

Phone Screen

THIS PAGE NOT ENTERED Center Number: ___ Participant Number: ___ __ _

Participant's Initials:

first	middle	fast

Phone Screen	
Directions: Give the caller a brief overview of the study. Exp Visit 1. Ask for verbal consent to record personal in order to determine eligibility. If the caller is elig Fill in blanks and check appropriate answer	information over the phone. Complete all phone screen questions gible, schedule them for Screening Visit 1.
Verbal consent given by respondent: □ ₀ No □ ₁ Yes	Interviewer's initials:
Date:/Source:	Age:
Last name: First name:	DOB:/ _{month} / _{year}
Address:	
Phone (home): Phone (work):	E-mail:
Height: ft in Weight: lbs BMI: _	Gender: 1 Male 2 Female
Medical History	
Have you been diagnosed with or ever experienced the following:	If Yes: Describe (being treated/how long ago/symptoms/type of/family history)
Heart attack, heart-related chest pain, or other heart condition	□ ₀ No □ ₁ Yes →
Abnormal heart rhythm	□ ₀ No □ ₁ Yes →
Cancer	\square_0 No \square_1 Yes \rightarrow
Shortness of breath or other breathing problem	\square_0 No \square_1 Yes \rightarrow
Diabetes (meds)	\square_0 No \square_1 Yes \rightarrow
High blood pressure (> 140/90)	\square_0 No \square_1 Yes \rightarrow
Anemia or other blood condition	\square_0 No \square_1 Yes \rightarrow
Thyroid or other metabolic disorder such as phenylketonuria	\square_0 No \square_1 Yes \rightarrow
Stomach or digestive disorders	\square_0 No \square_1 Yes \rightarrow
Immunologic disorder or AIDS	\square_0 No \square_1 Yes \rightarrow
Depression or any other psychiatric or neurologic disease	\square_0 No \square_1 Yes \rightarrow
Active liver disease and/or gallstones	\square_0 No \square_1 Yes \rightarrow
Kidney or urologic disorders	\square_0 No \square_1 Yes \rightarrow
Major abdominal or chest surgery	\square_0 No \square_1 Yes \rightarrow
Weight loss or gain of > 3 kg over the past 6 months	\square_0 No \square_1 Yes \rightarrow
Known metallic objects or implants in your body	\square_0 No \square_1 Yes \rightarrow
Anaphylaxis, severe allergies, or asthma CALERIE PHASE2 ANNO	TATION V8.0 24FEB2012



Phone Screen

TH	IS PAGE NOT ENTERED Center Number:	Participant Number:	Participant's Initials:
М	edications		
Ī	Have you received medication for depression or any other psychiatric disease in the past year?	\square_0 No \square_1 Yes \rightarrow If Yes: S	pecify medications:
2	Have you received more than one episode of medication for depression or any other psychiatric disease ever?	\square_0 No \square_1 Yes \rightarrow If Yes: S	pecify medications:
3	Have you been treated with steroids in the last six months?	□₀ No □₁ Yes	
4	Have you been treated with steroids for more than a month in the past five years?	□₀ No □₁ Yes	
5	Do you currently use regular medications other than birth control pills?	\square_0 No \square_1 Yes \rightarrow If Yes: Specifical Proof of the Specifical Proof of th	pecify medications:
W	omen		
1	Are you currently pregnant or breast feeding?	□₀ No □₁ Yes	
2	Do you plan to have children in the next two years?	□₀ No □₁ Yes	
3	Do you use some form of birth control?	\square_0 No \square_1 Yes \rightarrow If Yes: Specifical Proof of the Specifical Proof of th	pecify:
Pl	nysical Activity/Lifestyle		
1	Over the past year, have you engaged in a regular program of physical fitness involving heavy physical activity more than 5 times per week? (Examples of heavy physical activity include: jogging, running, riding fast on a bicy cle for 30 minutes or more; heavy gardening or other chores for an hour or more; active games or sports such as handball or tennis for an hour or more.)	of activ	Specify type and frequency rity:
2	Have you used drugs recreationally within the past two years?	No □₁ Yes	
3	Have you smoked within the past twelve months?	\square_0 No \square_1 Yes	
4	Have you given blood in the last 30 days?	□₀ No □₁ Yes	
5	Are you currently participating in another interventional trial?	□₀ No □₁ Yes	
6	Are you currently practicing a vegan dietary lifestyle?	\square_0 No \square_1 Yes	
7	Do you anticipate difficulties adhering to special diets and clinical visits over a two year period?	□ ₀ No □ ₁ Yes	
El	igibility Information To be completed by the intervi	ewer	
Re	view above items marked "Yes" against Exclusion criter	ia. Then please mark the app	propriate response below:
Eliç	gible: $\square_0 \ No \to If \ No$: Reason for not being eligible: $___$		
ı	☐ Yes → If Yes: Is participant interested in participating.		
	On hold → If on hold: For what reason?	<u> </u>	
	Contact to resume screening at	ter being on hold:/	th year —
Or	ientation (screening visit 1) scheduled:		
Co	mments:		
I	CALERIE PHASE2 ANNOTA	TION V8.0 24FEB2012	
l			



FORM/BLOCK = SCREENING

Screening Visit 1 Checklist

PAGEID = 3 INVSITE

PATID

Participant's Initials: First middle last Center Number: ___ Participant Number: ___ __ SUB INO - INVSITEILIPATIO

Screening Visit 1 C		
Date of initial clinic visit for	CLINICDT	
	day month year	-
Check completed items:	Other Panel Item not displayed this page:	CHECKLST
2 Informed consent	RTNCLINIC <xyesno></xyesno>	(TYPE 4)
3 HIPAA authorization		· (111 = ¬)
4 Study video		
5 Study brochure		
6 Weight and height me	easures, including BMI eligibility	
7 Demographic form		
8 Stanford Activity Asses	ssment	
9 General Dietary Ques	itionnaire	
10 Eating Inventory		
11 MAEDS		
12 SCID-II		
13 BDI-II		
14 Meeting with dietitian		
15 Meeting with study co	ordinator/manager	
16 Schedule Assessment (Calendar	
17 Inclusion/Exclusion crit	iteria review	
\square_0 No \rightarrow If No: Provide r	d to return for Screening Visit 2? RETVST <xyesno> reason (check all that apply):</xyesno>	
Lost in Will to	If an eligibility criterion FAILELIG ALL <xyes> Interest in the study LOSTINT ake too much time MUCHTIME Iduling conflicts with work or school SCHEDULE</xyes>	
☐ Doesn	n't like the study's procedures DLKSTDPR n't want to be involved in a research study DWINVSTD lling to be randomized UNWILRAN	Item not Displayed this page:
_	too far away/transportation problems TRANPROB	UNABCONT
_	Is help with child care CHLDCARE	ADDVISIT <tuadvt></tuadvt>
_	ed with no explanation REFEXPLN (specify):OTHERSP<\	/:50>
\square_1 Yes \rightarrow If Yes: Date of s	scheduled Screening Visit 2:/	NXTVISDT

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax inis form to wekt forms management at (717) 000-7 100



	Center Number:	Participant Number: _	Participant's Initials:
Clinic Weight			
Weight date and time: _	day / STUDYDT year	STUDYTM	SINTIALS <v:3> Staff initials: $\frac{1}{first middle lost}$</v:3>
OR Not done → Specify	reason (use codelist below):	STUDYND <tund></tund>	DATEHDR (TYPE 4)
Clinic weight (if the first two	o measurements are more than 0.1	kg apart, measure weight a third	time):
Weight 1:	kg WGHT1	ALL <f:9:3></f:9:3>	
Weight 2:	kg WGHT2		WEIGHT (TYPE 4)
Weight 3:	kg WGHT3		
Weight of gown:	GWGHT		
Height			
Height (if the first two meas	surements are more than 0.1 cm ap	oart, measure height a third time):	HEIGHT (TYPE 1)
1 First height:	cm HGHT1		
2 Second height:	cm HGHT2		
3 Third height:	HGHT3		
Not Done Codelist: 1 Par	ticipant refused 2 Clinician unal	ble to obtain 3 Insufficient time	4 Instrument failure 5 Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



THIS PAGE NOT ENTERED	Center Number: Participant Number:	Participant's Initials:
Date:/	Maintain completed form in participant file	at site.
, , , , , , , , , , , , , , , , , , , ,	Please print.	
Demographic Questionne	- niro	
Name: first name	middle initial	last nome
Street address:		
City:	State: 2	Zip:
Telephone (Home): ()	(Work): ()
	Do you mind being called at work? \square_0 No	o 1 Yes
	Best time to call, and where:	
E-mail address:	Cell phone: ()
Do you use e-mail regularly? ☐ ₀ N	o	
Date of birth:///	Age:	
·	•	
Social Security number:		
Occupation:		
Emergency Contact:		
Name:	,	last name
Telephone: ()	Relationship:	
Primary Care Physician		
Name:		
		last name
City:	State: 2	Zip:
Telephone: (CALER	IE PHASE2 ANNOTATION V8.0 24F	EB2012



Participant's Initials: ______

		tirst middle fas
D	emographics	
,	Date of birth:/	
2	Sex: \(\sum_1 \text{Male} \) \(\sum_2 \text{Female} \) \(\sum_2 \text{Female} \)	
3	Ethnicity (check only one):	
4	Race (check only one):	
5	Marital status (check only one):	
6	Living situation: Where do you live (check only one):	
7	Education: What is the highest level of formal education that you have completed (check only one)? (Note: If you have any questions as to which category you fall in, please contact the study representative.) [] Elementary school (0-8 th grade)	
	2 9-11 th grade 3 12 th grade or GED 4 Some college/Associates degree 5 College (includes multiple degrees) 6 Non-doctoral graduate degree 7 Doctoral degree (M.D., J.D., Ph.D., etc.)	
8	Family income: What is the total annual income of your household (check only one): 1	

Center Number: ___ Participant Number: ___ __ _

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Fax this Form to DCRI Forms Management at (919) 008-7100



	Screening
THIS PAGE NOT ENTERED Center Number: Participant Number:	Participant's Initials: First middle last
Date completed:/ _{month} / _{year}	
Stanford Brief Physical Activity Survey	
Section 1 On-The-Job Activity Please check the box next to the one statement that best described activity you usually performed while on this job this last year. If you are not gainfully embut perform work around home regularly, indicate that activity in this section.	
$\square_\mathtt{A}$ If you have no job or regular work, check box A and go on to Section II.	
I spent most of the day sitting or standing. When I was at work, I did such things as writing, ty telephone, assembling small parts, or operating a machine that takes very little exertion or street truck while at work, I did not lift or carry anything for more than a few minutes each day.	
I spent most of the day walking or using my hands and arms in work that required moderate ework, I did such things as delivering mail, patrolling on guard duty, mechanical work on autor machines, house painting, or operating a machine that requires some moderate activity work lift, my job required me to lift and carry things frequently.	mobiles or other large
I spent most of the day lifting or carrying heavy objects or moving most of my body in some of work, I did such things as stacking cargo or inventory, handling parts or materials, or I did wowho builds structures or a gardener who does most of the work without machines.	
□ _ε I spent most of the day doing hard physical labor. When I was at work, I did such things as d heavy tools, or carrying heavy loads (bricks, for example) to the place where they are to be a operated equipment, my job also required me to do hard physical work most of the day with	used. If I drove a truck or
Section II Leisure-Time Activity Please check the box next to the one statement that best descriped your leisure time during most of the last year.	ibes the way you spent
Most of my leisure time was spent without very much physical activity. I mostly did things like very playing cards. If I did anything else, it was likely to be light chores around the house or yar game like bowling or catch. Only occasionally, no more than once or twice a month, did I do like jogging, playing tennis or active gardening.	rd, or some easy-going
□ _G Weekdays, when I got home from work, I did few active things. But most weekends I was ablight exercise—going for walks, playing a round of golf (without motorized carts) or doing son house.	
□ _H Three times per week, on the average, I engaged in some moderate activity—such as brisk wo swimming or riding a bike—for 15-20 minutes or more. Or I spent 45 minutes to an hour or m difficult chores—such as raking or washing windows, mowing the lawn or vacuuming—or playi tennis, or basketball.	nore doing moderately
During my leisure time over the past year, I engaged in a regular program of physical fitness in heavy physical activity at least three times per week. Examples of heavy physical activity are: fast on a bicycle for 30 minutes or more; heavy gardening or other chores for an hour or more such as handball or tennis for an hour or more; or a regular program involving calisthenics and for 30 minutes or more.	jogging, running or riding e; active games or sports
, Over the past year, I engaged in a regular program of physical fitness along the lines describ	ed in the last paragraph (I)

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:

but I did it almost daily-five or more times per week.



THIS	PAGE NOT ENTERED Center Number: Participant Number:	Participant's I	nitials:
Date o	completed:day /OR Not done → Specify reason (use codelist below):		
Eati	ng Inventory		
1	When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating, even if I have just finished a meal.	☐₁ True	□₀ False
2	I usually eat too much at social occasions, like parties and picnics.	☐₁ True	o False
3	I am usually so hungry that I eat more than three times a day.		o False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.	☐₁ True	o False
5	Dieting is so hard for me because I just get too hungry.	☐₁ True	o False
6	I deliberately take small helpings as a means of controlling my weight.		o False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	☐₁ True	□₀ False
8	Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat.	□₁ True	□ ₀ False
9	When I feel anxious, I find myself eating.	☐₁ True	□₀ False
10	Life is too short to worry about dieting.		o False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	☐, True	□ _o False
12	I often feel so hungry that I just have to eat something.	☐ ₁ True	o False
13	When I am with someone who is overeating, I usually overeat too.	☐₁ True	□₀ False
14	I have a pretty good idea of the number of calories in common food.	☐ ₁ True	o False
15	Sometimes when I start eating, I just can't seem to stop.	☐₁ True	□₀ False
16	It is not difficult for me to leave something on my plate.		o False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	□₁ True	□₀ False
18	While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	☐₁ True	□₀ False

