have you been particularly self-conscious about your shape when in the company of other people?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
34 Has worry about your shape made you feel you ought to exercise?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

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Participant's Initials: _____

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PAGEID = 198

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

Handgrip Strength

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

Staff initials: _____
first middle last

DATEHDR (TYPE 4)

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

1 Dynamometer 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	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> ₀	_____ kg
Test 2—peak force	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> ₀	_____ kg
Test 3—peak force	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> 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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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? ☐ No ☐ Yes

SAME AS PAGE 78

ISOMETRC (TYPE 4)PS

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

3 Specify machine used (PBRC only): ☐ Cybex ☐ 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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PAGEID = 200

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

Clinic Weight

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

Staff initials: _____
first middle last

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

DATEHDR (TYPE 4)

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

Weight 1: _____ . _____ kg

SAME AS PAGE 4

WEIGHT (TYPE 4)

Weight 2: _____ . _____ kg

Weight 3: _____ . _____ kg

Weight of gown: _____ . _____ kg

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 = 201

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

Seven-Day Physical Activity Recall (PAR)

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

1 Were you employed in the last seven days?

☐ No → Skip to question 3 ☐ Yes

Interviewer initials: _____

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

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

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

Day #	Day of Week	Date ____/____/____ day month year	Sleep Time			Work Time			Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard		
7	(yesterday)	____/____/____ day month year	00:00 to 23:59 : : 00:00 to 23:59	00:00 to 23:59 : : 00:00 to 23:59	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 Code list: 1 Participant refused

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

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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

**Replacement Values
FOODRCD (TYPE 4)PS**

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	8	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
2	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	9	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
3	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	10	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
4	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	11	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
5	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	12	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
6	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	13	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing

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

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VO₂ Max

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

SAME AS PAGE 4

DATEHDR (TYPE 4)
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/trigeminy, NSVT [≥ 3 beats])?
☐₀ No
☐₁ Yes → If Yes: When did it occur (check all that apply)? ☐ During exercise ☐ During recovery

7 Peak VO₂: _____ mL/kg/min _____ L/min

8 Did the participant meet at least 2 of the 3 VO₂ max criteria (see box, right)?
☐₀ No
☐₁ Yes → If Yes: VO₂ max: _____ mL/kg/min _____ L/min

a Achieve a plateau in VO₂ (change ≤ 150 mL between the final two stages)
b RER ≥ 1.1
c HR max ± 5 bpm of age-predicted maximum

9 Exercise time: _____ : _____
minutes seconds

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

11 Borg RPE score at VO₂ peak/VO₂ max: _____ (6-20)

12 Peak RER: _____

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

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

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

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)
<small>first middle last</small>	Start Date: ____/____/____ <small>day month year</small>	Start Time ____:____ <small>00:00 to 23:59</small>	_____ _____ _____
	Stop Date: ____/____/____ <small>day month year</small>	Stop Time ____:____ <small>00:00 to 23:59</small>	

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

Delayed-type Hypersensitivity (DTH)

1 Was the DTH worksheet completed?

DTHADM1 (TYPE 3)

☐ No

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

☐ Yes → STOP. Do not administer test.

2 Date of injection: ____/____/____ OR Not done → Specify reason (use codelist below): ____

3 Injection by (initials):

SAME AS PAGE 85

4 Arm injected: ☐ Right ☐ 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

DTHADM2 (TYPE 4)PS

B = Second diameter perpendicular to A

Antigen	24 Hour (@ Visit 4)			48 Hour (@ Visit 5)		
	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:
1 Normal saline	_____ mm	_____ mm	<u> </u> <u> </u> <u> </u> (initials)	_____ mm	_____ mm	<u> </u> <u> </u> <u> </u> (initials)
2 Tetanus toxoid (TT) (check only one): <input type="checkbox"/> Tetanus toxoid (Sanofi-Pasteur) <input type="checkbox"/> Other: _____ Lot #: _____	_____ mm	_____ mm		_____ mm	_____ mm	
3 Candida (check only one): <input type="checkbox"/> Candin (AllerMed) <input type="checkbox"/> Other: _____ Lot #: _____	_____ mm	_____ mm		_____ mm	_____ mm	
4 Trichophyton (check only one): <input type="checkbox"/> Trichophyton Allergic Extract (AllerMed) <input type="checkbox"/> Other: _____ Lot #: _____	_____ mm	_____ mm		_____ mm	_____ mm	

Not Done Codelist: 1 Participant failure 5 Not required

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PAGEID = 207

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

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 1: _____ . _____ kg

SAME AS PAGE 4

WEIGHT (TYPE 4)

Weight 2: _____ . _____ kg

Weight 3: _____ . _____ kg

MOVED RMR PANEL TO PAGE 207A

Weight of gown: _____ . _____ kg

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	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____
Blood	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____
Oral glucose tolerance test (OGTT)	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____

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	URINE24 (TYPE 3) SAME AS PAGE 90	_____

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

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PAGEID = 207A

Layout of data entry screen has changes also

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

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	_____
Cart ID	<input type="checkbox"/> Tufts-003 (623-002) <input type="checkbox"/> WASH U-001 (623-003) <input type="checkbox"/> PBRC-016 (623-005) <input type="checkbox"/> Tufts-006 (623-006) <input type="checkbox"/> WASH U-002 (623-004) <input type="checkbox"/> 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

Seven-Day Physical Activity Recall ^(PAR)

Today's date: ____/____/____

Day (check only one):

<input type="checkbox"/> Mon	<input type="checkbox"/> Tues	<input type="checkbox"/> Wed	<input type="checkbox"/> Thurs	<input type="checkbox"/> Fri	<input type="checkbox"/> Sat	<input type="checkbox"/> Sun
------------------------------	-------------------------------	------------------------------	--------------------------------	------------------------------	------------------------------	------------------------------

OR Not done → Specify reason (use code list below):

Were you employed in the last seven days?

☐ No → Skip to question 3

☐ Yes

Interviewer initials:

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

<input type="checkbox"/> Mon	<input type="checkbox"/> Tues	<input type="checkbox"/> Wed	<input type="checkbox"/> Thurs	<input type="checkbox"/> Fri	<input type="checkbox"/> Sat	<input type="checkbox"/> Sun
------------------------------	-------------------------------	------------------------------	--------------------------------	------------------------------	------------------------------	------------------------------

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

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

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

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 (Useodelist 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)

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Clinic WeightWeight date and time: ____/____/____ 00:00 to 23:59
day month yearStaff initials: _____
first middle last

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

DATEHDR (TYPE 4)

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

SAME AS PAGE 4

Weight 1: _____ kg

Weight 2: _____ kg

Weight 3: _____ kg

Weight of gown: _____ kg

WEIGHT (TYPE 4)

Pregnancy Test**Complete only for females.**

Does participant have reproductive potential?

☐ No☐ Yes → If Yes: Date urine pregnancy test performed: ____/____/____
day month yearResults: ☐ Negative☐ Positive

PREGTEST (TYPE 4)

Outcomes Labs

SAME AS PAGE 33

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

OUTCMELB (TYPE 4)PS

Sample <small>If a sample is not obtained, indicate with a Not Done.</small>	Sample Complete?	If Not Done, Reason <small>(Use codelist below)</small>	Staff Initials
Blood	<input type="checkbox"/> No <input type="checkbox"/> 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.