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



THIS	S PAGE NOT ENTERED Center Number: Participant Number:	Participant's Initials: first middle last
Eat	ing Inventory (continued)	
19	Being with someone who is eating often makes me hungry to eat also.	☐₁ True ☐₀ False
20	When I feel blue, I often overeat.	☐₁ True ☐₀ False
21	I enjoy eating too much to spoil it by counting calories or watching my weight.	□₁ True □₀ False
22	When I see a real delicacy, I often get so hungry that I have to eat right away.	☐₁ True ☐₀ False
23	I often stop eating when I am not really full as a conscious means of limiting the amount I eat.	☐₁ True ☐₀ False
24	I get so hungry that my stomach often seems like a bottomless pit.	☐₁ True ☐₀ False
25	My weight has hardly changed at all in the last ten years.	☐₁ True ☐₀ False
26	I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	☐₁ True ☐₀ False
27	When I feel lonely, I console myself by eating.	□₁ True □₀ False
28	I consciously hold back at meals in order not to gain weight.	☐₁ True ☐₀ False
29	I sometimes get very hungry late in the evening or at night.	☐₁ True ☐₀ False
30	I eat anything I want, any time I want.	☐₁ True ☐₀ False
31	Without even thinking about it, I take a long time to eat.	☐₁ True ☐₀ False
32	I count calories as a conscious means of controlling my weight.	☐₁ True ☐₀ False
33	I do not eat some foods because they make me fat.	□₁ True □₀ False
34	I am always hungry enough to eat at any time.	☐₁ True ☐₀ False
35	I pay a great deal of attention to changes in my figure.	□₁ True □₀ False
36	While on a diet, if I eat a food that is not allowed, I often splurge and eat	
	other high calorie foods.	
	CALERIE PHASE2 ANNOTATION V8.0 24FEB2012	ipant's Initials:

calerie Phase 2

Screening

Participant's Initials: Center Number: _ Participant Number: THIS PAGE NOT ENTERED Eating Inventory (continued) Please check one answer that is most appropriate to you for each question below. How often are you dieting in a conscious 37 Rarely , Sometimes ___, Usually _____, Always effort to control your weight? Would a weight fluctuation of 5 pounds 38 □_o Rarely , Sometimes , Usually 3 Always affect the way you live your life? 39 How often do you feel hungry? Rarely Sometimes Usually _____, Always Do your feelings of guilt about overeating 40 , Sometimes , Usually Rarely ____, Always help you to control your food intake? How difficult would it be for you to stop Slightly difficult _ Easy 41 eating halfway through dinner and not eat Sery difficult ___, Moderately difficult for the next four hours? □ Not at all How conscious are you of what you are \square_1 Slightly 42 eating? ____, Moderately How frequently do you avoid "stocking up" __ Almost never Seldom 43 on tempting foods? _____, Usually ■ Almost always How likely are you to shop for low Unlikely , Slightly likely 44 calorie foods? , Moderately likely , Very likely Do you eat sensibly in front of others and 45 □ Never □ Rarely , Often , Always splurge alone? Unlikely ☐₁ Slightly likely How likely are you to consciously eat slowly 46 in order to cut down on how much you eat? , Moderately likely S Very likely _ Almost never , Seldom How frequently do you skip dessert because 47 you are no longer hungry? , At least once a week 3 Almost every day , Slightly likely How likely are you to consciously eat less Unlikely 48 than you want? , Moderately likely _ Very likely _ Never Rarely Do you go on eating binges though you are 49 not hungry? 2 Sometimes At least once a week To what extent does this statement describe your eating behavior? "I start dieting in the Not like me morning, but because of any number of , Little like me things that happen during the day, by Pretty good description of me evening I have given up and eat what 3 Describes me perfectly I want, promising myself to start dieting again tomorrow. On a scale of 0 to 5, where 0 means no _ Eat whatever you want, whenever you want it restraint in eating (eating whatever you , Usually eat whatever you want, whenever you want it often eat whatever you want, whenever you want it want, whenever you want it) and 5 means 51 total restraint (constantly limiting food $\square_{\scriptscriptstyle 3}$ Often limit food intake, but often "give in" intake and never "giving in"), what number ___ Usually limit food intake, rarely "give in" would you give yourself? Constantly limiting food intake, never "giving in"

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

icipant's Initials:



Screening							
THIS PAGE NOT ENTERED Center Number: Participed	nt Numbe	r:		Partici	pant's Ini	tials:	t middle last
Date completed:/							
Multiaxial Assessment of Eating Disorder Sym	ptom	S (MAE	DS)				
Instructions: Using the scale shown, please rate the following items on a sca	le from 1	to 7. Ple	ase ansv	ver as tr	thfully	as possi	ble.
	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose weight.			З	_4		6	
2 My sleep isn't as good as it used to be.			\square_3	\square_{4}	\square_5	6	
3 I avoid eating for as long as I can.			3	4	5	6	
4 Certain foods are "forbidden" for me to eat.			З	_4	\square_5	6	\square_{7}
5 I can't keep certain foods in my house because I will binge on them.			Пз		5	6	
6 I can easily make myself vomit.			З	□₄	\square_5	6	□ ₇
7 I can feel that being fat is terrible.			\square_3	4	5	6	
8 I avoid greasy foods.			3	_4	5	6	
9 It's okay to binge and purge once in a while.			3	_4	5	6	
10 I don't eat certain foods.			\square_3	_4	5	6	
11 I think I am a good person.			3	4	5	6	
12 My eating is normal.			\square_3		\square_5	6	□ ₇
13 I can't seem to concentrate lately.			3	4	5	6	
14 I try to diet by fasting.			\square_3	\square_{4}	\square_5	6	\square_{7}
15 I vomit to control my weight.			З	4	5	6	
16 Lately nothing seems enjoyable anymore.			З			6	
17 Laxatives help keep you slim.			\square_3	4	5		
18 I don't eat red meat.			3		\square_5	6	\square_7

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

icipant's Initials:

19 I eat so rapidly I can't even taste my food.



						irst middle last	
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)							
	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being overweight.						□6	
21 When I feel bloated, I must do something to rid myself of that feeling.			□₃				
22 I overeat too frequently.			3			□6	
23 It's okay to be overweight.			Пз		\square_{5}	□6	
24 Recently I have felt that I am a worthless person.			3		5		
25 I would be very upset if I gained 2 pounds.			\square_3			6	\square_{7}
26 I crave sweets and carbohydrates.			3			6	
27 I lose control when I eat.			\square_3	□₄		□₀	
28 Being fat would be terrible.						□6	
29 I have thought seriously about suicide lately.			\square_3			6	
30 I don't have any energy anymore.						6	
31 I eat small portions to control my weight.			Пз	□₄		□,	
32 I eat 3 meals a day.			Пз			□6	
33 Lately I have been easily irritated.			Пз			□6	
34 Some foods should be totally avoided.						6	
35 I use laxatives to control my weight.			\square_3			6	
36 I am terrified by the thought of being overweight.						□6	
37 Purging is a good way to lose weight.			\square_3			□6	
38 Lavoid fatty foods.							

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

ticipant's Initials: First middle last



Center Number: ___ _ Participant Number: ___ _ _ THIS PAGE NOT ENTERED Participant's Initials: ___ __

							irst middle fast
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued) Never Very Rarely Some- Often						Very	Always
		Rarely		times		Often	
39 Recently I have felt pretty blue.			\square_3	4		□6	
40 I am obsessed with becoming overweight.			Пз	□₄		□6	\square_{7}
41 I don't eat fried foods.						□6	
42 I skip meals.			Пз	□₄		□6	
43 Fat people are unhappy.							
44 People are too concerned with the way I eat.			Пз	□₄		□6	
45 I feel good when I skip meals.							
46 I avoid foods with sugar.			Пз	□₄		□,	
47 I hate it when I feel fat.			3			□6	
48 I am too fat.			Пз	□₄		□,	□,
49 I eat until I am completely stuffed.						□,	
50 I hate to eat.						□6	
51 I feel guilty about a lot of things these days.						□6	
52 I'm very careful of what I eat.			\square_3			□6	
53 I can "hold off" and not eat even if I am hungry.							
54 I eat even when I am not hungry.			Пз				
55 Fat people are disgusting.							
56 I wouldn't mind gaining a few pounds.			\square_3	□₄			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



THI	S PAGE NOT ENTERED Center Number: Participant Number:	Participant's Initials: first middle last
Date	e completed:/	
	ructured Clinical Interview for DSM-IV (SCID-II)	
1	Have you avoided jobs or tasks that involved having to deal with a lot of people?	□₀ No □₁ Yes
2	Do you avoid getting involved with people unless you are certain they will like you?	□₀ No □₁ Yes
3	Do you find it hard to be "open" even with people are you close to?	□₀ No □₁ Yes
4	Do you often worry about being criticized or rejected in social situations?	□₀ No □₁ Yes
5	Are you usually quiet when you meet new people?	□₀ No □₁ Yes
6	Do you believe that you're not as good, as smart, or as attractive as most other people?	? ONO On Yes
7	Are you afraid to try new things?	□₀ No □₁ Yes
8	Do you need a lot of advice or reassurance from other before you can make everyday decisions—like what to wear or what to order in a restaurant?	□₀ No □₁ Yes
9	Do you depend on other people to handle important areas in your life such as finances, child care, or living arrangements?	□₀ No □₁ Yes
10	Do you find it hard to disagree with people even when you think they are wrong?	□₀ No □₁ Yes
11	Do you find it hard to start or work on tasks when there is no one to help you?	□₀ No □₁ Yes
12	Have you often volunteered to do things that are unpleasant?	□₀ No □₁ Yes
13	Do you usually feel uncomfortable when you are by yourself?	□₀ No □₁ Yes
14	When a close relationship ends, do you feel you immediately have to find someone else to take care of you?	□₀ No □₁ Yes
15	Do you worry a lot about being left alone to take care of yourself?	□₀ No □₁ Yes
16	Are you the kind of person who focuses on details, order, and organization or likes to make lists and schedules?	□₀ No □₁ Yes
17	Do you have trouble finishing jobs because you spend so much time trying to get things exactly right?	□₀ No □₁ Yes
18	Do you or other people feel that you are so devoted to work (or school) that you have time left for anyone else or for just having fun?	No On Yes
19	Do you have very high standards about what is right and what is wrong?	□₀ No □₁ Yes
20	Do you have trouble throwing things out because they might come in handy some day?	□₀ No □₁ Yes
21	Is it hard for you to let other people help you unless they agree to do things exactly the way you want?	□₀ No □₁ Yes
22	Is it hard for you to spend money on yourself and other people even when you have enough?	□₀ No □₁ Yes
23	Are you often so sure you are right that it doesn't matter what other people say?	□₀ No □₁ Yes
24	Have other people told you that you are stubborn or rigid?	□₀ No □₁ Yes
S.	CALERIE PHASE2 ANNOTATION V8.0 24FEB2012	ipant's Initials:
	De not submit to DCDI. Detain at site at secure legation	



Center Number: Participant Number: Participant's Initials: THIS PAGE NOT ENTERED Structured Clinical Interview for DSM-IV (SCID-II) (continued) When someone asks you to do something that you don't want to do, do you say "yes" 25 , No , Yes but then work slowly or do a bad job? 26 If you don't want to do something, do you often just "forget" to do it? , No , Yes Do you often feel that other people don't understand you, or don't appreciate 27 _o No , Yes how much you do? 28 Are you often grumpy and likely to get into arguments? ∐_o No ___, Yes Have you found that most of your bosses, teachers, supervisors, doctors, and others 29 ___ No ____, Yes who are supposed to know what they are doing really don't? 30 Do you often think that it's not fair that other people have more than you do? ___, Yes _o No 31 Do you often complain that more than your share of bad things have happened to you? _o No ____, Yes 32 Do you often angrily refuse to do what others want and then later feel bad and apologize? ο No Yes 33 Do you usually feel unhappy or that life is no fun? o No ___, Yes Do you believe that you are basically an inadequate person and often don't feel good 34 __h No Yes about yourself? 35 Do you often put yourself down? _o No ___, Yes Do you keep thinking about bad things that have happened in the past or 36 L No ___, Yes worry about bad things that might happen in the future? 37 Do you often judge others harshly and easily find fault with them? L Yes _ No 38 Do you think that most people are basically no good? __ No ___, Yes 39 Do you almost always expect things to turn out badly? _o No _, Yes 40 Do you often feel guilty about things you have or haven't done? __ No ___, Yes Do you often have to keep an eye out to stop people from using you or hurting you? 41 o No ___, Yes Do you spend a lot of time wondering if you can trust your friends or 42 ____, Yes _o No the people you work with? Do you find that it is best not to let other people know much about you because 43 _o No ____, Yes they will use it against you? 44 Do you often detect hidden threats or insults in things people say or do? __ No , Yes Are you the kind of person who holds grudges or takes a long time to forgive 45 _o No _₁ Yes people who have insulted or slighted you? Are there many people you can't forgive because they did or said something to you 46 ____, Yes _o No a long time ago? 47 Do you often get angry or lash out when someone criticizes or insults you in some way? _o No _, Yes 48 Have you often suspected that your spouse or partner has been unfaithful? □₀ No ___, Yes CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

icipant's Initials:



THI	IS PAGE NOT ENTERED Center Number	oer:	Participant Number:	P	articipant's Initials:	first middle last
Sti	ructured Clinical Interview for D			d)		
49	When you are out in public and see people tal they are talking about you?	king, do you	often feel that		□₀ No	1 Yes
50	Do you often get the feeling that things that ha are really meant to give you a message?				□₀ No	1 Yes
51	When you are around people, do you often go or stared at?				□ ₀ No	
52	Have you ever felt that you could make thing about them?	gs happen ju	st by making a wi	sh or thinking	□₀ No	1 Yes
53	Have you had personal experiences with the	e supernatur	al?		□ ₀ No	1 Yes
54	Do you believe that you have a "sixth sense know and predict things that others can't?	" that allows	you to		□ ₀ No	1 Yes
55	Does it often seem that objects or shadows of that noises are actually people's voices?	are really pe	ople or animals or		□ ₀ No	1 Yes
56	Have you had the sense that some person or you cannot see anyone?	r force is aro	und you, even tho	ugh	□ ₀ No	1 Yes
57	Do you often see auras or energy fields arou	und people?			□ ₀ No	1 Yes
58	Are there very few people that you're really	close to out	side of your imme	diate family?	□₀ No	1 Yes
59	Do you often feel nervous when you are wit	h other peop	le?		□₀ No	1 Yes
60	Is it NOT important to you whether you have	e any close r	elationships?		□ ₀ No	1 Yes
61	Would you almost always rather do things of	lone than wi	th other people?		□ ₀ No	1 Yes
62	Could you be content without ever being sex	cually involve	ed with anyone?		□ ₀ No	1 Yes
63	Are there really very few things that give yo	u pleasure?			□ ₀ No	1 Yes
64	Does it NOT matter to you what people thinl	k of you?			□ ₀ No	1 Yes
65	Do you find that nothing makes you very ha	ppy or very	sad?		□ ₀ No	1 Yes
66	Do you like to be the center of attention?				□ ₀ No	1 Yes
67	Do you flirt a lot?				□ ₀ No	1 Yes
68	Do you often find yourself "coming on" to p	eople?			□ ₀ No	1 Yes
69	Do you try to draw attention to yourself by t	he way you	dress or look?		□ ₀ No	1 Yes
70	,				□₀ No	
71	Do you often change your mind about thing or what you have just read or seen on TV?	s depending	on the people you	re with	□ ₀ No	1 Yes
72	Do you have lots of friends that you are very	y close to?			□₀ No	1 Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

CRF, page 16



Participant Number: THIS PAGE NOT ENTERED Participant's Initials: Structured Clinical Interview for DSM-IV (SCID-II) (continued) Do people often fail to appreciate your very special talents or accomplishments? o No 1 Yes Have people told you that you have too high an opinion of yourself? _₀ No ____, Yes **7**5 Do you think a lot about the power, fame, or recognition that will be yours someday? ___, Yes _o No 76 Do you think a lot about the perfect romance that will be yours someday? J₀ No ___, Yes When you have a problem, do you almost always insist on seeing the top person? 77 o No __, Yes 78 Do you feel it is important to spend time with people who are special or influential? ∐₀ No ____, Yes Is it very important to you that people pay attention to you or admire you in some way? o No Yes Do you think that it's not necessary to follow certain rules or social conventions ደሰ ∐₀ No ____, Yes when they get in your way? Do you feel that you are the kind of person who deserves special treatment? O No , Yes Do you often find it necessary to step on a few toes to get what you want? , Yes _₀ No Do you often have to put your needs above other people's? o No _, Yes Do you often expect other people to do what you ask without question 84 ___, Yes __n No because of who you are? Are you NOT really interested in other people's problems or feelings? 85 o No 1 Yes 86 Have people complained to you that you don't listen to them or care about their feelings? J₀ No ___, Yes Are you often envious of others? 87 , Yes J₀ No Do you feel that others are often envious of you? 88 J₀ No __, Yes Do you find that there are very few people that are worth your time and attention? 89 _o No ___1 Yes Have you often become frantic when you thought that someone you really cared about was _₀ No ___, Yes going to leave you? 91 Do your relationships with people you really care about have lots of extreme ups and downs? o No , Yes 92 Have you all of a sudden changed your sense of who you are and where you are headed? J₀ No __₁ Yes Does your sense of who you are often change dramatically? Yes No No Are you different with different people or in different situations, so that you Yes ∐₀ No sometimes don't know who you really are? 95 Have there been lots of sudden changes in your goals, career plans, religious beliefs, and so on? o No , Yes Have you often done things impulsively? 96 ∐₀ No ____, Yes 97 Have you tried to hurt or kill yourself or threatened to do so? o No Yes 98 Have you ever cut, burned, or scratched yourself on purpose? ∐₀ No , Yes