Vaccine(s) given <small>(check all that apply):</small>		If Not Done, Reason <small>(Use codelist below)</small>	Staff Initials
<input type="checkbox"/> Hepatitis A → Check one: <input type="checkbox"/> Havrix (GSK) <input type="checkbox"/> Vaqta (Merck) <input type="checkbox"/> Other: <u>HEPSPEC V:30</u> Dose (check one): <input type="checkbox"/> Adult <input type="checkbox"/> Pediatric Lot #: <u>HEPLOT V:20</u> <input type="checkbox"/> Tetanus/diphtheria → Check one: <input type="checkbox"/> Decovac (Sanofi-Pasteur) <input type="checkbox"/> Other: <u>TETSPEC V:30</u> Lot #: <u>TETLOT V:20</u> <input type="checkbox"/> Pneumococcal vaccine → Check one: <input type="checkbox"/> Pneumovax (Merck) <input type="checkbox"/> Other: <u>PNEUSPEC V:30</u> Lot #: <u>PNEULOT V:20</u>	HEPA<XYES> HEPVAC<TUHVAC> HEPDOS<TUHDOS> TETVAC<TUTVAC> PNEUVAC<TUPVAC> DO NOT DISPLAY LMEALDT LMEALTM	SAME AS PAGE 90 	_____ _____ _____ _____ _____ _____ _____ _____

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

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

Clinic Weight

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

Staff initials: first middle last

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

DATEHDR (TYPE 4)

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

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Vital Signs

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

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

VITALS (TYPE 3)

1 Natural waist measurement

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

Staff initials: first middle last

Natural waist measurement 1: _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ cm

Natural waist measurement 3: _____ cm

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

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

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

Staff initials: first middle last

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

Staff initials: first middle last

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

Staff initials: first middle last

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

Staff initials: first middle last

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

OR Not done →

Specify reason (use codelist below): _____

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

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

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 = 213

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

12-Lead ECG

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

Safety Labs

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

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

SAFETYLB (TYPE 4)

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	_____ SAME AS PAGE 30	_____ first middle last
Urine	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	_____	_____ first middle last

Outcomes Labs

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

Date and time sample collection started: _____ 00:00 to 23:59
 day month year

OUTCMELB (TYPE 4)PS

SAME AS PAGE 102

Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	_____	_____ first middle last

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

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

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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

DLWCHT (TYPE 4)PS

4 Urine samples:

Collection	Sample	Date and Time Collected
Pre dosing (PD)	PDa	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
	PDb	_____ / _____ / _____ : _____ day month year 00:00 to 23:59
Day 0 (Visit 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

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Pregnancy Test

Complete only for females.

PREGTEST (TYPE 4)

Does participant have reproductive potential?

☐ No

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

SAME AS PAGE 33

Results: ☐ Negative

☐ Positive

DXA Scan

1 Has the participant taken a calcium supplement today?

DXASCAN (TYPE 4)

☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.

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

☐ No ☐ Yes

SAME AS PAGE 35

DXA Scan		DXA Rescan OR <input type="checkbox"/> 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
<input type="checkbox"/> Whole body	_____	<input type="checkbox"/> Whole body
<input type="checkbox"/> Forearm	_____	<input type="checkbox"/> Forearm
<input type="checkbox"/> Spine	_____	<input type="checkbox"/> Spine
<input type="checkbox"/> Hip	_____	<input type="checkbox"/> Hip

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 = 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

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

Seven-Day Physical Activity Recall (PAR)

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

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

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

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

Interviewer initials: _____

PARHDR (TYPE 4)

Day #	Day of Week	Date ____/____/____ day month year	Sleep Time		Work Time		Morning (in minutes)			Afternoon (in minutes)			Evening (in minutes)		
			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	(yesterday)	____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
6		____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
5		____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
4		____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
3		____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
2		____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____
1	(1 week ago)	____/____/____ day month year	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____ : ____ 00.00 to 23.59	____	____	____	____	____	____	____	____	____

SAME AS PAGE 71

PARCHT (TYPE 4)PS

Not Done Code list: 1 Participant refused 2 Clinic

CALERIE PHASE2 ANNOTATION 4.0 12JUN2008

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:

6-Day Food Record

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

Staff initials:

SAME AS PAGE 73

Replacement Values
FOODRCD (TYPE 4)PS

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	8	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
2	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	9	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
3	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	10	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
4	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	11	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
5	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	12	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
6	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	13	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 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 = 220

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

BDI-II

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

BDIQ (TYPE 4)

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

SAME AS PAGE 39

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last _____

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BDI-II (continued)**8 Self-criticalness:**

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

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

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

SAME AS PAGE 40

10 Crying:

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

11 Agitation:

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

12 Loss of interest:

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

13 Indecisiveness:

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

14 Worthlessness:

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

15 Loss of energy:

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

BDI-II (continued)

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

BDIQ (TYPE 4)

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

SAME AS PAGE 41

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

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

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

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____
first middle last

PAGEID = 223

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

Date completed: ____/____/____
day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

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

MAEDS (TYPE 4)PS

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
SAME AS PAGE 65							
1 Fasting is a good way to lose weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
2 My sleep isn't as good as it used to be.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
3 I avoid eating for as long as I can.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
4 Certain foods are "forbidden" for me to eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
5 I can't keep certain foods in my house because I will binge on them.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
6 I can easily make myself vomit.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
7 I can feel that being fat is terrible.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
8 I avoid greasy foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
9 It's okay to binge and purge once in a while.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
10 I don't eat certain foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
11 I think I am a good person.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
12 My eating is normal.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
13 I can't seem to concentrate lately.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
14 I try to diet by fasting.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
15 I vomit to control my weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
16 Lately nothing seems enjoyable anymore.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
17 Laxatives help keep you slim.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
18 I don't eat red meat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
19 I eat so rapidly I can't even taste my food.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 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)

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last _____

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

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

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

MAEDS (TYPE 4) PS

PAGEID = 226

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

Inpatient Admission and Discharge

1 Inpatient admission date and time: _____ / _____ / _____ : _____ ADMIT (TYPE 3)
day month year 00:00 to 23:59

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: _____ / _____ / _____ : _____ Staff initials: _____
day month year 00:00 to 23:59 first middle last

OR Not done → Specify reason (useodelist 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	RMR (TYPE 4)PS SAME AS PAGE 153	_____ first middle last
ADD CARTID TO RMR PANEL	Cart ID	<input type="checkbox"/> Tufts-003 (623-002) <input type="checkbox"/> WASH U-001 (623-003) <input type="checkbox"/> PBRC-016 (623-005) <input type="checkbox"/> Tufts-006 (623-006) <input type="checkbox"/> WASH U-002 (623-004) <input type="checkbox"/> 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

Center Number: _____

Participant Number: _____

Participant's Initials: _____

first middle last

Seven-Day Physical Activity Recall (PAR)

Today's date: ____/____/____ Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use code list below): _____1 Were you employed in the last seven days? ☐ No → Skip to question 3 ☐ Yes

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

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

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

Interviewer initials: _____

first middle last

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

PARCHT (TYPE 4) PS

SAME AS PAGE 71

Not Done Code list: 1 Participant refused 2 Clinician 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

Clinic WeightWeight date and time: ____/____/____ : ____
day month year 00:00 to 23:59Staff 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 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Pregnancy Test**Complete only for females.**

Does participant have reproductive potential?