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



THIS	PAGE NOT ENTERED Center Number: Participant Numbe	ticipant's Initials:	first middle last
Stru	uctured Clinical Interview for DSM-IV (SCID-II) (continued)		
99	Do you have a lot of sudden mood changes?	□ ₀ No	1 Yes
100	Do you often feel empty inside?	□ _o No	1 Yes
101	Do you often have temper outbursts or get so angry that you lose control?	□ _o No	1 Yes
102	Do you hit people or throw things when you get angry?	□₀ No	
103	Do even little things get you very angry?	□ ₀ No	1 Yes
104	When you are under a lot of stress, do you get suspicious of other people or feel especial spaced out?	lly _{□₀ No}	1 Yes
105	Before you were 15, would you bully or threaten other kids?	□ ₀ No	
106	Before you were 15, would you start fights?	□ ₀ No	
107	Before you were 15, did you hurt or threaten someone with a weapon, like a bat, brick, broken bottle, knife, or gun?	□ ₀ No	1 Yes
108	Before you were 15, did you deliberately torture someone or cause someone physical pa and suffering?	in □ _o No	
109	Before you were 15, did you torture or hurt animals on purpose?	□ ₀ No	1 Yes
110	Before you were 15, did you rob, mug, or forcibly take something from someone by threatening him or her?	□ ₀ No	1 Yes
111	Before you were 15, did you force someone to have sex with you, to get undressed in fro of you, or to touch you sexually?	ont No	
112	Before you were 15, did you set fires?	□ ₀ No	
113	Before you were 15, did you deliberately destroy things that weren't yours?	□ ₀ No	
114	Before you were 15, did you break into houses, other buildings, or cars?	□ ₀ No	1 Yes
115	Before you were 15, did you lie a lot or "con" other people?	□ ₀ No	1 Yes
116	Before you were 15, did you sometimes steal or shoplift things or forge someone's signature?	□ ₀ No	1 Yes
117	Before you were 15, did you run away from home and stay away overnight?	□ _o No	1 Yes
118	Before you were 13, did you often stay out very late, long after the time you were supposed to be home?	□ _o No	1 Yes
119	Before you were 13, did you often skip school?	□ ₀ No	
	CALERIE PHASE2 ANNOTATION V8.0 24FEB2012	icipant's Initials:	first middle last
	= + HILL IA BANKA WALKING ALANA		



Screening Visit 2 Checklist

Screening Visit 2 Checklist	
 Did participant return for Screening Visit 2? □₀ No → If No: Skip to question 15 and provide reason. □₁ Yes → If Yes: Date of initial clinic visit for Screening Visit 2: 	Display RTNCLINIC <xyesno></xyesno>
Check completed items:	(TYPE 4)
2 Fasting blood sample	
3 Urine sample	
4 Vitals (temperature, pulse, blood pressure)	SAME AS PAGE 3
5	
6 Medical and medication history	
7 Concomitant medications log	
8 Physical examination	
9 Barriers interview	
10 Body morph assessment	
11 Additional interviews (SCID-II and/or IDED-IV)	
12 Meeting with dietitian to review dietary screening questionn	aire
13 14-day food record procedure reviewed	
14 Meeting with study coordinator/manager	
15 Is the participant expected to return for Screening Visit 3?	
\square_0 No \rightarrow If No: Provide reason (check all that apply):	
Failed an eligibility criterion	
Lost interest in the study	
Will take too much timeScheduling conflicts with work or school	
Doesn't like the study's procedures	
Doesn't want to be involved in a research study	
Unwilling to be randomized	
Lives too far away/transportation problems	
☐ Needs help with child care	
Refused with no explanation	
Unable to contact Display UNABCON	Т
Other (specify):	·
\square_1 Yes \rightarrow If Yes: Date of scheduled Screening Visit 3: $\underline{\hspace{1cm}}_{day}$ /_	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



Baseline Submission 1 Screening

Cen	ter Number: _	Pai	rticipant Number:	Participant's Initials:				
Date completed:/_Same as page			TUDYND, r SINITIALS	DATEHDR (TYPE				
Screening Medical History								
List any clinically significant pre-existing condition(s).								
Body System ASSESS <tunchy> Assessments</tunchy>								
BODYSYS <tubody></tubody>	No	Yes	If Y	es, Specify Diagnosis				
1 Head, Ears, Eyes, Nose, Throat	□₀	□₁→	M	EDHIST (TYPE 4)PS				
2 Dermatologic	□₀	□₁→	YESE	XP <v:100></v:100>				
3 Cardiovascular	□₀	□₁→						
4 Respiratory	□₀	□₁→	<u>(</u>	CODELIST TUNCHY				
5 Gastrointestinal	口。	□₁→) = NO/NOCHANGE L = YES				
6 Endocrine/Metabolic	□₀	□₁→						
7 Genitourinary		□₁→						
8 Neurological	口。	□₁→						
9 Blood/Lymphatic	口。	□₁→						
10 Musculoskeletal		□₁→						
11 Hepatic	口。	□₁→						
12 Drug Allergies	口。	□₁→						
13 Other Allergies	□。	□₁→						
14 Psychological/Psychiatric	口。	□₁→						
15 Other (including contraception methods, females only)	口。	□₁→						
Physician's Signature								
Signature: NOT DATABA	SED			Date: NOT DATABASED year				
CALERIE PHASE	2 ANNOTA	ATION V	8.0 24FEB2012	,,				



Baseline Submission 1 Screening

AGEID = 24	24 THIS IS A REPEATING PAGE		Screening					
	Center Number:	Participant Number:	Participant's Initials: first middle last					
Date completed:/	_/_SAME AS PAGE 23	DATEH	OR (TYPE 4)					
Medication History								
Record any medications taken from 6 months prior through screening period, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Include any steroid use within the last 5 years.								
Medication	Start Date	Stop Date	Indication					
MEDNUM <1:2> MEDS <v:100></v:100>	day month year MEDSTRDT	OR	RMED (TYPE 4)R					
2	day month year	MEDSTPDT day month year OR 1 Continuing ME	DCONT <xyes></xyes>					
3	day month year	or	MEDIND <v:110></v:110>					
4	doy month year	OR 1 Continuing						
5	day month year	OR 1 Continuing						
6 WHODRUG_B2 WHONAME <v:80></v:80>	doy month year	or						
WHOCODE <v:32> WORKFLOW <v:5> CODER <v:20></v:20></v:5></v:32>	day month year	or						
CODETM <datetime <v:2="" conflvl=""> MATCHES <v:4></v:4></datetime>	day month year	or \square_1 Continuing						
9	doy month year	or D1 Continuing						
WHODRUG_ATC_B2 10 ATCTERM <v:110> ATCCODE<v:40> WORKFLO2<v:5></v:5></v:40></v:110>	day month year	or						
CODETM2 <datetim conflvl2<v:2=""> MATCHES2<v:4></v:4></datetim>	E>	or						
CODER2 <v:20></v:20>								

Page Numbering: Sequentially number each page in the right hand corner, i.e. 24.1, 24.2, 24.3. Insert additional pages as needed.



THIS PAGE NOT ENTERED

Center Number: ____ Participant Number: ____ Participant's Initials: _____ fest middle lost

Physical Examination Date of examination:/OR Not done → Specify reason (use codelist below):								
Date of examination:/								
Body System	Normal Abnormal		Not Done	If Abnormal or Not Done: Explain				
General appearance:		□₀→	₉₇ →					
2 Head, Ears, Eyes, Nose, Throat:		□₀→	□97→					
3 Neck:		□₀→	□97→					
4 Heart:		□₀→	₉₇ →					
5 Lungs:		□₀→	₉₇ →					
6 Abdomen:	\square_1	□₀→	□ ₉₇ →					
7 Lymph nodes:		□₀→	₉₇ →					
8 Extremities/Skin:		□₀→	₉₇ →					
9 Neurological:		□₀→	₉₇ →					
10 Musculoskeletal:		□₀→	₉₇ →					
	Normal	Abnormal	Not Done*					
11 Genitourinary:		□₀→	□97→					
12 Breast:		□₀→						
Physician's Signature								
Signature: CALERIE PHASE2 ANNOTATION V8.0 24FEB2012								

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



Screening Visit 3 Checklist

Center Number:	Participant Number:	_ Participant's Initials:	first middle last
----------------	---------------------	---------------------------	-------------------

Screening Visit 3 Checklist
Did participant return for Screening Visit 3? □₀ No → If No: Skip to question 5 and provide reason. □₁ Yes → If Yes: Date of initial clinic visit for Screening Visit 3:
Check completed items: (TYPE 4)
2 Reviewed all lab results (blood, urine, and pregnancy test)
3 Repeated blood sample, if needed
4 14-day food record collected and reviewed
5 Has the participant been contacted and agreed to additional visit (check only one)? □ No, no additional visits → If No additional visits: Provide reason (check all that apply): □ Failed an eligibility criterion □ Lost interest in the study □ Will take too much time □ Scheduling conflicts with work or school □ Doesn't like the study's procedures □ Doesn't want to be involved in a research study □ Unwilling to be randomized □ Lives too far away/transportation problems □ Needs help with child care
Refused with no explanation Unable to contact Other (specify):
☐1 Yes → If Yes: Additional visit scheduled (check only one):
☐ ₁ Screening Visit 4 → Date of scheduled Screening Visit 4:/
Display ☐ ₂ Baseline visit → Date of scheduled Baseline Visit:/

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



Screening Visit 4 Checklist

	Center Number: Participant Number:		Partiapant's Initials:	first middle las
S	creening Visit 4 Checklist Optional—Submit this form only if Screening	Visit 4 was	scheduled	
1	Did participant return for Screening Visit 4? □₀ No → If No: Skip to question 4 and provide reason. □₁ Yes → If Yes: Date of initial clinic visit for Screening Visit 4:/	year	CHECKL (TYPE 4)	
Ch	eck completed items:		(111 = 4)	,
2	Reviewed all lab results (blood, urine, and pregnancy test)			
3	14-day food record collected and reviewed (if needed)	SAME AS	S PAGE 22	
4	Has the participant been contacted and agreed to proceed with a Baseline Visit (che	eck only one)?		
	\square_0 No \rightarrow If No: Provide reason (check all that apply):	, .		
	Failed an eligibility criterion			
	Lost interest in the study			
	Will take too much time			
	Scheduling conflicts with work or school			
	Doesn't like the study's procedures			
	Doesn't want to be involved in a research study			
	Unwilling to be randomized			
	Lives too far away/transportation problems			
	Needs help with child care			
l	Refused with no explanation			
	Unable to contact			
ı	Other (specify):			



PAGEID = 28

	Center Number: Participant Number:	Participant's Initials: first middle last					
Ir	nformed Consent						
,	Did participant present for baseline visit:	NSENT (TYPE 1)					
		Control to specificació — Perio — specimento control transcrivatio					
	Scheduling conflicts with work or St.	SHEDULE					
	☐ Doesn't want to be involved in a researc DWUNVSTD ☐ Unwilling to be random WILRAN						
	□ ₈ Lives too far away/transportation prob TenANPROB □ ₉ Needs help with child @HUDの食房量ed child care needs)						
	□ 10 Refused with no explarRichEXPL □ 11 Unable to contact UNABCO □ 98 Other (specify): OTHER						
l	□₁ Yes						
2	Date and time study baseline informed consent signed: CONSNTDT year	CONSNTTM - 00:00 to 23:59					



Participant's Initials: Center Number: ___ Participant Number: ___ __

SUPRESS SEQNO<1:3>		PS	ITD (TYPE 2)
SEQNO <i:3></i:3>	CNSNTDTL <tucsti< th=""><th>> Check only one</th><th></th></tucsti<>	> Check only one	
Sample type	Participant consent given for future studies by Calerie and external	Participant consent given for future studies by Calerie	Participant consent not given
SAMPTYPE <tusamt></tusamt>	investigators	- Calcilo	
Blood archive	□₁ 1=	□₂ 2=	□₃ 3=
2 Urine archive		\square_2	\square_3
3 Muscle biopsy archive		\square_2	\square_3
4 Fat biopsy archive			

<TUSAMT>

1= 1 BLOOD ARCHIVE

2= 2 URINE ARCHIVE

3= 3 MUSCLE BIOPSY ARCHIVE

4= 4 FAT BIOPSY ARCHIVE

<TUCSTD>

1= 1 EXTERNAL INVESTIGATORS

2= 2 CALERIE CONSENT

3= 3 CONSENT NOT GIVEN



PAGEID = 29

Center Number: Partic	ipant Number: Participant's Initials:
Clinic Weight	
Weight date and time: ${day}/{month}/{year} = {00.00 \text{ fo}} : {23.59}$ OR Not done \rightarrow Specify reason (use Codelist below): ${}$	Staff initials: DATEHDR (TYPE 4) AS PAGE 4
Clinic weight (if the first two measurements are more than 0.1 kg apart, measu	7.0 · · · · · · · · · · · · · · · · · · ·
Weight 1: kg	WEIGHT (TYPE 4)
Weight 2: kg	,
Weight 3: kg	
Weight of gown:kg	
Vital Signs Assessment date and time:/	ALTM VITALS (TYPE 3)
If waist measurement not done → Specify reason (use codelist below): V Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist	Staff initials:
Natural waist measurement 1:WMEAS1 cm Natural waist measurement 2:WMEAS2 cm	All measurements <f:9:3> unless otherwise indicated</f:9:3>
Natural waist measurement 3:WMEAS3 cm	
2 Umbilical point waist measurement (if the first two measurements are more tumbilical point waist circumference a third time):	han 1.0 cm apart, measure
Umbilical point waist measurement 1: <u>UMEAS1</u> _cm	
Umbilical point waist measurement 2:UMEAS2_ cm	
Umbilical point waist measurement 3: UMEAS3	DINITIAL MA
PULSE<1:3> 3 Pulse: bpm OR Not done → Specify reason (use codelist	PULND <tund> below): Staff initials: TINTIAL <v:3></v:3></tund>
TEMP 4 Temperature: °C OR Not done → Specify reason (
RESP<1:2> Respirations: per minute OR Not done → Specify reason (a)	(use codelist below): Staff initials: RINTIAL < V:3> RESPND <tund> use codelist below): Staff initials:</tund>
6 Blood pressure (check only one): 1 Left arm 2 Right arm BPSYS1 BPDIA1 Pressures <1:3> BPSYS2 BPDIA2 BPSYS2 BPDIA2 BPSYS2 BPDIA2 BPSYS2 BPDIA2	Staff initials: Staff initials: Staff initials: First middle last BPND <tund> io 23:59 Specify reason (use codelist below): M</tund>
systolic diastolic 00:00 (BPSYS3 BPDIA3 BP3T 6c Blood pressure 3:/ mm Hg Time:	VITALDT
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3	misornicieni ililie 4 misiromeni taliore 3 Not required



PAGEID = 30

Cente	r Number: Participant t	Number: Pa	orticipant's Initials: First middle last			
12-Lead ECG						
Date and Time		FindingsECG (TYPE	E 4) Staff Initials			
DATEHDR (TYPE 4) ———————————————————————————————————	Is ECG (check only one): E	lly significant (specify): ECG2SP <v:50></v:50>	SINTIALS first middle last			
Safety Labs						
Date and time of last meal: \[\frac{\lambda{qy}}{\lambda{qy}} / \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{qy}}{\lambda{qy}} \frac{\lambda{month}}{\lambda{qy}} \frac{\lambda{qy}}{\lambda{qy}} \frac{\lambda{qy}}{\lambda{qy}						
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials			
Blood	□₀ No □₁ Yes		first middle lost			
URS Urine	SMPCOL <xyesno></xyesno>	URSMPND <tund> </tund>	URNINIT <v:3></v:3>			
Not Done Codelist: 1 Participant refused 2 Clin	ician unable to obtain 3 Insuff	icient time 4 Instrument fail	lure 5 Not required			



PAGEID = 31

Cente	er Number: _	Part	ticipant Number: Participant's Initials: first middle last				
Date completed: / _{month} / _{year} _	_ SAME	AS PAGE	E 23 DATEHDR (TYPE 4)				
Abbreviated Medical History							
List any clinically significant changes occurring	since Screen	ing medical	l history was completed.				
	Assessments						
Body System	No Change	Yes	If Yes, Specify Diagnosis				
1 Head, Ears, Eyes, Nose, Throat		□₁→	MEDHIST (TYPE 4)PS				
2 Dermatologic	□₀	□₁→					
3 Cardiovascular	□₀	□₁→	SAME AS PAGE 23				
4 Respiratory	□₀	□₁→					
5 Gastrointestinal	□₀	□₁→					
6 Endocrine/Metabolic	□₀	\square_1 \rightarrow					
7 Genitourinary	□₀	$\square_1 \rightarrow$					
8 Neurological	□₀	$\square_1 \rightarrow$					
9 Blood/Lymphatic	□₀	\square_1 \rightarrow					
10 Musculoskeletal	□₀	\square_1 \rightarrow					
11 Hepatic	□₀	$\square_1 \rightarrow$					
12 Drug Allergies	□₀	$\square_1 \rightarrow$					
13 Other Allergies	□₀	□₁→					
14 Psychological/Psychiatric	□₀	$\square_1 \rightarrow$					
15 Other		□₁→					
Physician's Signature							
Signature:CALERIE PHASE	2 ANNOT <i>A</i>	ATION V8	3.0 24FEB2012 Pate://				



PAGEID = 32

	Center Nu	ımber:	Participant Nu	umber: Participant's Initials: first middle la
Physical Examination				
Date of examination: $\phantom{aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa$	_/		GE 4 UDYH, STUD	Staff initials:
Do do Conto o		Assessment	5	Maharanalan Nat Bassa Faralaha
Body System PEXAM <tupexm></tupexm>	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain
_ ¶ General appearance:		□₀→ M <tuasse< td=""><td>₉₇ →</td><td>PEXAM (TYPE 4)PS</td></tuasse<>	₉₇ →	PEXAM (TYPE 4)PS
2 Head, Ears, Eyes, Nose, Throat:		WI <tuasse □₀→</tuasse 	> □ ₉₇ →	ABNDSP <v:200></v:200>
=3 Neck:		□₀→	□97→	
= 4 Heart:		□₀→	□97→	
5 Lungs:		□₀→	□97→	
6 Abdomen:		□₀→	₉₇ →	
7 Lymph nodes:		□₀→	₉₇ →	
8 Extremities/Skin:		□₀→	₉₇ →	
9 Neurological:		□₀→	□97→	
10 Musculoskeletal:		□₀→	₉₇ →	
	Normal	Abnormal	Not Done*	
=11 Genitourinary:		□₀→	□97→	
= 12 Breast:		□₀→	₉₇ →	
Physician's Signature				
Investigator:	T DATABA			NOT DATABASED Date:/
* Not done at this examination OR_Referre	d participant to	primary care r	ohysician for ex	ат.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Not Done Codelist: 1 Participa

5 Not required

nt failure



Center Number: ___ Participant Number: ___ __ Participant's Initials: ___ __ _

PAGEID = 33

	first middle (
Clinic Weight	
Weight date and time:/	Staff initials:
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	veight a third time):
Weight 1: kg SAME AS F	PAGE 4 WEIGHT (TYPE 4)
Weight 2: kg	
Weight 3: kg	
Weight of gown: kg	
Pregnancy Test	
Complete only for females. REPOTEN <xyesn< td=""><td>O> PREGTEST (TYPE 4)</td></xyesn<>	O> PREGTEST (TYPE 4)
Does participant have reproductive potential?	
□ _o No	PRGTSTDT
□ No □ Yes → If Yes: Date urine pregnancy test performed:/	month year —
Results:	
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficient time 4 Instrument failure 5 Not required



PAGEID = 34

		Center Number:	Participant Number: Pa	articipant's Initials:			
D	oubly Labeled V	V ater (DLW)					
1	Date and time of DLW d	osing:/DLW		R (TYPE 4) if initials: SINTIALS			
	OR Not done \rightarrow Specify	reason (use codelist below):	DLWND <tund></tund>				
2	DLW dose mixture ID an	DLWMAN <v:2></v:2>	DLWBOTNO <i:3> CA</i:3>				
		DIMMINIAT FOR	DLWMIX <i:5></i:5>				
3	Exact weight of DLW mix	xture:DLWMIXWT <f:9:3< th=""><th>grams</th><th></th></f:9:3<>	grams				
4	Urine samples:		DLWCHT (TY	PE 4)PS			
	Collection	Sample DLWSMPNO <tud< th=""><th>LW></th><th>ted</th></tud<>	LW>	ted			
	Pre dosing (PD)	1 = PDa	day	DLWCOLTM 00:00 to 23:59			
		2 = PDb	day month year	00:00 to 23:59			
	Day 0 (Visit 2)	3 = D0a	/	00:00 to 23:59			
		4 = D0b	/	00:00 to 23:59			
	Day 7 (Visit 3)	5 = D7a	/	00:00 to 23:59			
		6 = D7b	/	00:00 to 23:59			
	Day 14 (Visit 4)	7 = D14a	/	00:00 to 23:59			
		8 = D14b	/	00:00 to 23:59			
	NOTE: INCLUDE THESE ITEMS IN THE DLWHDR PANEL ABOVE						
5	Affix CRF page label(s)	corresponding to this urine se	ample set: DLWLBL1<	V:15>			
			Label Not displaye				
			Here DLWLBL2<				

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time

5 Not required

4 Instrument failure



PAGEID = 35

	Center Number:	Participant Number:	Participant's Initials:
DXA Scan			
 Has the participant taken a calcium so	vith scan and document i YESNO> radioisotopes performed	n the Subject Scan Log to in	e scheduled DXA exam?
DXA Scan		DXA Res	RENA <xyes> scan OR □_% NA</xyes>
Date of scan:////	ADT	Date of rescan:/_	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		ea Scanned call that apply
WBDY ALL <xyes> ☐ Whole body</xyes>	WBDYND ALL	<tund> RE ☐ Whol</tund>	WBDY ALL <xyes> e body</xyes>
FARM	FARMND	RE	FARM
☐ Forearm		Fored	rm
SPINE	SPINEND	RE	SPINE
Spine		☐ Spine	
HIP	HIPND	RE	HIP
☐ Hip		☐ Hip	
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 Insufficient time 4 In	strument failure 5 Not required



PAGEID = 42

AGLID - 42	Center Number:	Participant N	Number:	Participant's Ir	nitials:
Date completed:/ _{month} /_	OR Not don	e → Specify re AS PAGE 36	ason (use codelist be	low): DATEHDR	(TVDE A
Profile of Mood States				DATELIDA	4
Instructions: Please describe how y	ou feel right now by cl	necking one bo	x for each of the wo	ords listed below. OMS (TYPE	4)PS
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
POMSQ <tupoma> I Friendly</tupoma>	POMSA <tuf □₀</tuf 			3	
2 Tense	\square_{0}			3	
3 Angry				\square_3	
4 Worn out	\square_{o}	\square_1	\square_{2}	\square_3	\square_{4}
5 Unhappy				\square_3	\square_{4}
6 Clear-headed	\square_{o}	\square_1	\square_2	Пз	\square_{4}
7 Lively	\square_{o}			\square_3	4
8 Confused	\square_{0}	\square_1	\square_{2}	\square_3	\square_{4}
9 Sorry for things done				3	4
10 Shaky	□₀			\square_3	
11 Listless				З	
12 Peeved	\square_{o}	\square_1	\square_{2}	\square_3	\square_{4}
13 Considerate				З	
14 Sad				\square_3	
15 Active					
16 On edge					
17 Grouchy					
18 Blue					
19 Energetic					
20 Panicky	\Box_{\circ}				
Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. 150, North Tonawanda, NY 14120-0950. In Canada, 377			license to Multi-Health System	ns Inc. All rights reserved.	In the U.S.A., P.O. Box
Not Done Codelist: 1 Participant refuse	d 2 Clinician unable to	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N Participant's I	ot required

Send to DC

Durham NC 27705



PAGEID = 43	Center Number:	Participant Number:		Participant's Initials:		
Profile of Mood States	(continued)					
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely	
=21 Hopeless						
=22 Relaxed	\square_{o}		\square_{2}	\square_3	4	
=23 Unworthy	SAME	AS PAGE 42		3	4	
=24 Spiteful	\square_{o}		\square_{2}	Пз	4	
_25 Sympathetic				3	4	
26 Uneasy	\square{o}		\square_{2}	Пз	4	
				\square_3	4	
28 Unable to concentrate				Пз	4	
29 Fatigued				\square_3	4	
30 Helpful			\square_{2}	Пз	4	
31 Annoyed				3	4	
32 Discouraged	\square{o}		\square_{2}	\square_3	4	
_33 Resentful				\square_3	4	
34 Nervous	\square{o}		\square_{2}	\square_3	4	
_35 Lonely				\square_3	4	
36 Miserable	\square{o}		\square_2	\square_3	4	
_37 Muddled	□₀			Пз	4	
38 Cheerful	\square_{o}		\square_2	Пз	4	
39 Bitter	□₀			□₃	4	
40 Exhausted	\square_{o}			\square_3	4	
41 Anxious				\square_3	\square_4	
42 Ready to fight				Пз		
43 Good-natured						

Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. McNair Ph.D., and JW P. Heuchert, Ph.D. under exclusive license to Multi-Health Systems Inc. All rights reserved. In the U.S.A., P.O. Box 950, North Tonawanda, NY 14120-0

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



PAGEID = 44

	Center Number: _	Participant	Number:	Participant's I	nitials: middle last
Profile of Mood States (ontinued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit POMS (TYP	Extremely PE 4)PS
44 Gloomy	\square_{o}	\square_1	\square_{2}	\square_3	
45 Desperate				3	4
= 46 Sluggish	□₀SAME	AS PAGE 42	\square_{2}	\square_3	\square_4
47 Rebellious				3	4
= 48 Helpless				\square_3	\square_{4}
49 Weary				3	4
50 Bewildered				3	\square_4
= 51 Alert				3	4
= 52 Deceived	\square_{o}	\square_1	\square_{2}	\square_3	\square_4
= 53 Furious				3	4
= 54 Efficient				3	\square_4
55 Trusting	\square_{o}			\square_3	4
56 Full of pep	\square_{o}			\square_3	
57 Bad-tempered				3	4
58 Worthless	□₀			\square_3	
59 Forgetful	\square_{\circ}			\square_3	4
60 Carefree				\square_3	\square_{4}
61 Terrified				3	4
62 Guilty	□₀			3	4
63 Vigorous				3	4
64 Uncertain about things				3	4
65 Bushed				3	4
Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M.	McNair Ph.D., and JW P. Heu	chert, Ph.D. under exclusive	e license to Multi-Health Sys	tems Inc. All rights reserved.	In the U.S.A., P.O. Box

Participant's Initials: first middle last Send to DCRI Forms Management • 2400 Pratt St. • Room 0311 Terrace Level • Durham NC 27705

Baseline Submission 1 Visit 2

PAGEID = 45

		Center Number:	Participant Number	er:		Participant'	s Initials:	irst middle last				
Da	ite completed:day //	OR Not done → SAME AS P	Specify reason AGE 36	(use code	list below): DATE	HDR (TYPE	4)				
P	erceived Stress Scale (PSS)						*				
ln	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的。											
		ALL <tupss></tupss>		Never	Almost Never	Some- times	Fairly Often	Very Often				
1	In the last month, how often h unable to control the importa			□. IG				□ ₄				
2	In the last month, how often by your ability to handle your pe		nt about HANDPROB	\Box_{o}	\square_1		\square_3	\square_4				
3	In the last month, how often h going your way?	nave you felt that thin					Пз	□ ₄				
4	In the last month, how often h piling up so high that you cou			□ _о Н				□4				
N	ot Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n 3 Insufficient	time 4	Instrument	ailure 5	Not requi	red				

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAGEID = 46

, , , ,	3LID = 40	Center Number:	Participant N	umber:	Partic	cipant's Initials	first middle last				
Dat	te completed:/ _{month} /	OR Not do	one → Specify red AS PAGE 36	ison (use codel	st below): DATEHD	OR (TYP	E 4)				
Pi	ttsburgh Sleep Quality I	ndex (PSQI)									
lns	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.										
Dυ	ring the past month	DED	LID J.O.			TYPE 4					
1	When have you usually gone	to bed?:	BEDMIN<1:2 23:59	2>							
2	How long (in minutes) has it to	•	•	•		esFALLAS	SLP <i:3></i:3>				
3	When have you usually gotter	n up in the mor	ning? (VAKEHF	R <i:2> 59 WAKEMI</i:2>	N <i:2></i:2>						
4	How many hours of actual sleep (This may be different than the number of hours	, ,	•	ACTSLP <f< th=""><th>:9:3></th><th></th><th></th></f<>	:9:3>						
5	During the past month, how o sleeping because you (check o	•		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		WITHIN30	\square_{o}			\square_3				
	b Wake up in the middle of the	ne night or earl	y morning MIDNG	нмб			З				
	• Have to get up to use the b	athroom	GOBTHRM	\square_{0}			З				
	d Cannot breathe comfortabl	y BF	REATHE	\square_{\circ}			З				
	e Cough or snore loudly	SNORE		\square_{0}			3				
	f Feel too cold	COLD					З				
	g Feel too hot	НОТ		\square_{\circ}			\square_3				
	h Have bad dreams	BADDRM		\square_{\circ}			З				
	i Have pain	PAIN		\square_{0}			З				
	j Other reason(s), please des you have had trouble sleep reason(s):	7				\square_{2}	\square_3				
6	During the past month, how o medicine (prescribed or "over the cour	ften have you t hter") to help you	raken u sleep? _{MEDST}	KN □₀							
	89,with permission from Elsevier Science. of Done Codelist: 1 Participant refused	2 Clinician unable t	o obtain 3 Insuffi	cient time 4 l	nstrument failure	5 Not re	auired				
. 10		PHASE2 ANNO			- Combined Tallole	2 140116	Yonea				

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



PAGEID = 47

	Center Number: Partiapo	ont Number:	Pari	icipani's ininais	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (continued)				
		Never	Once or twice	Once or twice each week	week
7	During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? AWKESOC <tuslpb></tuslpb>		PSQI2	(TYPE 3]
		No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8	During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?	□。 KPENTHUS<	□ ₁		
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall? SLPQLTY <tuslpe< td=""><td>)> □₀</td><td></td><td></td><td>\square_3</td></tuslpe<>)> □ ₀			\square_3

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAGEID = 48

NOLID - IO	Center Number:	Participant Number:	Participant's Initials:	first middle las