PREGTEST (TYPE 4)

☐ No☐ Yes → If Yes: Date urine pregnancy test performed: ____/____/____
day month yearResults: ☐ Negative
☐ Positive

SAME AS PAGE 33

Outcomes LabsDate and time sample collection started: ____/____/____ : ____
day month year 00:00 to 23:59

OUTCMELB (TYPE 4)PS

Sample <i>If a sample is not obtained, indicate with a Not Done.</i>	Sample Complete?	If Not Done, Reason <i>(Use codelist below)</i>	Staff Initials
Blood	<input type="checkbox"/> No <input type="checkbox"/> 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 _____ first middle last
Vaccine(s) given <i>(check all that apply):</i>	<input type="checkbox"/> Hepatitis A → Check one: <input type="checkbox"/> ₁ Havrix (GSK) <input type="checkbox"/> ₂ Vaqta (Merck) <input type="checkbox"/> ₉₉ Other: _____ Dose (check one): <input type="checkbox"/> ₁ Adult <input type="checkbox"/> ₂ Pediatric Lot #: _____	SAME AS PAGE 211 HEPDOS<TUHDOS>	_____ first middle last

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Clinic Weight

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

Staff initials: first middle last

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

DATEHDR (TYPE 4)

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

Weight 1: _____ kg

SAME AS PAGE 4

Weight 2: _____ kg

WEIGHT (TYPE 4)

Weight 3: _____ kg

Weight of gown: _____ kg

Vital Signs

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

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

VITALS (TYPE 3)

1 Natural waist measurement

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

Staff initials: first middle last

Natural waist measurement 1: _____ cm

SAME AS PAGE 29

Natural waist measurement 2: _____ cm

Natural waist measurement 3: _____ cm

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

Umbilical point waist measurement 1: _____ cm

Umbilical point waist measurement 2: _____ cm

Umbilical point waist measurement 3: _____ cm

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

Staff initials: first middle last

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

Staff initials: first middle last

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

Staff initials: first middle last

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

Staff initials: first middle last

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

OR Not done →

Specify reason (use codelist below): _____

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

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

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

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12-Lead ECG

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

Safety Labs

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

Pregnancy Test

Complete only for females. Does participant have reproductive potential? <input type="checkbox"/> No <input type="checkbox"/> Yes → If Yes: Date urine pregnancy test performed: ____/____/____ day month year Results: <input type="checkbox"/> Negative <input type="checkbox"/> Positive	PREGTEST (TYPE 4) SAME AS PAGE 33
--	--

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

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

DLWCHT (TYPE 4)PS

4 Urine samples:

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

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

Affix
Test Sample
Label Here

Affix
Retest Sample
Label Here

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

Physical Examination

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

Staff initials: _____
first middle last

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

DATEHDR (TYPE 4)

SAME AS PAGE 32

Body System	Assessments			If Abnormal or Not Done: Explain
	Normal	Abnormal	Not Done	
1 General appearance:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	PEXAM (TYPE 4)PS
2 Head, Ears, Eyes, Nose, Throat:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	SAME AS PAGE 32
3 Neck:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
4 Heart:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
5 Lungs:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
6 Abdomen:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
7 Lymph nodes:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
8 Extremities/Skin:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
9 Neurological:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
10 Musculoskeletal:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
	Normal	Abnormal	Not Done *	
11 Genitourinary:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	
12 Breast:	<input type="checkbox"/> _1	<input type="checkbox"/> _0 →	<input type="checkbox"/> _97 →	

Physician's Signature

Investigator: _____ Date: ____/____/____
signature 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

1 Has the participant taken a calcium supplement today? DXASCAN (TYPE 4)
☐ No ☐ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.

2 Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?
☐ No ☐ Yes SAME AS PAGE 35

DXA Scan		DXA Rescan OR <input type="checkbox"/> NA
Date of scan: ____/____/____ <small>day month year</small>		Date of rescan: ____/____/____ <small>day month year</small>
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply
<input type="checkbox"/> Whole body	_____	<input type="checkbox"/> Whole body
<input type="checkbox"/> Forearm	_____	<input type="checkbox"/> Forearm
<input type="checkbox"/> Spine	_____	<input type="checkbox"/> Spine
<input type="checkbox"/> Hip	_____	<input type="checkbox"/> Hip

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

RAND SF-36

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

RANDSF1 (TYPE 3)

SAME AS PAGE 36

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

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

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

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

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

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

5 Lifting or carrying groceries ☐₁ ☐₂ ☐₃

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

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

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

9 Walking more than a mile ☐₁ ☐₂ ☐₃

10 Walking several blocks ☐₁ ☐₂ ☐₃

11 Walking one block ☐₁ ☐₂ ☐₃

12 Bathing or dressing yourself ☐₁ ☐₂ ☐₃

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

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Participant's Initials: first middle last _____

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

Rand SF-36 (continued)

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

RANDSF2 (TYPE 3)

SAME AS PAGE 37

Yes No

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

☐₁ ☐₂

14 Accomplished less than you would like

☐₁ ☐₂

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

☐₁ ☐₂

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

☐₁ ☐₂

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

Yes No

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

☐₁ ☐₂

18 Accomplished less than you would like

☐₁ ☐₂

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

☐₁ ☐₂

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

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

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

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

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

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

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Participant's Initials: first middle last _____

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RAND SF-36 (continued)

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

SAME AS PAGE 38

RANDSF3 (TYPE 3)

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

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

23 Did you feel full of pep?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
-------------------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

24 Have you been a very nervous person?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
--	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

25 Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

26 Have you felt calm and peaceful?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
--	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

27 Did you have a lot of energy?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

28 Have you felt downhearted and blue?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

29 Did you feel worn out?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
----------------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

30 Have you been a happy person?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

31 Did you feel tired?	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6
-------------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

32 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5

How true or false is each of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
---	------------------------	--------------------	-------------------	---------------------	-------------------------

33 I seem to get sick a little easier than other people.	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

34 I am healthy as anybody I know.	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
---	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

35 I expect my health to get worse.	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
--	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

36 My health is excellent.	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
-----------------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

BDI-II

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

BDIQ (TYPE 4)

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

SAME AS PAGE 39

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PAGEID = 239

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

BDI-II (continued)

8 Self-criticalness:

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

BDIQ (TYPE 4)

9 Suicidal thoughts or wishes:

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

SAME AS PAGE 40

10 Crying:

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

11 Agitation:

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

12 Loss of interest:

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

13 Indecisiveness:

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

14 Worthlessness:

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

15 Loss of energy:

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

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BDI-II (continued)

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

BDIQ (TYPE 4)

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

SAME AS PAGE 41

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

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

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

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

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PAGEID = 241

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Profile of Mood States

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

POMS (TYPE 4) PS

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

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Profile of Mood States (continued)

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

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

Profile of Mood States (continued)

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

POMS (TYPE 4)PS

SAME AS PAGE 44

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first middle last

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- Fairly Very
times times Often Often

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

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first middle last

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

Pittsburgh Sleep Quality Index (PSQI)

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

During the past month... 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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
b Wake up in the middle of the night or early morning	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
c Have to get up to use the bathroom	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
d Cannot breathe comfortably	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
e Cough or snore loudly	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
f Feel too cold	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
g Feel too hot	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
h Have bad dreams	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
i Have pain	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s): _____	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3
6 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3

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PAGEID = 246

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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Date completed: ____/____/____ OR Not done → Specify reason (useodelist 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 "0 = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

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

DISFEM1 (TYPE 4)PS

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

Section 1—Sexual Cognition/Fantasy

SAME AS PAGE 48

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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
1.3 Erotic or romantic situations	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
1.4 Caressing, touching, undressing, or foreplay	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
1.5 Sexual intercourse, oral sex, touching to orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

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

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PAGEID = 248

Center Number: ____

Participant Number: ____

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

Section 2—Sexual Arousal

SAME AS PAGE 49

DISFEM1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.2 Actively seek sexual satisfaction	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.3 Feel sexually aroused with a partner	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
	Never	Rarely	Sometimes	Usually	Always	DISFEM2 (TYPE 4)PS			
2.4 Have normal lubrication with masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4				
2.5 Have normal lubrication throughout sexual relations	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.2 Masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.3 Casual kissing and petting	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.4 Sexual foreplay	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.5 Sexual intercourse, oral sex, etc.	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4.2 The intensity of your orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4.3 The ability to have multiple orgasms <i>(if typical for you)</i>	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4.4 Feelings of closeness and togetherness with your partner	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4.5 Your sense of control <i>(timing)</i> of your orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4
4.6 Feeling a sense of relaxation and well-being after orgasm	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4

PAGEID = 250

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?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

	Not at all	Slightly	Moderately	Highly	Extremely	DISFEM3 (TYPE 4)PS
5.2 During this period, how interested have you been in sex?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	

						DISFEM4 (TYPE 4)PS
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	

	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

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

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

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

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

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

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	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.3 Erotic or romantic situations	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.4 Caressing, touching, undressing, or foreplay	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
1.5 Sexual intercourse, oral sex, touching to orgasm	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈

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

Section 2—Sexual Arousal

SAME AS PAGE 53

DISMALE1 (TYPE 4)PS

During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.2 A full erection during a sexual fantasy or daydream	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
2.4 A full erection during masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _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	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.2 Masturbation	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.3 Casual kissing and petting	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.4 Sexual foreplay	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8
3.5 Sexual intercourse, oral sex, etc.	<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5	<input type="checkbox"/> _6	<input type="checkbox"/> _7	<input type="checkbox"/> _8

Section 4—Orgasm DISMALE2 (TYPE 4)PS

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

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?	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	DISMALE2 (TYPE 4)PS			
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> 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?	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆	<input type="checkbox"/> ₇	<input type="checkbox"/> ₈

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SAME AS PAGE 36

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

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first middle last

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Food Craving Inventory (FCI-II)

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

CRAVE (TYPE 4)PS

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

Over the past month, how often have you experienced a craving for...	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake SAME AS PAGE 59	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
2 Pizza	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
3 Fried chicken	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
4 Gravy	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
5 Sandwich bread	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
6 Sausage	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
7 French fries	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
8 Cinnamon rolls	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
9 Rice	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
10 Hot dog	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
11 Hamburger	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
12 Biscuits	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
13 Ice cream	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
14 Pasta	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
15 Fried fish	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
16 Cookies	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
17 Chocolate	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
18 Pancakes or waffles	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
19 Corn bread	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
20 Chips	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
21 Rolls	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
22 Cereal	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
23 Donuts	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
24 Candy	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
25 Brownies	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
26 Bacon	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
27 Steak	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5
28 Baked potato	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5

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

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PAGEID = 257

Center Number: _____ Participant Number: _____ Participant's Initials: _____
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day month year

SAME AS PAGE 36

DATEHDR (TYPE 4)

Eating Inventory

- 1 When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal. ☐ True ☐ False TFEQA (TYPE 4)PS
- 2 I usually eat too much at social occasions, like parties and picnics. ☐ True ☐ False
- 3 I am usually so hungry that I eat more than three times a day. ☐ True ☐ False SAME AS PAGE 60
- 4 When I have eaten my quota of calories, I am usually good about not eating anymore. ☐ True ☐ False
- 5 Dieting is so hard for me because I just get too hungry. ☐ True ☐ False
- 6 I deliberately take small helpings as a means of controlling my weight. ☐ True ☐ False
- 7 Sometimes things just taste so good that I keep on eating even when I am no longer hungry. ☐ True ☐ False
- 8 Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat. ☐ True ☐ False
- 9 When I feel anxious, I find myself eating. ☐ True ☐ False
- 10 Life is too short to worry about dieting. ☐ True ☐ False
- 11 Since my weight goes up and down, I have gone on reducing diets more than once. ☐ True ☐ False
- 12 I often feel so hungry that I just have to eat something. ☐ True ☐ False
- 13 When I am with someone who is overeating, I usually overeat too. ☐ True ☐ False
- 14 I have a pretty good idea of the number of calories in common food. ☐ True ☐ False
- 15 Sometimes when I start eating, I just can't seem to stop. ☐ True ☐ False
- 16 It is not difficult for me to leave something on my plate. ☐ True ☐ False
- 17 At certain times of the day, I get hungry because I have gotten used to eating then. ☐ True ☐ False
- 18 While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it. ☐ True ☐ False

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Eating Inventory (continued)

19 Being with someone who is eating often makes me hungry to eat also. ☐₁ True ☐₀ False

20 When I feel blue, I often overeat. SAME AS PAGE 61 TFEQA (TYPE 4)PS ☐₁ True ☐₀ False

21 I enjoy eating too much to spoil it by counting calories or watching my weight. ☐₁ True ☐₀ False

22 When I see a real delicacy, I often get so hungry that I have to eat right away. ☐₁ True ☐₀ False

23 I often stop eating when I am not really full as a conscious means of limiting the amount I eat. ☐₁ True ☐₀ False

24 I get so hungry that my stomach often seems like a bottomless pit. ☐₁ True ☐₀ False

25 My weight has hardly changed at all in the last ten years. ☐₁ True ☐₀ False

26 I am always hungry so it is hard for me to stop eating before I finish the food on my plate. ☐₁ True ☐₀ False

27 When I feel lonely, I console myself by eating. ☐₁ True ☐₀ False

28 I consciously hold back at meals in order not to gain weight. ☐₁ True ☐₀ False

29 I sometimes get very hungry late in the evening or at night. ☐₁ True ☐₀ False

30 I eat anything I want, any time I want. ☐₁ True ☐₀ False

31 Without even thinking about it, I take a long time to eat. ☐₁ True ☐₀ False

32 I count calories as a conscious means of controlling my weight. ☐₁ True ☐₀ False

33 I do not eat some foods because they make me fat. ☐₁ True ☐₀ False

34 I am always hungry enough to eat at any time. ☐₁ True ☐₀ False

35 I pay a great deal of attention to changes in my figure. ☐₁ True ☐₀ False

36 While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. ☐₁ True ☐₀ False

Eating Inventory (continued)

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

37	How often are you dieting in a conscious effort to control your weight?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
39	How often do you feel hungry?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	<input type="checkbox"/> 1 Rarely	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Usually	<input type="checkbox"/> 4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	<input type="checkbox"/> 1 Easy <input type="checkbox"/> 3 Moderately difficult	<input type="checkbox"/> 2 Slightly difficult <input type="checkbox"/> 4 Very difficult		
42	How conscious are you of what you are eating?	<input type="checkbox"/> 1 Not at all <input type="checkbox"/> 3 Moderately	<input type="checkbox"/> 2 Slightly <input type="checkbox"/> 4 Extremely		
43	How frequently do you avoid "stocking up" on tempting foods?	<input type="checkbox"/> 1 Almost never <input type="checkbox"/> 3 Usually	<input type="checkbox"/> 2 Seldom <input type="checkbox"/> 4 Almost always		
44	How likely are you to shop for low calorie foods?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
45	Do you eat sensibly in front of others and splurge alone?	<input type="checkbox"/> 1 Never	<input type="checkbox"/> 2 Rarely	<input type="checkbox"/> 3 Often	<input type="checkbox"/> 4 Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
47	How frequently do you skip dessert because you are no longer hungry?	<input type="checkbox"/> 1 Almost never <input type="checkbox"/> 3 At least once a week	<input type="checkbox"/> 2 Seldom <input type="checkbox"/> 4 Almost every day		
48	How likely are you to consciously eat less than you want?	<input type="checkbox"/> 1 Unlikely <input type="checkbox"/> 3 Moderately likely	<input type="checkbox"/> 2 Slightly likely <input type="checkbox"/> 4 Very likely		
49	Do you go on eating binges though you are not hungry?	<input type="checkbox"/> 1 Never <input type="checkbox"/> 3 Sometimes	<input type="checkbox"/> 2 Rarely <input type="checkbox"/> 4 At least once a week		