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

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

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "O = 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 "O = could not be worse" to "8 = could not be better." Other satisfaction scales go from "O = 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									
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 RE	1 or 2 per month	1 per week	2 or 3 per week DSFA>	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
EMALEQ <tufque> 1 F.1 A sexually attractive person</tufque>	По								
21_2 Erotic parts of a man's body (e.g., face, shoulders, legs)	□,			З	□₄				
³ 1.3 Erotic or romantic situations	По			З			□ ₆		
41-4 Caressing, touching, undressing, or foreplay	□₀			Пз	□₄		□6	□ ₇	□ ₈
5≒5 Sexual intercourse, oral sex, touching to orgasm				Пз			□ ₆	□ ₇	□8
Copyright © 1987 by Leonard R. Derogatis, PhD. Not Done Codelist: 1 Participant refused 2 Clinician und			Insufficie			nent failur		ot require	

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

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



PAGEID = 49

		Center Nu	mber:	Po	rticipant N	umber: _		Par	ticipant's I	nitials:	st middle last
	Derogatis Interview for	Sexual l	Functi	on (DIS	F-SR) (F)	Female V	ersion (d	ontinued)		
	Section 2—Sexual Arousal	SAME AS	PAGE 4	-8			DISI	FEM1	(TYPE	4)PS	•
	During the past 30 days or since to time you filled out this inventory, did you have the following experi	how often	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
6 =	2.1 Feel sexually aroused whi	le alone					4	5	□6		
7 =	2.2 Actively seek sexual satisf	action				\square_3	□₄	\square_5	□6		□8
8 =	⁼ 2.3 Feel sexually aroused with partner	n a									
	FEMALEQ <tufque></tufque>		Never	Rarely	Sometimes	Usually	Always	DISFE	M2 (T	YPE 4	4)PS
9 =	2.4 Have normal lubrication wasturbation	vith	RESI	PONSE	<tudsi< th=""><th>FB></th><th></th><th></th><th></th><th></th><th></th></tudsi<>	FB>					
10	⇒2.5 Have normal lubrication throughout sexual relation	ns					□₄				

Copyright © 1987 by Leonard R. Derogatis, PhD.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



PAGEID = 50

	Center Nu	mber:	P	articipant N	umber: _		Po	articipant's	Initials:	rst middle last
	Derogatis Interview for Sexual I	Functi	on (DIS	SF-SR) (F)	Female \	/ersion (d	ontinue	d)		
	Section 3—Sexual Behavior/Experiences	SAM	E AS P	AGE 48		DIS	FEM1	(TYPI	E 4)PS	
,	During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
11	3.1 Reading or viewing romantic or erotic books or stories	□。			Пз			□6		□ ₈
12	=3.2 Masturbation	□.			□₃	□₄	□ ₅	□₀	□ ₇	□8
13	_3.3 Casual kissing and petting	□.			□₃	□4	□ ₅	Пб		□ ₈
14	3.4 Sexual foreplay	□.	П		□₃	□₄		□6	□7	□8
15	3.5 Sexual intercourse, oral sex, etc.	□.			□₃	□4		□6	□7	□8
	Section 4—Orgasm FEMALEQ <tufque< th=""><th>Ξ></th><th></th><th></th><th></th><th>DIS</th><th>FEM3</th><th>(TYPI</th><th>E 4)PS</th><th></th></tufque<>	Ξ>				DIS	FEM3	(TYPI	E 4)PS	
	During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all		Moderately DNSE<7		Extremely >				
16	4.1 Your ability to have an orgasm	□.			□₃					
17	=4.2 The intensity of your orgasm	□.			□₃	□4				
18	=4.3 The ability to have multiple orgasms (if typical for you)				□₃	□ ₄				
19	4.4 Feelings of closeness and togetherness with your partner				□₃	□₄				
20	4.5 Your sense of control (timing) of your orgasm									
	4.6 Feeling a sense of relaxation and well-being after orgasm	□.			□₃					
	Copyright © 1987 by Leonard P. December DED						1			

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



PAGEID = 51

7.02IB = 01	Center Number:	Participant Number:	Participant's Initials:	first middle la	zsf

	Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)									
	Section 5—Drive and Relationship	SAME	AS PAC	GE 48	D	ISFEN	11 (TY	PE 4)I	PS	
		Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22	5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	О			3	4	5	□6		□ ₈
		Not at all	Slightly	Moderately	Highly	Extremely	FEM3	3 (TYP	E 4)PS	3
23	5.2 During this period, how interested have you been in sex?	o			□₃	4	SAME	E AS PA	GE 50	
24	5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_3	□₄	FEM4	l (TYP	E 4)PS	3
	FEMALEQ <tufque></tufque>	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
25	5.4 In general, what would represent the best description of the quality of your sexual functioning?	RE □₀	SPONS	E <tud< th=""><th>SFD></th><th></th><th></th><th></th><th>□₇</th><th></th></tud<>	SFD>				□ ₇	

Copyright © 1987 by Leonard R. Derogatis, PhD.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

calerie

Baseline Submission 1 Visit 2

ters encodes so	PAGEID = 52	Center Number:	Participant Number:	Participant's Initials:	first middle last
-----------------	-------------	----------------	---------------------	-------------------------	-------------------

DATEHOR (TYPE 4)

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

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

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

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to

follow. Although it is brief, take your time with the invertescribes your personal experience. If you have any questions, please ask the person who	,					scale n						
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 RES	1 per week	2 or 3 per week	4 to 6 per week SFA>	1 per day	2 or 3 per day	4 or more per day			
MALEQ <tumque> 1</tumque>	□₀				□ ₄	₅	□6		□8			
2 _1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	□。			\square_3	□₄	\square_5	□₀		□8			
3 T.3 Erotic or romantic situations	□₀				□ ₄		□₀		□8			
4 =1.4 Caressing, touching, undressing, or foreplay	□。	П		Пз	□₄		□6	□7				
5 =1.5 Sexual intercourse, oral sex, touching to orgasm	□。			Пз	□₄		□6	□7	□,			
Copyright © 1987 by Leonard R. Derogatis, PhD.												
Not Done Codelist: 1 Participant refused 2 Clinician un	able to ob	otain 3	Insufficier	nt time	4 Instrun	nent failur	e 5 N	ot require	•d			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



PAGEID = 53

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

Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued) Section 2—Sexual Arousal SAME AS PAGE 52 **DISMALE1 (TYPE 4)PS** Not at Less 1 or 2 1 per 2 or 3 4 to 6 1 per 2 or 3 4 or During the past 30 days or since the last time per all than 1 week per per day per more you filled out this inventory, how often did per per month week week day you have the following experiences? month day 6 = 2.1 A full erection upon awakening 2.2 A full erection during a sexual fantasy or daydream 2.3 A full erection while looking at a sexually arousing person, movie, or picture 2.4 A full erection during masturbation 9 =2.5 A full erection throughout the phases of a normal sexual response cycle, 10 =□, that is from undressing and foreplay through intercourse and orgasm

Copyright © 1987 by Leonard R. Derogatis, PhD.

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



PAGEID = 54

	Center Num	ber:	Par	ticipant Nu	mber:		Pa	rticipant's	initials:	st middle last
	Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)									
_	section 3—Sexual Behavior/Experiences	SAME	AS PA	GE 52	DI	SMAL	E1 (T	YPE 4	1)PS	
У	ouring the past 30 days or since the last time rou filled out the inventory, how often did rou engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	l per week	2 or 3 per week	4 to 6 per week	l per day	2 or 3 per day	4 or more per day
11 =	erotic books or stories				3	4	5	6		□8
12 =	3.2 Masturbation	□.			\square_3	4	□ ₅			□ ₈
13 =	3.3 Casual kissing and petting					4	5	□ ₆		□8
14 =	3.4 Sexual foreplay	□,				4	□ ₅	6		□ ₈
15 =	3.5 Sexual intercourse, oral sex, etc.	□.				4	5	□ ₆		□8
5	section 4—Orgasm MALEQ <tumque></tumque>	RES	PONSE	E <tuds< th=""><th>SFC></th><th>DISN</th><th>/ALE</th><th>2 (TYF</th><th>PE 4)P</th><th>S</th></tuds<>	SFC>	DISN	/ALE	2 (TYF	PE 4)P	S
y	ouring the past 30 days or since the last time to filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely				
16 =	1.1 Your ability to have an orgasm	□.				4				
17 🚅	3.2 The intensity of your orgasm	□.			\square_3	□4				
18 ≠	.3 The length or duration of your orgasm	□₀				4				
19 =	4.4 The amount of seminal liquid that you ejaculate	□.								
20 =	5.5 Your sense of control (timing) of your orgasm					4				
= 21 —	well-being after orgasm	□.								
Co	pyright © 1987 by Leonard December 1987									

Participant's Initials: first middle last Send to DCRI Forms Management · 2400 Pratt St. · Room 0311 Terrace Level · Durham NC 27705



PAGEID = 55

	Cente	Number:		Participant	Number:		F	articipant's	s Initials:	irst middle last
	Derogatis Interview for Sexua	al Fund	tion (DISF-SR) (M) Male \	Version (ontinue	4)		
	Section 5—Drive and Relationship	SA	ME AS	PAGE 5	52	DIS	SMALE	1 (TY	PE 4)F	PS
		Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
22	3.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?				□₃	□₄		□6	□7	□8
		Not at all	Slightly	Moderately	Highly	Extremely	MALF	-2 (TY	PE 4)F	es.
23	5.2 During this period, how interested have you been in sex?	□.			□₃	□4		E AS PA	•	Ü
24	_5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	□。			□₃	□₄ DI	SMAL	.E3 (T`	YPE 4)	PS
	MALEQ <tumque></tumque>	Could not be worse	Very poor	Poor	Somewhat inadequate		Above average	Good	Very good	Could not be better
0.5	5.4 In general, what would represent			RESPC	NSE <t< th=""><th>UDSFD</th><th>></th><th></th><th></th><th></th></t<>	UDSFD	>			

Copyright © 1987 by Leonard R. Derogatis, PhD.

the best description of the quality of your sexual functioning?

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAGEID = 56 Center Number: Par	ticipant Num	.h.a		Doutisio ou	u/a laitiala.		
SAME AS PAGE 36	DATEHE	OR (TYI	PE 4)		ii s iliilidis.	first middle last	
Date completed: $_{day}$ / / OR Not done \rightarrow Space Sp	Date completed:/OR Not done → Specify reason (use codelist below):						
Food Cravings Questionnaire—Trait							
Please indicate the extent to which you agree with each statement belo	ow, in gene	eral, by ch	ecking the	appropr	iate box.		
	Never	Danaha	Some-			E 4)PS	
TRAIT <tufcqa> TRAITA<tufcqb></tufcqb></tufcqa>	OR NA	Rarely	times	Offen	Usually	Always	
Being with someone who is eating often makes me hungry.	П		3	4	5	□ ₆	
When I crave something, I know I won't be able to stop eating once I start.	\square_1		Пз		5	□6	
3 If I eat what I am craving, I often lose control and eat too much.			3	4	5	□ ₆	
I hate it when I give in to cravings.			3	_4	5	□ ₆	
Food cravings invariably make me think of ways to get what I want to eat.			3	4	5	□ ₆	
€ I feel like I have food on my mind all the time.			Пз	4	5	□6	
I often feel guilty for craving certain foods.			З	4	5	□ ₆	
8 I find myself preoccupied with food.			Пз	_4	5	□₀	
9 I eat to feel better.			Пз	4	5	□ ₆	
10 Sometimes, eating makes things seem just perfect.			3		5	□,	
1 Thinking about my favorite foods makes my mouth water.			З	4	5	□ ₆	
12 I crave foods when my stomach is empty.	\square_1		Пз	4	□ ₅	□6	
13 I feel as if my body asks for certain foods.			3	4	5	□6	
14 I get so hungry that my stomach seems like a bottomless pit.			Пз	_4		□₀	
15 Eating what I crave makes me feel better.			Пз	4	5	□6	
16 When I satisfy a craving, I feel less depressed.			3		5	□ ₆	
17 When I eat what I am craving, I feel guilty about myself.			З		5	□ ₆	
**Whenever I have cravings, I find myself making plans to eat.			З	□₄			
19 Eating calms me down.			Пз		5	□ ₆	
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficie	nt time 4	Instrument	failure	5 Not requ	ired	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAGEID = 57 Center Number: Partic	Participan	nt's Initials:	first middle last			
Food Cravings Questionnaire—Trait (continued)						
SAME AS PAGE 56	Never OR NA	Rarely	Some- times		Usvally	-
=20 I crave foods when I am bored, angry, or sad.			FCQ		(TYPE	4)PS
=21 feel less anxious after eat.						6
=22 If I get what I am craving, I cannot stop myself from eating it.			Пз	□₄		
=23 When I crave certain foods, I usually try to eat them as soon as I can.						□ ₆
=24 When I eat what I crave, I feel great.			З			□6
=25 I have no will power to resist my food crave.			\square_3		5	6
=26 Once I start eating, I have trouble stopping.			3		5	□6
=27 I can't stop thinking about eating, no matter how hard I try.					5	6
=28 I spend a lot of time thinking about whatever it is I will eat next.			□₃		5	6
29 If I give in to a food craving, all control is lost.			З		5	6
30 When I'm stressed out, I crave food.			З		5	□,
31 I daydream about food.			З		5	6
_32 Whenever I have a food craving, I keep on thinking about eating until I actually eat the food.			Пз		5	□6
=33 If I am craving something, thoughts of eating it consume me.			□₃		5	6
=34 My emotions often make me want to eat.			З		5	□,
35 Whenever I go to a buffet, I end up eating more than what I needed.			3			□ ₆
_36 It is hard for me to resist the temptation to eat appetizing foods that are in my reach.			Пз			
=37 When I am with someone who is overeating, I usually overeat too.			Пз			□6
=38 When I eat food, I feel comforted.			\square_3			6
and a summer for all and a sufficient Variations of						

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:

Send to DCRI For management Area running Room out retract level. Durhe

Durham NC 27705

ca	leri	e	Phase 2
----	------	---	---------

PAGEID = 58	Center Number:	Participant Number:	Participant's Initials: first middle last
Date completed:/	year OR Not do no	PAGE 36 (use codelist below	EHDR (TYPE 4)

Food Cravings Questionnaire—State (FCQ-S)

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

while others refer to one or more specific foods. Please respond to each item as honestly as possible. FCQSTATE (TYPE 4)PS							
STATEQ <tufcqc> STATEA<tufcqd></tufcqd></tufcqc>	Strongly Disagree	Disarros	Neutral	Agree	Strongly Agree		
I have an intense desire to eat [one or morespecific foods].				4			
2 I'm craving [one or more specific foods].			\square_3	\square_4	□₅		
=3 I have an urge for [one or more specific foods]			\square_3	□ ₄			
Eating [one or more specific foods] would make thing seem just perfect.	s		\square_3	\square_{4}	5		
_5 If I were to eat what I am craving, I am sure my mood would improve.			Пз	4	5		
Eating [one or more specific foods] would feel wonderful.			З	\square_4	5		
If I ate something, I wouldn't feel so sluggish and lethargic.			□₃		5		
Satisfying my craving would make me feel less groud and irritable.	y D		□₃				
9 I would feel more alert if I could satisfy my craving.			□₃	4	5		
10 If I had [one or more specific foods], I could not stop eating it.			□₃		5		
_11 My desire to eat [one or more specific foods] seems overpowering.			□₃		5		
=12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			□₃	\Box_{4}	5		
=13 I am hungry.			3		5		
=14 If I ate right now, my stomach wouldn't feel as empty			Пз	\square_4	5		
_15 I feel weak because of not eating.			\square_3	4	5		