50 To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."

☐ 1 Not like me
☐ 2 Little like me
☐ 3 Pretty good description of me
☐ 4 Describes me perfectly

51 On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?

☐ 0 Eat whatever you want, whenever you want it
☐ 1 Usually eat whatever you want, whenever you want it
☐ 2 Often eat whatever you want, whenever you want it
☐ 3 Often limit food intake, but often "give in"
☐ 4 Usually limit food intake, rarely "give in"
☐ 5 Constantly limiting food intake, never "giving in"

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day month year

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					Very confident that you can resist the desire to eat				
	0	1	2	3	4	5	6	7	8	9
1 I can resist eating when I am anxious (nervous).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 I can control my eating on the weekends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 I can resist eating even when I have to say "no" to others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 I can resist eating when I feel physically run down.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 I can resist eating when I am watching TV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 I can resist eating when I am depressed (or down).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 I can resist eating when there are many different kinds of food available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 I can resist eating even when I feel it is impolite to refuse a second helping.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 I can resist eating even when I have a headache.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Weight Efficacy Lifestyle Questionnaire (WEL) (continued)

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

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Date completed: ____/____/____
day month year

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

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

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

	Never	Very Rarely	Rarely	Sometimes	Often	Very Often	Always
SAME AS PAGE 65							
1 Fasting is a good way to lose weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
2 My sleep isn't as good as it used to be.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
3 I avoid eating for as long as I can.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
4 Certain foods are "forbidden" for me to eat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
5 I can't keep certain foods in my house because I will binge on them.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
6 I can easily make myself vomit.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
7 I can feel that being fat is terrible.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
8 I avoid greasy foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
9 It's okay to binge and purge once in a while.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
10 I don't eat certain foods.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
11 I think I am a good person.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
12 My eating is normal.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
13 I can't seem to concentrate lately.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
14 I try to diet by fasting.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
15 I vomit to control my weight.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
16 Lately nothing seems enjoyable anymore.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
17 Laxatives help keep you slim.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
18 I don't eat red meat.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
19 I eat so rapidly I can't even taste my food.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7

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

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last

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

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

PAGEID = 265

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

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

SAME AS PAGE 36

DATEHDR (TYPE 4)

Body Shape Questionnaire (BSQ)

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

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

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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Durham NC 27705

Body Shape Questionnaire (BSQ) (continued)

Over the Past Four Weeks... SAME AS PAGE 69	Never	Rarely	Sometimes	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
19 Have you felt excessively large and rounded?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
20 Have you felt ashamed of your body?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
21 Has worry about your shape made you diet?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
22 Have you felt happiest about your shape when your stomach has been empty?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
23 Have you thought that you are the shape you are because you lack self-control?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
25 Have you felt that it is not fair that other women/men are thinner than you?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
26 Have you vomited in order to feel thinner?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
28 Have you worried about your flesh being dimply?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
30 Have you pinched areas of your body to see how much fat is there?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
32 Have you taken laxatives in order to feel thinner?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
33 Have you been particularly self-conscious about your shape when in the company of other people?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
34 Has worry about your shape made you feel you ought to exercise?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

PAGEID = 267

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 (useodelist below): **SAME AS PAGE 4**

1 Dynamometer 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	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> ₀	_____ kg
Test 2—peak force	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> ₀	_____ kg
Test 3—peak force	<input type="checkbox"/> ₀	_____ kg	<input type="checkbox"/> 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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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? ☐ No ☐ Yes

SAME AS PAGE 78

ISOMETRC (TYPE 4)PS

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

3 Specify machine used (PBRC only): ☐ Cybex ☐ 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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PAGEID = 269

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 1: _____ kg

SAME AS PAGE 4

WEIGHT (TYPE 4)

Weight 2: _____ kg

Weight 3: _____ kg

Weight of gown: _____ kg

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

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

Seven-Day Physical Activity Recall (PAR)

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

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

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

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

Interviewer initials: _____

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

SAME AS PAGE 71

PARCHT (TYPE 4) PS

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

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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 PHASEE2 ANNOTATION V8.0 24FEB2012

6-Day Food Record

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

Staff initials: _____

SAME AS PAGE 73

**Replacement Values
FOODRCD (TYPE 4)PS**

Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	8	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
2	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	9	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
3	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	10	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
4	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	11	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
5	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	12	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing
6	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing	13	____/____/____ day month year	<input type="checkbox"/> 1 Reliable <input type="checkbox"/> 2 Unreliable <input type="checkbox"/> 3 Missing

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

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VO₂ Max

- 1** Date and time of test: _____ / _____ / _____ : _____
day month year 00:00 to 23:59
- SAME AS PAGE 4**
- DATEHDR (TYPE 4)**
- Staff initials: _____
- OR Not done → Specify reason (useodelist below): _____ **SAME AS PAGE 81**
- VOMAX (TYPE 3)**
- 2** At what time was the participant's last meal/snack eaten? _____
00:00 to 23:59
- 3** Rest ECG: Rhythm (check only one): ☐₁ Sinus ☐₂ Atrial fibrillation ☐₉₉ Other
Ventricular conduction (check only one): ☐₁ Normal ☐₂ LBBB ☐₃ RBBB
- 4** Heart rate (HR) data: Resting heart rate: _____ bpm
Age-predicted heart rate: _____ bpm
Heart rate (max): _____ bpm
- 5** Reason(s) for termination of testing (check all that apply):
☐ Symptom limited (dyspnea, fatigue)
☐ Angina/ischemia++ → Complete all that apply: HR when true cardiac angina occurred: _____ bpm OR ☐₉₉ NA
HR when ischemic ECG changes occurred: _____ bpm OR ☐₉₉ 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 VO₂: _____ mL/kg/min _____ L/min
- 8** Did the participant meet at least 2 of the 3 VO₂ max criteria (see box, right)?
☐₀ No
☐₁ Yes → If Yes: VO₂ max: _____ mL/kg/min _____ L/min
- a Achieve a plateau in VO₂ (change ≤ 150 mL between the final two stages)

b RER ≥ 1.1

c HR max ± 5 bpm of age-predicted maximum
- 9** Exercise time: _____ : _____
minutes seconds
- 10** Blood pressure at VO₂ peak/VO₂ max: _____ / _____ mm Hg
systolic diastolic
- 11** Borg RPE score at VO₂ peak/VO₂ max: _____ (6-20)
- 12** Peak RER: _____
- 13** VE at VO₂ peak/VO₂ max: _____ L/min

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

Send to DCRI Form

**CALERIE PHASEE2 ANNOTATION V8.0
24FEB2012**

Durham NC 27705

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 <i>If a sample is not obtained, indicate with a Not Done.</i>	Sample Complete?	If Not Done, Reason <i>(Use codelist below)</i>	Staff Initials
Blood	<input type="checkbox"/> No <input type="checkbox"/> 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 <i>(Use codelist below)</i>
_____ first middle last	Start Date: _____/_____/_____ day month year	Start Time _____:_____ 00:00 to 23:59	_____ ADMIT (TYPE 3) SAME AS PAGE 87
	Stop Date: _____/_____/_____ day month year	Stop Time _____:_____ 00:00 to 23:59	

Inpatient Admission and Discharge

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

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

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

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

Delayed-type Hypersensitivity (DTH)

DTHADM1 (TYPE 3)

1 Was the DTH worksheet completed?

☐ No

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

☐ Yes → STOP. Do not administer test.

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

3 Injection by (initials): ____
first middle last

SAME AS PAGE 85

4 Arm injected: ☐ Right ☐ 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): <input type="checkbox"/> Tetanus toxoid (Sanofi-Pasteur) <input type="checkbox"/> Other: _____ Lot #: _____	_____ mm	_____ mm		_____ mm	_____ mm	
3 Candida (check only one): <input type="checkbox"/> Candidin (AllerMed) <input type="checkbox"/> Other: _____ Lot #: _____	_____ mm	_____ mm	_____ first middle last (initials)	_____ mm	_____ mm	_____ first middle last (initials)
4 Trichophyton (check only one): <input type="checkbox"/> Trichophyton Allergic Extract (AllerMed) <input type="checkbox"/> 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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CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Durham NC 27705

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 1: _____ kg

SAME AS PAGE 4

WEIGHT (TYPE 4)

Weight 2: _____ kg

MOVED THE RMR PANEL TO PAGE 276A

Weight 3: _____ kg

Weight of gown: _____ kg

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	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____ first middle last
Blood	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____	_____ first middle last
Oral glucose tolerance test (OGTT)	<input type="checkbox"/> No <input type="checkbox"/> 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	URINE24 (TYPE 3) SAME AS PAGE 90	_____ first middle last

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

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PAGEID = 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	<input type="checkbox"/> None OR Check all that apply:		OUTCME2 (TYPE 4)
	<input type="checkbox"/> Oral contraceptive → Specify: _____		Record on Concomitant Medications page
	<input type="checkbox"/> 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)	____/____/____ <small>day month year</small>	____:____ <small>00:00 to 23:59</small>		
Hormone level blood draw 1 (males only)	____/____/____ <small>day month year</small>	____:____ <small>00:00 to 23:59</small>	_____	<small>first middle last</small>
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 ____/____/____ <small>day month year</small>	RMR (TYPE 4)PS _____	<small>first middle last</small>
Cart ID	<input type="checkbox"/> Tufts-003 (623-002) <input type="checkbox"/> WASH U-001 (623-003) <input type="checkbox"/> PBRC-016 (623-005) <input type="checkbox"/> Tufts-006 (623-006) <input type="checkbox"/> WASH U-002 (623-004) <input type="checkbox"/> PBRC-017 (623-001)		

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

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PAGEID = 277

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

Seven-Day Physical Activity Recall (PAR)

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

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

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

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

Interviewer initials: _____

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

PARCHT (TYPE 4)PS

SAME AS PAGE 71

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

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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)

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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: **TIMEPT<TUTMPT> see attached page for codelist**

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

AE # AE NUM<I:4>	Adverse Event	Serious AE INTEN<TUTEN> <input type="checkbox"/> No <input type="checkbox"/> Yes*	Intensity <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	Causality (check only one) <input type="checkbox"/> None <input type="checkbox"/> Doubtful <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Very likely	Action Taken Due to AE (check all that apply) <input type="checkbox"/> None <input type="checkbox"/> Intervention temporarily discontinued <input type="checkbox"/> Medical therapy required <input type="checkbox"/> Intervention permanently discontinued <input type="checkbox"/> Other (specify): _____	Outcome AE OUTCME<TUOCME> <input type="checkbox"/> Still present and unchanged <input type="checkbox"/> Improving <input type="checkbox"/> Resolved <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death	Start/End Date OR Check if Continuing
—	AESPEC<V:100> AESER<XYESNO>	<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Doubtful <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Very likely	ALL<XYES> <input type="checkbox"/> None <input type="checkbox"/> Intervention temporarily discontinued <input type="checkbox"/> Medical therapy required <input type="checkbox"/> Intervention permanently discontinued <input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Still present and unchanged <input type="checkbox"/> Improving <input type="checkbox"/> Resolved <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death	Start Date: AE STRDT ____/____/____ month year End Date: AE STPDT ____/____/____ month year OR <input type="checkbox"/> Continuing AECONT<XYES>
—	MEDRA MEDRTEXT<V:100> MEDRCODE<V:8> WORKFLOW<V:5> CODETM<DATETIME> CONFLVL<V:2> MATCHES<V:4> CODER<V:20>	<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Doubtful <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Very likely	AECAUSE<TUCAUS> <input type="checkbox"/> None <input type="checkbox"/> Intervention temporarily discontinued <input type="checkbox"/> Medical therapy required <input type="checkbox"/> Intervention permanently discontinued <input type="checkbox"/> Other (specify): _____ ACNONE ACTEMPD ACMEDREQ ACPERMD ACOTHR ACOTHSP<V:30>	<input type="checkbox"/> Still present and unchanged <input type="checkbox"/> Improving <input type="checkbox"/> Resolved <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death	Start Date: ____/____/____ month year End Date: ____/____/____ month year OR <input type="checkbox"/> Continuing
—	MEDRCODE<V:8> WORKFLOW<V:5> CODETM<DATETIME> CONFLVL<V:2> MATCHES<V:4> CODER<V:20>	<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Doubtful <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Very likely	<input type="checkbox"/> None <input type="checkbox"/> Intervention temporarily discontinued <input type="checkbox"/> Medical therapy required <input type="checkbox"/> Intervention permanently discontinued <input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Still present and unchanged <input type="checkbox"/> Improving <input type="checkbox"/> Resolved <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death	Start Date: ____/____/____ month year End Date: ____/____/____ month year OR <input type="checkbox"/> Continuing
—		<input type="checkbox"/> No <input type="checkbox"/> Yes*	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> None <input type="checkbox"/> Doubtful <input type="checkbox"/> Possibly <input type="checkbox"/> Probably <input type="checkbox"/> Very likely	<input type="checkbox"/> None <input type="checkbox"/> Intervention temporarily discontinued <input type="checkbox"/> Medical therapy required <input type="checkbox"/> Intervention permanently discontinued <input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Still present and unchanged <input type="checkbox"/> Improving <input type="checkbox"/> Resolved <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death	Start Date: ____/____/____ month year End Date: ____/____/____ month year OR <input type="checkbox"/> Continuing

*If Serious is Yes, submit expedited SAE form.