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAC	3EID = 39	Center Numbe	or: Pa	rticipant Number:		Participant's I	nitials: first middle last
Dat	e completed:/ _{montl}	/ ORS	XME'AS → ÅR	ecify reason (us	e codelist bel aw	TEHDR_(T	YPE 4)
	od Craving Inven						
	each of the foods listed belo					RAVE (TY	PE 4)PS
_No	te: A craving is defined as an Over the past month			r food or food t Rarely			Always/Almost
	have you experienced	a craving for	Never	(once or twice)	Sometimes	Often	Every Day
=1	Cake FCIQ <tucrva< th=""><th>\></th><th></th><th></th><th>□₃</th><th>4</th><th>5</th></tucrva<>	\>			□₃	4	5
= 2	Pizza	FCIA <tucr< th=""><th>VB>□1</th><th></th><th>□₃</th><th>4</th><th></th></tucr<>	VB>□1		□₃	4	
=3	Fried chicken				₃		
_ 4	Gravy				□₃	\square_4	
<u>=</u> 5	Sandwich bread				□₃	□₄	5
<u>=</u> 6	Sausage				□₃	□₄	5
_7	French fries				₃	\square_4	
8	Cinnamon rolls				□₃	□₄	5
= 9	Rice				□₃		
=10	Hot dog		\square_1		□₃	\square_4	\square_5
=11	Hamburger				₃	4	5
<u>=</u> 12	Biscuits				₃	\square_{4}	5
<u>=</u> 13	Ice cream				₃	4	5
₌ 14	Pasta		\square_1		\square_3	\square_{4}	\square_5
<u>=</u> 15	Fried fish				\square_3		
=16	Cookies				₃		
=17	Chocolate				₃		
=18	Pancakes or waffles				□₃	\square_{4}	
=19	Corn bread				\square_3		
=20	Chips				\square_3	\square_{4}	
<u>=</u> 21	Rolls				₃		
_22	Cereal				\square_3	\square_{4}	
<u>_</u> 23	Donuts				\square_3		
<u>_</u> 24	Candy				□₃		
_25	Brownies				₃		
_26	Bacon						
<u>=</u> 27	Steak						
=28	Baked potato				□₃		
No	t Done Codelist: 1 Participa		able to obtain	3 Incufficient tim	101	nt failure 5 N	lot required
		CALERIE PHASE2	ANNOTATIO	7N V8.0 24FL	EB2012	Participant's	Initials:

Baseline Submission 1 Visit 2

PAGEID = 60

	Center N	Number:	Participant Number:	Pa	rticipant's Ir	first middle last
Date c	completed:/ _{month} / _{year}	OR SAME AS	Specify reason (use co	delist below:	IDR (T	YPE 4)
Eati	ng Inventory					
F	When I smell a sizzling steak or s difficult to keep from eating, even	ee a juicy pie if I have just	tinisnea a meai.	_	_,	PE 4)PS □₀ False
2	I usually eat too much at social o	casions, like	parties and picnic	INV <tutfa> s.</tutfa>	True	o False
3	I am usually so hungry that I eat	more than th	ree times a day.], True	□₀ False
4	When I have eaten my quota of conot eating anymore.	alories, I am	usually good abo	out [], True	o False
5	Dieting is so hard for me because	l just get too	hungry.], True	□₀ False
6	I deliberately take small helpings	as a means o	of controlling my	veight.], True	o False
7	Sometimes things just taste so god I am no longer hungry.	od that I keep	on eating even v	vhen [], True	□₀ False
8	Since I am often hungry, I sometine expert would tell me that I have he something more to eat.			_], True	□₀ False
<u>Q</u>	When I feel anxious, I find myself	eating.], True	□₀ False
10	Life is too short to worry about di	eting.], True	o False
11	Since my weight goes up and dov more than once.	vn, I have go	ne on reducing di	ets], True	□₀ False
1 2	I often feel so hungry that I just h	ave to eat so	mething.], True	o False
[3	When I am with someone who is	overeating, l	usually overeat to	ю. [], True	□₀ False
1 4	I have a pretty good idea of the r	umber of cal	ories in common	ood.], True	□₀ False
1 5	Sometimes when I start eating, I j	ust can't seer	n to stop.], True	□₀ False
= 16	It is not difficult for me to leave so	mething on r	my plate.], True	□₀ False
<u>ī</u> 7	At certain times of the day, I get he to eating then.	ungry becau	se I have gotten u	used], True	□₀ False
1 8	While on a diet, if I eat food that for a period of time to make up fo		d, I consciously ec	t less], True	□₀ False
Not D	one Codelist: 1 Participant refused 2 Clinici	an unable to obta	in 3 Insufficient time	4 Instrument fail	ure 5 N	ot required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



PAGEID = 61

	Center Number: Participant Number:	Participant's Initials: first middle last
Eat	ing Inventory (continued)	
=19	Being with someone who is eating often makes me hungry to eat also.	☐₁ True ☐₀ False
_20	SAME AS PAGE 60 When I feel blue, I often overeat.	FEQA (TYPE 4)PS ☐, 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
<u>=</u> 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
<u>-</u> 28	I consciously hold back at meals in order not to gain weight.	☐₁ True ☐₀ False
⁼ 29	I sometimes get very hungry late in the evening or at night.	☐₁ True ☐₀ False
= 30	I eat anything I want, any time I want.	☐₁ True ☐₀ False
=31	Without even thinking about it, I take a long time to eat.	□₁ True □₀ False
= ³²	I count calories as a conscious means of controlling my weight.	☐₁ True ☐₀ False
=33	I do not eat some foods because they make me fat.	☐₁ True ☐₀ False
= 34	I am always hungry enough to eat at any time.	☐₁ True ☐₀ False
35	I pay a great deal of attention to changes in my figure.	☐₁ True ☐₀ False
= 36	While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods.	☐₁ True ☐₀ False

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1 Visit 2

PAGEID = 62

		Center Number:	Participant Number:	Participant's Initials:
Eat	ing Inventory (continued)			
Plea	se check one answer that is most	appropriate to you	for each question below. TF	EQB (TYPE 3)
37	How often are you dieting in effort to control your weight	n a conscious	☐₁ Rarely ☐₂ Sometimes R <tufreq></tufreq>	□₃ Usually □₄ Always
38	Would a weight fluctuation of affect the way you live your		☐₁ Rarely ☐₂ Sometimes FLUCT <tufreq></tufreq>	□₃ Usually □₄ Always
39	How often do you feel hung	ry?	☐₁ Rarely ☐₂ Sometimes	THUNG <tufreq> ☐₃ Usually ☐₄ Always</tufreq>
40	Do your feelings of guilt abo help you to control your foo		☐₁ Rarely ☐₂ Sometimes ELGUIL <tufreq></tufreq>	□₃ Usually □₄ Always
41	How difficult would it be for eating halfway through dinr for the next four hours?		□, Easy Moderately difficult	☐₂ Slightly difficult ☐₄ Very difficult
42	How conscious are you of weating?		□₁ Not at all □₃ Moderately	☐₂ Slightly ☐₄ Extremely
43	How frequently do you avoi on tempting foods? ST	d "stocking up" OCKING <tusto< th=""><th>, Almost never</th><th>☐₂ Seldom ☐₄ Almost always</th></tusto<>	, Almost never	☐₂ Seldom ☐₄ Almost always
44	How likely are you to shop to calorie foods?	for low L <tulike></tulike>	☐₁ Unlikely ☐₃ Moderately likely	□₂ Slightly likely □₄ Very likely
45	Do you eat sensibly in front splurge alone?	of others and G <tusplu></tusplu>	□₁ Never □₂ Rarely	□₃ Often □₄ Always
46	How likely are you to consci in order to cut down on how	ously eat slowly much you eat?	☐, Unlik #ATSLOW<tulik< b=""> ☐, Moderately likely</tulik<>	E>₂ Slightly likely □₄ Very likely
47	How frequently do you skip you are no longer hungry?	dessert because	Almost never	□₂ Seldom □₄ Almost every day
48	How likely are you to consci		□₁ Unlikely □₃ Moderately likely	☐₂ Slightly likely ☐₄ Very likely
49	Do you go on eating binges not hungry? BINGES<7		Never 3 Sometimes	2 Rarely 4 At least once a week
50	To what extent does this stat your eating behavior? "I sta morning, but because of any things that happen during th evening I have given up and promising myself to start die tomorrow."	rt dieting in the number of e day, by eat what I want, ting again	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of ☐₄ Describes me perfectly BEHAVIOR <tubeha></tubeha>	
51	On a scale of 0 to 5, where restraint in eating (eating whenever you want it) total restraint (constantly limintake and never "giving in" would you give yourself?	natever you and 5 means iting food	Eat whatever you want, was at whatever you want, was often eat whatever you want, was often limit food intake, based on the constantly limiting food intake, ba	want, whenever you want it want, whenever you want it but often "give in" rarely "give in"

CALERIE PHASE2 ANNOTATION V8.0 24FEB2013

Participant's Initials: _

Send to DCRI Forms Management 2700 run on Room out Terrate sever Durham NC 27705

Baseline Submission 1 Visit 2

PAGEID = 63	Center Number:	Participant Number:	Participant's Initials: first middle last
Date completed:/ _{month} /	year	Specify reason (use codelist below DAT): EHDR (TYPE 4)

Weight Efficacy Litestyle Questionnaire (WEL)

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

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat. Check this number for each item. WELQ (TYPE 4)PS

Ια	ım confident that:	you c	an resi		esire to		yo			onfide i e desire	
	WELQUES <tuwelq></tuwelq>	•	/ELAN	15VV< 2	TUWE 3	LA> 4	5	6	7	8	9
1	I can resist eating when I am anxious (nervous).	□,						□ ₆			
2	I can control my eating on the weekends.	\square_{\circ}			\square_3		\square_{5}	□ ₆		□ ₈	□ ₉
3	I can resist eating even when I have to say "no" to others.	□,				4		□ ₆			
4	I can resist eating when I feel physically run down.	□,			Пз					8	
5	I can resist eating when I am watching TV.				З			6		8	
<u>6</u>	I can resist eating when I am depressed (or down).	\Box_{\circ}			\square_3	\square_{4}	\square_{5}	_6		□ ₈	□,
7 =	I can resist eating when there are many different kinds of food available.	□,			Пз	□4		6		8	
8	I can resist eating even when I feel it is impolite to refuse a second helping.				Пз	□₄		□ ₆			□,
9 =	I can resist eating even when I have a headache.							6		8	
l No	ot Done Codelist: 1 Participant refused 2 Clinician unable	e to obta	in 3	Insufficie	ent time	4 Ins	trument	failure	5 No	t require	d

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



PAGEID = 64

	Center Number: _		Partici	oant Nur	nber: _			Particip	oant's Init	tials:	middle last
Weight Efficacy Lifestyle	Questionna	ire (w	/EL) (cc	ntinue	4)						
I am confident that:	PAGE 63			e nt at a st the d	ll that esire to			u can r		onfider e desire	
		0	1	2	3	4	5	6	7	8	9
=10 I can resist eating when I ar	n reading.	□₀			Пз		\square_5			□ ₈	□ ₉
=11 can resist eating when I are (or irritable).	m angry	□₀	П		Пз		5	6			
12 I can resist eating even whe a party.	n I am at	\square{o}			\square_3	\square_{4}		6		8	
= 13 I can resist eating even whe pressuring me to eat.	n others are	По			З	4		□ ₆		□ ₈	
=14 I can resist eating when I ar	m in pain.	\square_{o}			\square_3	\square_{4}	\square_5	6			
15 I can resist eating just beforebed.	e going to	□₀	П		Пз		5	6			
16 I can resist eating when I have experienced failure.	ive	\square_{o}			\square_3		\square_5	6		□ ₈	
17 I can resist eating when high	h-calorie foods	□₀	П		Пз		5	□ ₆		8	
18 I can resist eating even whe others will be upset if I don'		\square_{\circ}					\square_5	□ ₆			
19 I can resist eating when I fe uncomfortable.	el	По						□ ₆		8	
=20 I can resist eating when I ar	n happy.		Π,		Π,					Π.	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



Odio	
PAGEID = 65	

TAGEID	Center Numb	er: Particip	ant Numbe	ər:		Partici	pant's Ini	tials:	middle last
Date completed: /	/ OR	SAME AS PAGE Not done → Specify	36 reason	luse code	DA plist below	エロロロ	R (TY	PE 4	.)
Date completed:/	-				IVI	ÁEDS	(TYF	PE 4)F	PS
Multiaxial Assessn	nent of Eating D	isorder Sym	ptom	S (MAE	DS)				
Instructions: Using the scale :	shown, please rate the fol	lowing items on a sco	le from 1						
MAEDQ <tumaey></tumaey>		MAEDA <tumae< th=""><th>Never Z></th><th>Very Rarely</th><th>Rarely</th><th>Some- times</th><th>Often</th><th>Very Often</th><th>Always</th></tumae<>	Never Z>	Very Rarely	Rarely	Some- times	Often	Very Often	Always
=1 Fasting is a good wo	ay to lose weight.				З	□₄	5	6	7
=2 My sleep isn't as go	od as it used to be.				\square_3	□₄		6	
=3 I avoid eating for as	long as I can.				\square_3	_4	5		
=4 Certain foods are "f	orbidden" for me to	eat.			Пз			6	
=5 I can't keep certain fo binge on them.	ods in my house bec	ause I will			Пз				
6 I can easily make m	yself vomit.				\square_3			6	
7 I can feel that being	fat is terrible.				3	_4	5		
=8 I avoid greasy food:	5.				Пз		5	6	7
=9 It's okay to binge ar	nd purge once in a v	while.			Пз			6	
_10 I don't eat certain fo	ods.				Пз			6	
_11 I think I am a good	person.				З			6	
=12 My eating is normal	•				Пз			□,	7
=13 can't seem to conc	entrate lately.				\square_3	4	5	6	
=14 I try to diet by fastin	g.				\square_3		\square_5	6	
=15 I vomit to control my	weight.				\square_3	4	5		
=16 Lately nothing seem	s enjoyable anymor	e.			\square_3			6	
=17 Laxatives help keep	you slim.				З			6	
=18 don't eat red meat					З			□,	
=19 eat so rapidly car	't even taste my foo	od.			З			□ ₆	
Not Done Codelist: 1 Particip	ant refused 2 Clinician u	nable to obtain 3 In	nsufficient	time 4	Instrume	nt failure	5 No	t require	d
	CALEDIE DHASE2	ANNOTATION	0 0 245	ED201	2				