SAE Description: _____
 1 Death
 2 Persistent disability/incapacity
 3 Discontinuation of study
 4 Hospitalization
 5 Congenital anomaly or birth defect
 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

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

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Durham NC 27705

Concomitant Medications Log

PAGEID = 281+

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

Concomitant Medications Log

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

Send copies of this form with each submission starting with baseline:

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

Medication	Start Date or <input checked="" type="checkbox"/> if Pre-study	Stop Date or <input checked="" type="checkbox"/> if Continuing	Indication
1	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	CONMED2 (TYPE 4)R
2	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	SAME AS PAGE 281
3	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
4	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
5	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
6	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
7	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
8	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
9	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
10	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
11	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	
12	____/____/____ day month year OR <input type="checkbox"/> Pre-study	____/____/____ day month year OR <input type="checkbox"/> Continuing	

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

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Concomitant Medications Log

PAGEID = 281

Center Number: Participant Number: CONMED1 (TYPE 4)PS

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

PAGEID = 282

FORM/BLOCK = ADVERSE EVENTS

Serious Adverse Event Form

Report type: ☐ Initial **SAETYPE<TURPTP>**

☐ Follow-up #: _____ Center Number: _____ Participant Number: _____ Participant's Initials: _____

SAE Details: SAE Term (Medical Diagnosis): SAEDIAG<V:100> <hr/> SAE Onset Date: ____/____/____ SAESTRDT <small>day month year</small> SAE Stop Date: ____/____/____ SAESTPDT <small>day month year</small>		Participant's Details: Date of birth: ____/____/____ <small>day month year</small> SAEFORM (TYPE 4)R Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Serious Reporting Criteria: <i>(check all that apply)</i> <input type="checkbox"/> Death DEATH ALL <XYES> <input type="checkbox"/> Life-threatening LIFETHRT DISINCAP <input type="checkbox"/> Persistent or significant disability or incapacity <input type="checkbox"/> Prolonged or required hospitalization PRLGHOSP <input type="checkbox"/> Congenital anomaly or birth defect CONGDEF <input type="checkbox"/> Other significant event requiring medical and/or surgical intervention OTHRSIG	Causality & Intensity: <i>(check only one)</i> SAECAUS<TUGAUS> Causality: <input type="checkbox"/> 1 None <input type="checkbox"/> 2 Doubtful <input type="checkbox"/> 3 Possibly <input type="checkbox"/> 4 Probably <input type="checkbox"/> 5 Very likely Intensity: SAEINTEN<TUTEN> <input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe	Outcome (at time of report): <i>(check only one)</i> SAEOTCME<TUOCME> <input type="checkbox"/> 1 Still present and unchanged <input type="checkbox"/> 2 Improving <input type="checkbox"/> 3 Resolved <input type="checkbox"/> 4 Resolved with sequelae <input type="checkbox"/> 5 Death → If Death: Date of death: DEATHDT ____/____/____ <small>day month year</small> 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: <i>(check all that apply)</i> <input type="checkbox"/> None ACNONE <input type="checkbox"/> Intervention temporarily discontinued → Complete and fax the Temporary Discontinuation from CR Intervention form ACTEMPD <input type="checkbox"/> Medical therapy required ACMEDREQ <input type="checkbox"/> Intervention permanently discontinued → Complete and fax the Permanent Discontinuation from CR Intervention form ACPERMD <input type="checkbox"/> 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

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	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> 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**

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**

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: _____ / _____ / _____ **REPORTDT**
day month year

2 Name of person making this report: _____ **NOT DATABASED**

B BMI below 18.5 kg/m²

3 Date of threshold value: _____ / _____ / _____ **THRESDT**
day month year

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

5 Weight: _____ kg **WEIGHT1**

6 Calculated BMI: _____ kg/m² **CALBMI1**

All measurements
<F:9:3>

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?

- ☐ No → If No: Indicate the reason why it was not temporarily discontinued: **EXPLAIN<V:50>**
☐ 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: _____ / _____ / _____ **FLWUPDT**
day month year

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>**

- ☐ No → If No: Indicate the reason CR was not permanently discontinued (check only one):
☐ BMI returned to 18.5 kg/m² or higher **PERMRSN<TUBMI>**
☐ Other (specify): _____ **EXPLNOTH<V:50>**
☐ 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

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

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

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

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

1 Date of initial report: _____ / _____ / _____
day month year

REPORTDT

2 Name of person making this report: _____

NOT DATABASED

B Initial Elevation in BDI Score ≥ 20

3 Date of initial elevation: _____ / _____ / _____
day month year

INELEVDT

4 BDI score: _____

INITBDI <I:3>

C Repeat BDI Score

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

5 Date of follow-up questionnaire: _____ / _____ / _____
day month year

REPBDIDT

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?

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

TMPRSN<TUBDI>

☐ 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.

☐ Other (specify): _____

EXPLAIN<V:50>

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

E Follow-up BDI Score

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

8 Date of follow-up questionnaire: _____ / _____ / _____
day month year

FLWUPDT

9 BDI score: _____

FLWUPBDI<I:3>

ADDITIONAL PANEL ITEMS NEXT PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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>

- ☐ No → If No: Indicate why CR was not permanently discontinued (check only one):
- ☐ BDI score returned below 20 PERMRSN<TUDEPR>
- ☐ Mental health professional indicated it is safe to resume
- ☐ Other (specify): _____ EXPLAIN2<V:50>
- ☐ 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 north year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

2 Name of person making this report: _____

NOT DATABASED

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<1:3>

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<1:3>

- 9 Was an alert issued for the current body size scale? _____
ALL 3 <XYESNO> CBSSCALE ☐ No ☐ Yes → If Yes: t-score: _____
CBSCORE
- 10 Was an alert issued for the ideal body size scale? _____
IBSSCALE ☐ No ☐ Yes → If Yes: t-score: _____
IBSCORE
- 11 Was there confirming acceptability of the extreme body size shown? _____
EBSSCALE ☐ No ☐ 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 _____ ☐ No ☐ Yes ANERVOSA
- Bulimia nervosa _____ ☐ No ☐ Yes BNERVOSA
- Binge eating _____ ☐ No ☐ Yes BINGE
- Sub threshold eating disorder _____ ☐ No ☐ Yes SUBTHRES
- ALL <XYESNO>

ADDITIONAL PANEL ITEMS NEXT PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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>**

PERMDIS<XYESNO>

13 Was the participant permanently discontinued from the CR intervention?

- ☐ No → If No: Indicate why CR was not permanently discontinued (check only one):
- ☐ Did not meet diagnostic criteria for these eating disorders **PERMRSN<TUDISO>**
- ☐ Other (specify): **EXPLAIN<V:50>**
- ☐ 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

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

2010 DCRI – Confidential

Calerie Phase 2 CRF V9.0 28 SEP 2010

CRF, page 290.

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.

A Identifying information

ELEVATEK (TYPE 4)

1 Date of initial report: _____ / _____ / _____ REPORTDT

NOT DATABASED

2 Name of person making this report: _____

B Initial Elevation in Potassium Level

3 Date of initial elevation: _____ / _____ / _____ 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: _____ / _____ / _____ 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>

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

☐ 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.

☐ Other (specify): EXPLAIN<V:50>

☐ 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: _____ / _____ / _____ FLWUPDT

9 Potassium level: _____ mEq/L KLEVEL3

ADDITIONAL PANEL ITEMS NEXT
PAGE

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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>

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

PERMRSN<TUELVN>

☐ Potassium returned to 5.0 mEq/L or lower☐ Other (specify):

EXPLAIN2<V:50>

☐ 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 DATABASD

Study Manager's Signature:

Signature: _____

Date: ____/____/____
 day month year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

2010 DCRI – Confidential

Calerie Phase 2 CRF V9.0 28 SEP 2010

CRF, page 292.

Anemia Episode Report

PAGEID = 293

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

Anemia Episode

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

A Identifying Information

ANEMIA1 (TYPE 4)

1 Date of initial report: ____/____/____ **REPORTDT**

2 Name of person making this report: _____

NOT DATABASED

All measurements

<F:9:3>

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: ____/____/____ **LABDT**

	Value	Lower Limit of Normal (LLN)	Below LLN?
4 Hemoglobin:			<input type="checkbox"/> No <input type="checkbox"/> Yes
5 Hematocrit:	HGLOB1	GLOBLLN1	<input type="checkbox"/> No <input type="checkbox"/> Yes
6 RBC:	HCRIT1	CRITLLN1	<input type="checkbox"/> No <input type="checkbox"/> Yes
7 Iron level:	RBC1 IRON1	RBCLLN1 IRONLLN1	<input type="checkbox"/> No <input type="checkbox"/> Yes

C

BLCRITDT		BLCRIT	
FUCRITDT		FLUPCRIT	NOT DATABASED

D Repeat Test:

DECREASE

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

11 Date of repeat lab test: ____/____/____

	Value	REPTLABDT	Lower Limit of Normal (LLN)	Below LLN?
12 Hemoglobin:				<input type="checkbox"/> No <input type="checkbox"/> Yes
13 Hematocrit:				<input type="checkbox"/> No <input type="checkbox"/> Yes
14 RBC:	HGLOB2		GLOBLLN2	<input type="checkbox"/> No <input type="checkbox"/> Yes
15 Iron level:	HCRIT2 RBC2 IRON2		CRITLLN2 RBCLLN2 IRONLLN2	<input type="checkbox"/> No <input type="checkbox"/> Yes

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Anemia Episode Report

PAGEID = 294

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

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>**

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

☐ 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>

☐ Other (specify): **HLPOTHSP<V:50>**

☐ Yes → If Yes: Date on which patient was advised: ____/____/____
day month year

F One Month Follow-up Test

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

17 Date of one month follow-up lab test: ____/____/____
day month year

All measurements

<F:9:3>

ALL<XYESNO>

	Value	Lower Limit of Normal (LLN)	Below LLN?
18 Hemoglobin:	HGLOB3	GLOBLLN3	<input type="checkbox"/> No <input type="checkbox"/> Yes
19 Hematocrit:	HCRIT3	CRITLLN3	<input type="checkbox"/> No <input type="checkbox"/> Yes
20 RBC:	RBC3	RBCLLN3	<input type="checkbox"/> No <input type="checkbox"/> Yes
21 Iron level:	IRON3	IRONLLN3	<input type="checkbox"/> No <input type="checkbox"/> 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>**

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

☐ 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.

TPMRSN<TUANEP>

☐ Other (specify): **EXPLAIN<V:50>**

☐ 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

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

Anemia Episode Report

PAGEID = 295

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

Anemia Episode (continued)

H Two Month Follow-up Value

ANEMIA3 (TYPE 4)

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

23 Date of two month follow-up lab test: _____ / _____ / _____
day month year FUMTH2DT

ALL<XYESNO>

	Value	Lower Limit of Normal (LLN)	Below LLN?
24 Hemoglobin:	HGLOB4	GLOBLLN4	<input type="checkbox"/> No <input type="checkbox"/> Yes
25 Hematocrit:	HCRIT4	CRITLLN4	<input type="checkbox"/> No <input type="checkbox"/> Yes
26 RBC:	RBC4	RBCLLN4	<input type="checkbox"/> No <input type="checkbox"/> Yes
27 Iron level:	IRON4	IRONLLN4	<input type="checkbox"/> No <input type="checkbox"/> Yes

All measurements
<F:9:3>

I Permanent Discontinuation

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

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

☐ Hemoglobin panel and iron levels returned to acceptable values PERMRSN<TUANEQ>

☐ Other (specify): EXPLAIN2<V:50>

☐ 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

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 VO₂ 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: ____/____/____ REPORTDT

2 Name of person making this report: _____ NOT DATABASED

B Date when the ventricular ischemia was observed

3 Date: ____/____/____ 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>

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

EXPLAIN<V:50>

☐ 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: ____/____/____ STRESSDT

6 Did the study confirm the presence of ventricular ischemia?

☐ No

☐ Yes

ISCHEMIA<XYESNO>

E Permanent Discontinuation

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

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

☐ The study did not confirm the presence of ventricular ischemia.

☐ Other (specify): _____

PERMRSN<TUVENT>

EXPLAIN2<V:150>

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

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

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

calerie**Phase 2****Temporary Discontinuation
from CR Intervention**

THIS IS A REPEATING PAGE

PAGEID = 298

DISCTYPE<TURPT>

Check one: ☐ Initial ☐ Follow-upCenter 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 **TMPTDISDT** **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

Height: _____ . _____ cm

Gender: ☐ Male ☐ Female

Weight: _____ . _____ kg

BMI (if applicable): _____

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

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				____ / ____ / ____ day month year	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	____ / ____ / ____ day month year
				____ / ____ / ____ day month year	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	____ / ____ / ____ day month year
				____ / ____ / ____ day month year	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	____ / ____ / ____ day month year

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	____ / ____ / ____ day month year	ADDITIONAL PANEL ITEM NEXT PAGE	
	____ / ____ / ____ day month year		
	____ / ____ / ____ day month year		
	____ / ____ / ____ day month year		

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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 DATABSED

Intervention Resumption

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

If Yes: Date intervention was resumed: ____/____/____ RESUMEDT
day month year

Investigator's Signature

Investigator: _____ Date: ____/____/____
signature day month year

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Center Number: _____

Participant Number: _____

Participant's Initials: _____
first middle last

Permanent Discontinuation

- 1** Date of permanent discontinuation: ____/____/____ PRMDISDT
day month year PERMDISC (TYPE 1)
- 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 \geq 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 \geq 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>
 - ☐ 18 Other: PERMOTHR<V:50>

Participant's Details:

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

Height: _____ cm

Gender: ☐ Male ☐ Female

Weight: _____ kg

BMI (if applicable): _____

Relevant Medical History:

NOT DATABASED

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

Permanent Discontinuation (continued)

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

Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> Yes	____/____/____ day month year
				____/____/____ day month year	<input type="checkbox"/> No <input type="checkbox"/> 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: _____ Date: ____/____/____
signature day month year

CALERIE PHASE2 ANNOTATION V4.012JUN2008

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

Completed by **Calerie staff:**

THIS IS A REPEATING PAGE

TIMEPT<TUTMPT>

Participant Number:

Center Number:

Participant's Initials:

	first	middle	last
1	1	1	1
2	1	1	1
3	1	1	1
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97	1	1	1
98	1	1	1
99	1	1	1
100	1	1	1

Daily Home Weight Log

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

month day SSUEDT

Were you issued a new scale? ☐₀ No ☐₁ Yes → If Yes: Date first used: **ISS**
month

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

[illegible]

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: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59	Time: <input type="text"/> _1 AM <input type="text"/> _2 PM _____ : _____ 00:00 to 11:59
Weight: _____ : _____ lb	Weight: _____ : _____ lb	Weight: _____ : _____ lb	Weight: _____ : _____ lb	Weight: _____ : _____ lb	Weight: _____ : _____ lb	Weight: _____ : _____ lb
Check scale memory						

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

During DLW Periods

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: ____/____/____ **DEVDT**
day month year
ALL<XYES>

TIMEPT<TUTMPT>

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

☐ Study/laboratory procedures (specify): **STUDYLAB** **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

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



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



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



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



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>					