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



PAGEID = 66

MAEDS (TYPE 4)PS

Center Number:	_ Participant N	umber: _		Pai	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of Eating Disorde	er Sympto	oms (MAEDS)	continue	d)		
SAME AS PAGE 65	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
=20 I do everything I can to avoid being overweight	t					6	
=21 When I feel bloated, I must do something to rid my of that feeling.	rself		Пз			□6	
=22 I overeat too frequently.			3			6	
_23 It's okay to be overweight.			3			6	
_24 Recently I have felt that I am a worthless person	ı. 🗀		3			6	
_25 I would be very upset if I gained 2 pounds.			3	□₄		6	
_26 I crave sweets and carbohydrates.			3	_4		6	
_27 lose control when eat.			3			6	
_28 Being fat would be terrible.			3	_4			
_29 I have thought seriously about suicide lately.			3	\square_4		□,	
_30 I don't have any energy anymore.			3	4		6	
31 I eat small portions to control my weight.			Пз	□₄	\square{5}	□6	
_32 l eat 3 meals a day.			3	□ ₄		6	
_33 Lately I have been easily irritated.			3	\square_4		6	
_34 Some foods should be totally avoided.			3	_4		6	
_35 I use laxatives to control my weight.			3	\square_4			
_36 I am terrified by the thought of being overweigh	ht.			4		6	
_37 Purging is a good way to lose weight.			_3	\square_{4}		□6	
_38 I avoid fatty foods.			3			□6	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:

first middle last

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



PAGEID = 67

MAEDS (TYPE 4)PS

Center Number:	Participant N	umber: _		Pai	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of Eating Disorder	Sympto	ms (MAEDS)	continue	d)		
SAME AS PAGE 65	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.			3	_4		□ ₆	
= 40 I am obsessed with becoming overweight.			□₃	□₄		□,	
41 I don't eat fried foods.			3	□₄		□6	
= 42 skip meals.			_3	□4		□。	
43 Fat people are unhappy.			3			□,	
44 People are too concerned with the way I eat.			□₃	□₄		□,	□ ₇
45 I feel good when I skip meals.			_3	□₄		□6	
■ 46 I avoid foods with sugar.			□3	□₄		□6	\square_{7}
47 I hate it when I feel fat.			Пз	□₄		6	
= 48 I am too fat.			□₃	□₄	\square_5	□6	\square_{7}
49 I eat until I am completely stuffed.			3	□ ₄		6	
50 I hate to eat.			□₃	□₄		□6	□,
51 I feel guilty about a lot of things these days.			□₃	□₄		□6	
= 52 I'm very careful of what I eat.			\square_3	□₄	\square_{5}	□6	□,
53 I can "hold off" and not eat even if I am hungry.			3	□ ₄		□,	
= 54 I eat even when I am not hungry.			□₃	□₄	\square_{5}	□,	
= 55 Fat people are disgusting.			3	□4		□,	
56 I wouldn't mind gaining a few pounds.			□₃	□₄		□,	
CALERIE PHASE2 ANNOTATION V	/9 0 24EE	D2012					

Participant's Initials:

First middle last

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

Baseline Submission 1 Visit 2

PAGEID = 68	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	year OR Not done -	ASPECIFY reason (use codelist below DAT		

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

PIE	ease read each question and check the box for the appropriate choice. Plea	ise answe	er all the c	questions			
	ver the Past Four Weeks QUES <tubsqx> BSQANSW<tubsqw></tubsqw></tubsqx>	Never	Rarely	Some- times	Often	Very Often	Always
<u>=</u> 1	Has feeling bored made you brood about your shape?				4		
=2	Have you been so worried about your shape that you have been feeling that you ought to diet?			Пз		□₅	
_3	Have you thought that your thighs, hips, or bottom are too large for the rest of you?			Пз			
4	Have you been afraid that you might become fat (or fatter)?			Пз			
5 =	Have you worried about your flesh not being firm enough?				4		
6 =	Has feeling full (e.g., after eating a large meal) made you feel fat?			Пз			□。
7 =	Have you felt so bad about your shape that you have cried?				4		□6
8 =	Have you avoided running because your flesh might wobble?			\square_3			
9	Has being with thin women/men made you feel self-conscious about your shape?						
=10	Have you worried about your thighs spreading out when sitting down?			Пз			□₀
=11	Has eating even a small amount of food made you feel fat?			Пз	4		□,
=12	Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?			Пз			□6
13 =	B Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?						
=14	Has being naked, such as when taking a bath, made you feel fat?						□ ₆
=15	Have you avoided wearing clothes which make you particularly aware of the shape of your body?						
	Have you imagined cutting off fleshy areas of your body?			Пз			□₀
N	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuf	ficient time	4 Instr	ument fail	ure 5 N	lot require	ed

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline Submission 1

PAGEID = 69

BSQ (TYPF 4)PS

Center Number:	Participant Number:	Participant's Initials:	first middle	las
Center Homber:	raniapani Nomber:	raniapani s iniliais:	first middle	

Body Shape Questionnaire (BSQ) (continued)	-00 - c	4 .	4			30 50
Over the Past Four Weeks SAME AS PAGE 68	Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?				_4		□6
= 18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?			□₃	□₄	\square_5	
19 Have you felt excessively large and rounded?			3	4	5	□ ₆
20 Have you felt ashamed of your body?			3	□4	5	□6
21 Has worry about your shape made you diet?	□₁		□₃	□4		□6
22 Have you felt happiest about your shape when your stomach has been empty?]3	□₄		
23 Have you thought that you are the shape you are because you lack self-control?			3	_4	5	
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?			□3	□₄	5	
25 Have you felt that it is not fair that other women/men are thinner than you?			□₃	□₄	5	□₀
= 26 Have you vomited in order to feel thinner?			□₃	□₄	5	□6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?			3	4	5	□6
28 Have you worried about your flesh being dimply?	□₁		□₃	□₄	\square_5	
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?	□₁		□₃	_4	5	□6
30 Have you pinched areas of your body to see how much fat is there?			3	□₄	5	□6
= 31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?			□₃	_4	5	□6
32 Have you taken laxatives in order to feel thinner?	\square_1		□₃	□₄	\square_5	
33 Have you been particularly self-conscious about your shape when in the company of other people?				□4		□6
34 Has worry about your shape made you feel you ought to exercise?			3	□ ₄	\square_5	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



PAGEID = 70

	Center Number	r: Par	ticipant Number:	Participant's Initials:	irst middle last
Clinic Weight					
Weight date and time:	/	00:00 to 23:59		Staff initials: first middle	last
OR Not done → Specify rec	uson (use codelist below):	_		DATEHDR (TYPE 4)	1001
Clinic weight (if the two measu	rements are more than 0.1 kg		weight a third time) ME AS PAGE 4	:	
Weight 1:	kg			WEIGHT (TYPE 4)	
Weight 2:	kg				
Weight 3:	kg				
Weight of gown:	kg				
Not Done Codelist: 1 Particip	pant refused 2 Clinician und	able to obtain	3 Insufficient time	4 Instrument failure 5 Not requir	red

Not Done Codelist: 1 Participant refused

Baseline Submission 1 Visit 3

									Center Nu	umber: _	P	articipant	Number: _		Po	rticipant's	Initials:	rst middle last
PA(غاد	ID =	1					THIS IT	EM NOT DA	ATABAS	SED			PAI	RHDR	(TYPE	<u>: 4) </u>	
S	e١	/en-	-D	ay Physical I	Activ	ity Reca	(PAR)											
T	oda	y's do	ate	e:/_ PARI)T	Day	(check only one):	☐ Mon ☐ Tu	es Wed	Thurs [Fri S	Sat Su	n OR No	t done →	Specify re	eason (use	RND <t< th=""><th>UND></th></t<>	UND>
																	e I	middle last
12	1	f Yes:	w	u employed in the la hich days (check all tha	at apply)?	,		MOI Mon	V1 TUES1	WEI Wed	OTT'TH I Thurs ☐	URS1_ T _{fri} [FRI1 Sat	SAT1	SUN1		SIN	ITIALS
				ays do you consider											ΔI	L <xyes< th=""><th>></th><th></th></xyes<>	>	
Do	\neg	Day o	Т		7		Time	Work			ning (in mi		After	noon (in n	ninutes)	Even	ing (in min	iutes)
#	1	Week	k	Date TUPDAY>		In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7	- 1		Ì	/		00:00 to 23:59	00:00 to 23:59	:	:					PAI	RCHT	(TYPF	4)PS	
(yes da	- 1	로		SDPARDT	<i>r</i> ear	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
<u>ا</u> 6		S CC		//		D1TM-AV		WRKSTR	TM WRKS	ГРТМ								
ľ		ÖLU		day month y	[®] INB E	D2TM-AV	VAKE2TM	00:00 to 23:59	00:00 to 23:59									
Г	1	₹		, , ,		00:00 to 23:59	: 00:00 to 23:59	_	_	AL	_ <l:3></l:3>	MORI	MOD					
5		NON	-	day month y	rear	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59			МО	RHARE)				
r	\top	A B	_			:	:					N	NORVH	RD				
4	.	TAB	-	day month y	year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59				—AF	TRMO				
\vdash	4	J SAS	- 11			00:00 to 23:59	00:00 to 23:59						/	FTRH/	\RD			-
3			-	/		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	: 00:00 to 23:59					AFTR'	/HRD			
L	\perp			aay montn y	year	00:00 to 23:59	00:00 to 23:59							Е	VEMOI)		
] 2			-	//		00:00 to 23:59		:	PAGE FOR	CALCU		15					EVE	HARD
L			\perp	day month y	pear	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59	EV	EVHRD							
יו				/		00:00 to 23:59	00:00 to 23:59											
(7 y	eek o)			day month y	year .	00:00 to 23:59	00:00 to 23:59	00:00 to A3L5L T	IMES DERI	VED U	SING S	DPARE	T					
_																		

CRF, page 71

CALCULATIONS FOR 7dPAR

SLEEP TIME

AWAKE1TM AND AWAKE2TM ASSOCIATED WITH SDPARDT +1 when

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

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

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

TOTAL SLEEP TIME

TOTSLEEP = SLP2TM + SLP1TM

TOTAL WORK TIME

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

ALL TIMES DERIVED USING SDPARDT



PAGEID = **72**

	Center Number: Farnapani Number: Farnapani s initials:
S	even-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) About the same LSTWK <tuphys></tuphys>
In	terviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? One PARPROB Yes
6	Do you think this was a valid Seven-Day PAR interview? One No One PARVLD< XYESNO>
7	Were there any activities reported by the participant that you don't know how to classify? ONO THACT <xyesno></xyesno>



PAGEID = 73

	Day Food Record plete below OR Not done → Specify	r reason (use Codelist k	pelow):	FOODND <tund> Staff init</tund>	ials: SINTIALS						
	,	,		Replacement Values							
Day of DLW	Date of Record RECQ	Record Quality (check only one) UAL <tuqual></tuqual>	Day of DLW	FOODRCD (TYPE	Record Quality (check only one)						
DLW 1	'DAY <tufdrd>/</tufdrd>	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	878	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9₽	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
3		☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10 0	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
4		☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11 ±	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
. 5		☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12 2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
6		☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	133≟	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing						
Not	Done Codelist: 1 Participant refused	2 Clinician unable to ob	otain 3	3 Insufficient time 4 Instrument failure	5 Not required						



PAGEID = 74

FORM/BLOCK = BASELINE2

	Center Nu	mber: Participant Number:	Participant's Initials:
Clinic Weight			
Weight date and time:	day month year	: : :	Staff initials: first middle lost
E86900 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	y reason (use codelist below):		DATEHDR (TYPE 4)
Clinic weight (if the two r	neasurements are more than 0.	.1 kg apart, measure weight a third ti	ime):
Weight 1:	kg	SAME AS PAG	E 4
Weight 2:	kg		WEIGHT (TYPE 4)
Weight 3:	kg		
Weight of gown:	kg		
Not Done Codelist: 1 Po	articipant refused 2 Clinician	n unable to obtain 3 Insufficient tin	ne 4 Instrument failure 5 Not required

Baseline Submission 2

Center Number:	Participant Number:	Po	rticipant's Initials:	first midd	0 1
		PARHDR	(TYPE 4)	first midd	re rast

Toda	ay's date Were yo	e://	Day ven days?		□ ₀ No	→ Skip to que	estion 3	□₁ Yes	;				eason (use riewer ini	4:l	low):
3	Which d	Vhich days (check all that appl) lays do you consider your	weekend, or n	on-work, days p Time			Wed		Fri	Sat	Sun Sun rnoon (in i	minutes)	Ever	ning (in mir	nutes
Day #	Day of Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Ve
7 (yester- day)			00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					_PA	RCHT	(TYPE	4)PS	_
6		/	00:00 to 23:59 - : - : - : - : : : : : : : : : : : : :	00:00 to 23:59		00:00 to 23:59									_
5		/	00:00 to 23:59 : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									_
4		/	00:00 to 23:59 : 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59			SAME	AS PAC	\$E 71 				_
3		/	00:00 to 23:59 : 00:00 to 23:59	00:00 to 23:59 	00:00 to 23:59	00:00 to 23:59									_
2		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	::									_
1 (1 week ago)		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									-



PAGEID = 76

	Center Number: Fartiapant Number: Fartiapant's Initials: firstmiddle_lost
S	even-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)
	Less SAME AS PAGE 72 3 About the same
In	terviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview?
6	Do you think this was a valid Seven-Day PAR interview? One No One Yes
7	Were there any activities reported by the participant that you don't know how to classify? \square_0 No \square_1 Yes



PAGEID = 77

Center Number: Participant Number: Participant's Initials: first middle last											
Hai	ndgrip Strength										
Date and time of assessment: $\frac{1}{2} - \frac{1}{2} - \frac{1}{2} = \frac{1}{$											
1 D	ynometer handle positior	:: <u>DYN</u> O <i:2></i:2>		HANDGRIP (T	YPE 4)PS						
	2 Dominant hand (check only one): ☐₁ Left ☐₂ Right ☐₃ Ambidextrous DOMHND <tudomh></tudomh>										
 	Handgrip Strength ESTNO <tupft></tupft>	Zero Meter Check	Right Hand RIGHT <f:9:3></f:9:3>	Zero Meter Check	Left Hand LEFT <v:9:3></v:9:3>						
	=Test 1—peak force	□₀	kg	\Box_{o}	kg						
	kg										
	=Test 3—peak force		kg	\Box_{o}	kg						
Not D	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										



PAGEID = 78

		Ce	enter Number:	Participant N	lumber: _		Particip	ant's Initials: first middle last				
ls	ometric/Isokine	ic Knee Ex	xtension and	Flexion								
	Date and time of assessment: $\frac{1}{day} = \frac{1}{year} = \frac{1}{00.00 \text{ to } 23:59}$ Staff initials: $\frac{1}{first \text{ middle four}}$ OR Not done \rightarrow Specify reason (use codelist below): SAME AS PAGE 4 DATEHDR (TYPE 4)											
OI	R Not done → Specity rea:	on (use codelist l	below): SAIVIE AS	PAGE 4		DATEHL	JR (1 '	(PE 4)				
1												
2	2 Recent injury or pain—left knee? \square_0 No \square_1 Yes LKIP <xyesno> ISOMETRC (TYPE 4)PS</xyesno>											
3	Specify machine used (Pl	RC only): 🔲 C	Cybex	MACHIN	IE <tu< th=""><th>SED></th><th></th><th></th></tu<>	SED>						
	All values corrected			HTLEG <f Right</f 		LEFTLE(1	3> If Not Done, Specify Reason				
							- 9	CHET ROPELIST PORNOS				
3	See next page for 50 sec knee extension TUGRAV codelist	2 = pec 3 =	ak torque		N.m		N.m					
		toto	al work		N.m		N.m					
			erage power		watts		watts					
4	$60^{\circ}/\text{sec}$ knee flexion		ak torque		N.m		N.m					
			al work		N.m		N.m	-				
			erage power		watts	50 00 00 0	watts					
5	180°/sec knee extension	5.50	ak torque	300 M 30	N.m		N.m					
			al work	5-17-17-17-17-17-17-17-17-17-17-17-17-17-	N.m		N.m					
			erage power		watts		watts					
			rk fatigue index	1000 - 100 - 1	%		. %					
6	180°/sec knee flexion	N-200000	ak torque		N.m		N.m					
		1007000	al work	78. A. A.	N.m		N.m					
		14= ave	erage power		watts		watts					
		15= _{wo}	rk fatigue index	·	%		.%					
7	Isometric knee extension:	trial 1 ¹⁶⁼ peo	ak torque		N.m		N.m					
		trial 2 ¹⁷⁼ pec	ak torque	500 00 00 00 00 00 00 00 00 00 00 00 00	N.m		N.m	10-20-30				
		trial 3 ¹⁸⁼ pec	ak torque		N.m		N.m					
8	Isometric knee flexion:	100 Carlotte	ak torque		N.m		N.m					
		20-	ak torque	2000 100 100	N.m		N.m					
			ak torque	-	N.m		N.m					
			404				-					

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

5 Not required

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

TUGRAV 1=KE60PT 2=KE60TW 3=KE60AP 4=KF60PT 5=KF60TW 6=KF60AP 7=KE180PT 8=KE180TW 9=KE180AP 10=KE180WFI 11=KF180PT 12=KF180TW 13=KF180AP 14=KF180WFI 15= IKE1 16= IKE2 17= IKE3 18=IKF1 19=IKF2

20=IKF3



PAGEID = 79

		Center Number:	Participant Number: Participant's Initials:
D	oubly Labeled V	Vater (DLW)	
1	Date and time of DLW d	osing:/ _{month} /	year O0.00 to 23:59 Staff initials: first middle last
	OR Not done → Specify	reason (use codelist below):	DLWHDR (TYPE 4)
2	DLW dose mixture ID an	d bottle number: –	
3	Exact weight of DLW mix	kture:	grams
4	Urine samples:	SAME AS PAGE 34 No Display Item 1 an	·
	Collection	Sample DLWSMPNO <tud< th=""><th>Date and Time Collected</th></tud<>	Date and Time Collected
	Day 0 (Visit 4)	3 = D0a	/
		4 = D0b	/
	Day 7 (Visit 5)	5 = D7a	/
		6 = D7b	/
	Day 14 (Visit 7)	7 = D14a	/
		8 = D14b	//
5	Affix CRF page label(s)	corresponding to this urine s	ample set: Affix Label Here

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



PAGEID = 80

	Center Number: Participant Nu	mber: Participant's Initials:
Clinic Weight		
Weight date and time:/	/; year; 00:00 to 23:59	Staff initials: first middle last
OR Not done → Specify reason (see C	odelist below):	DATEHDR (TYPE 4)
Clinic weight (if the two measurements are	e more than 0.1 kg apart, measure weight a	third time):
Weight 1:	kg SAME AS F	PAGE 4
Weight 2:	kg	WEIGHT (TYPE 4)
Weight 3:	kg	
Weight of gown:	kg	
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Insuffic	ient time 4 Instrument failure 5 Not required



PAGEID = 81

		Center Number:	Participant Num	ber:	Participant's Initials:	first middle last
V	O ₂ Max					
1	Date and time of test:/	SAME AS PAGE 4			itaff initials: first mide	
	OR Not done \rightarrow Specify reason (use	codelist below):	· Al TM (asso	VO ociated with STU	MAX (TYPE	3)
2	At what time was the participant's la	ıst meal/snack eaten?	: 00:00 to 23:59	RE	STRHYM <tu< th=""><th>RHYT></th></tu<>	RHYT>
3	Rest ECG: Rhythm (check only one): Ventricular conduction (ch	\Box_1 Sinus eck only one): \Box_1 Normal	Atrial fib	orillation 98 Othe	r ONDUCT <tuv< th=""><th>CON></th></tuv<>	CON>
4	Heart rate (HR) data: Resting heart i	rate:b heart rate:b	PPM AGERATEN	TE		
5	Reason(s) for termination of testing (Symptom limited (dyspnea, fatigue) Angina/ischeANGSEMPlete all t Serious arrhythmias (VT or SVT) Changes in blood pressure CHGB Ventricular ischemia (schedule stress Orthopedic/extremity complaints (po	hat apply: HR when true HR when ische RYTHM VENISCH image study, complete ventr	emic ECG chang	ges occ <mark>Er@&CHNC</mark>	ANGNA< bpm or [], } 1.50+101 A2;	6 NA
6 7	Did frequent ventricular ectopy occur one No one of Yes: When did it occur (PVOMEAS1 Peak VO₂: MEET GRANG ANY E	r (e.g., ≥ 7 PVCs/min, bi/tri-s check all that apply)? ☐ D PVOMEAS2	geminy, NSVT 🗏			RY <xyes< th=""></xyes<>
8	Did the participant meet at least Med one one one one one one one one one on			between the final b RER ≥ 1.1	u in VO₂ (change ≤ two stages of age-predicted ma	
9	Exercise time: EXERSEC<1:2>	VOSYS VODIA				
10	Blood pressure at VO ₂ peak/VO ₂ mo	BORG<1:2>	mm Hg			
11	Borg RPE REALITYOF, peak/VO ₂ mo	ax: (6-20)	All BPM <			
12	Peak RER: VEPE	ΑΚ	Other Me	asures , 8,12,13,14) <f:< th=""><th>9:3></th><th></th></f:<>	9:3>	
13	S VE at VO ₂ peak/VO ₂ max: VEVO	PEAMin				
14	VE/VO ₂ at VO ₂ peak/VO ₂ max	L/min				

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

CRF, page 82

calerie Phase 2

Baseline Submission 2

Center Number:	Participant Number:	Par	ticipant's Initials:	first middl	
		PARHDR	(TYPE 4)	first middl	le l'ast

Se	Seven-Day Physical Activity Recall (PAR)														
Tod	Today's date:/														
		ou employed in the last seve				→ Skip to que						Interv	iewer init	ials:	middle last
2	If Yes: W	Which days (check all that apply)?	•		Mon	Tues	Wed	Thurs	Fri 🗌	Sat	Sun				
3	Which d	lays do you consider your w	veekend, or n	on-work, days?	Mon	Tues	Wed	Thurs	Fri 🗌	Sat	Sun				
Day	Day of		Slee	o Time	Work	Time	Mor	ning (in m		After	noon (in n		Even	ing (in mir	
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7 (yester- day)		/	00:00 to 23:59	00:00 to 23:59	: 00:00 to 23:59	00:00 to 23:59					PAI	RCHT	(TYPE	4)PS	
6		/	00:00 to 23:59 : : : : : : :	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
5		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	::00:00 to 23:59									
4		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59			SAME :	AS PAC	SE 71				
3		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
2		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1 (1 week ago)		/	00:00 to 23:59	00:00 to 23:59		: : : : : :									



PAGEID = 83

		Center Number:	Participant Number:	Participant's Initials:
S	seven-Day Physical Activity	y Recall (PAR) (c	continued)	
4	, , , , , , , , , , , , , , , , , , ,	er the past three month	hs, was last week's phy	
l	or about the same (check only one)? \square_1 More			PARQ (TYPE 4)
		SAME AS PA	AGE 72	
In	nterviewer: Please answer questions be	low and note any com	nments on interview.	
5	Were there any problems with the Seven of No	en-Day PAR interview?	?	
6	Do you think this was a valid Seven-Do	zy PAR interview?		
7	Were there any activities reported by t □₀ No □₁ Yes	the participant that you	u don't know how to cl	assify?



PAGEID = 84

		Center Number:	Partic	ipant Number: Particip	Participant's Initials: first middle last					
6-D	ay Food Record									
Com	plete below OR Not done → Specify	/ reason (use Codelist b	elow): _		rials: First middle last					
	SAME AS PAGE 73		FOODRCD (TYPE 4)PS Replacement Values							
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)					
1	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	8	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
2	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	9	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
3	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	10	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
4		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	11	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
5		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	12	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
6	/	1 Reliable 2 Unreliable 3 Missing	13	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
Not l	Done Codelist: 1 Participant refused	2 Clinician unable to ob	tain 3	Insufficient time 4 Instrument failure	5 Not required					
Not	Done Codelist: 1 Participant refused		tain 3	Insufficient time 4 Instrument failure						



			Center Nur	nber: Po	rticipant Numbe	r:	Partiapant's Initial	first middle last			
	De	elayed-type Hyperse	ensitivity (D	TH)							
		Was the DTH worksheet comple □ ₀ No □ ₁ Yes → If Yes: Were any Exc EXCLMET			oceed with te	st	M1 (TYPE 3)			
	2	Date of injection:DTHA	DMDT th year	_ OR Not done →	Specify reasor	(use codelist below):	DTHND <tun< td=""><td>ID></td></tun<>	ID>			
3 Injection by (initials): DTHINIT <v:3></v:3>											
	4 Arm injected: ☐₁ Right ☐₂ Left ARM <tudtha></tudtha>										
	5 DTH results: Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. A = Largest diameter DTHADM2 (TYPE 4)PS B = Second diameter perpendicular to A										
		Antigen	24 Hour (@ Visit 4)			48	B Hour (@ Visit 5)				
		ANTIGEN <tuanti></tuanti>	DIAMA <f:9:3> A (diameter)</f:9:3>	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:			
ANTITY	DE,	1 Normal saline	<u>DIAM</u> E	B <f:9:3> mmD</f:9:3>	TH2INIT V:3>	mm	mm				
TUTYPE		2 Tetanus toxoid (III) (check only one): 1 Tetanus toxoid (Sanofi- Pasteur) SPECIFY < 098 Other: Lot #: LOTNUM < V:25		mm	v.3>	mm	<u>TUTYPE</u> — <u>CODE (¶S)</u> 1 = STANI 98 = OTHE				
		3 Candida (check only one):	mm	mm	first middle last	mm	mm	first middle last			
<u>TI</u> 1 2	= NC	4 Trichophyton (check only one):	mm	mm 5 = NORM 6 = TETAN			mm				
3	= CA	NDIDA 24		7 = CANDI	DA 48						
4	= 1741	(IChkOTeHekisFON P 2 4cipant refu	used 2 Clinician	una8letoT4R10H		ti 48 4 Instrumer	nt failure 5 Not re	equired			



	Center Number: Participant Number: Participant's Initials:
Cl	inic Weight
	sight date and time: $\frac{1}{day} / \frac{1}{month} / \frac{1}{year} = \frac{1}{00.00 \text{ to } 23:59}$ Staff initials: $\frac{1}{first \mod 100}$ Not done \rightarrow Specify reason (use Codelist below): $\frac{1}{modello}$ DATEHDR (TYPE 4)
Cli	nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
w	sight 1: SAME AS PAGE 4
W	weight 2: ——·— kg WEIGHT (TYPE 4)
W	sight 3: kg
W	sight of gown: kg
	ital Signs
As	sessment date and time:/
Ī,	If waist measurement not done → Specify reason (use codelist below): VITALS (TYPE 3) Natural waist measurement
	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time): Staff initials: first middle last
	Natural waist measurement 1: cm
	Natural waist measurement 2: cm SAME AS PAGE 29
	Natural waist measurement 3: cm
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):
	Umbilical point waist measurement 1: cm
	Umbilical point waist measurement 2: cm
	Umbilical point waist measurement 3: cm
3	Pulse: bpm OR Not done → Specify reason (use codelist below): Staff initials:
4	Temperature: °C OR Not done → Specify reason (use codelist below): Staff initials:
5	Respirations: per minute OR Not done → Specify reason (use codelist below): Staff initials:
6	Blood pressure (check only one): 1 Left arm 2 Right arm Staff initials: first middle last
	6a Blood pressure 1:/ mm Hg
	6b Blood pressure 2:/ mm Hg Time::
	6c Blood pressure 3:/ mm Hg Time::: _
No	t Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



PAGEID = 87

	Center Number: Parti	cipant Number: Particip	ant's Initials: first middle last	
Pregnancy	Test			
Complete only	for females.	PREGTEST	(TYPE 4)	
□ ₀ No □ ₁ Yes → If	cant have reproductive potential? SAME AS PAGE PAGE AS PAGE AS PAGE PAGE PAGE PAGE PAGE PAGE			
Core Temp	erature			
Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure ADMIT (TYPE 3	If Not Done, Reason (Use codelist below)	
SINTIALS	Start Date: CTSTRDT day /	Start Time CTSTRTM 00:00 to 23:59	CTND <tund></tund>	
first middle last	CTSTPDT Stop Date: /	Stop Time CTSTPTM 00:00 to 23:59		
Inpatient A	Admission and Discharge			
1 Inpatient adn	nission date and time:/			
Not Done Codelis	st: 1 Participant refused 2 Clinician unable to obtain 3	3 Insufficient time 4 Instrument failure	5 Not required	
			- 1 101 10401104	

CRF, page 88

calerie Phase 2

PAGEID = 88

Baseline Submission 2 Visit 7

Center Number:	Participant Number:	Participant's Initials:	first middle la	- In a
		PARHDR (TYPE 4)	TITST MINDONE IN	251

Se	Seven-Day Physical Activity Recall (PAR)														
Tod	Today's date:/														
		day month ye ou employed in the last seve		, , ,		→ Skip to que						Interv	iewer ini	tials: first	widella last
	-	/hich days (check all that apply)?	-		☐ Mon	Tues	_			Sat	Sun			msr .	naddle ldsr
3	Which d	ays do you consider your w			? Mon	Tues				Sat					
Day	Day of	Date	Slee	o Time	Work	Time	Mor	ning (in mi		After	noon (in n		Even	ing (in min	
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7 (yester- day)		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					PAI	RCHT	(TYPE	4)PS	
6		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
5		/	00:00 to 23:59	00:00 to 23:59	:::00:00 to 23:59	00:00 to 23:59									
4		/	00:00 to 23:59	00:00 to 23:59	:::	00:00 to 23:59			SAME :	AS PA(——	SE 71 ———				
3		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
2		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1 (7 week ago)		/	00:00 to 23:59	00:00 to 23:59	:: 00:00 to 23:59	00:00 to 23:59									



PAGEID = 89

	Center Number: Participant Number: Participant's Initials:
S	even-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) And the same less SAME AS PAGE 72
	3 About the same
In	nterviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? No Yes
6	Do you think this was a valid Seven-Day PAR interview? No Yes
7	Were there any activities reported by the participant that you don't know how to classify?



PAGEID = 90

		Center Number:	Participant Number: _	Particip	ant's Initials:
Outcomes Labs					
Date and time of last med			LMEALTM 00:00 to 23:59 SAMPTM year 00:00 to 23:	OUTCMELB	(TYPE 4)PS
OTCMSAMP<	Sample TUOTCM>	SA	Sample Complete? MPCOL <xyesno></xyesno>	If Not Done, Reason (Use codelist below)	Staff Initials
1 = Ca1	recholamines		□ ₀ No □ ₁ Yes	SAMPND <tund< td=""><td>SAMPINII First middle last</td></tund<>	SAMPINII First middle last
2 =	Blood		□, No ADÖITIONAL ITEN	IS ON NEXT SLIE	PE FOR
3 = Oral glucose			THE OUTCMELB F	PANEL	first middle last
4 = Vaccination If a sample is not obtained,		•		BIOPSY (T	YPE 4)PS
Biopsy Labs					
Sample BIOPSY <tubio< th=""><td>OP></td><td></td><td>Collection</td><td>If Not Done, Reason (Use codelist below)</td><td>Staff Initials</td></tubio<>	OP>		Collection	If Not Done, Reason (Use codelist below)	Staff Initials
1= Muscle biops	у	day month year		OPSYND <tund:< td=""><td>BIOPINIT first middle last</td></tund:<>	BIOPINIT first middle last
2= Fat biopsy		/mont	/		first middle last
24-hour Urine C	ollection				
Total Volume Collected		Date of le Collection	Time of Sample Collectio	If Not Done Reason (Use codelist be	Staff Initials
TVOLURN <i:6></i:6>	URN /	art Date: STRDT	Start Time: URNSTRTM 00:00 to 23:59	URINE24	ND> <u>URNINIT</u>
	URN	STPDT	Stop Time: URNSTPTM 00:00 to 23:59		first middle last

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

3 Insufficient time

4 Instrument failure

2 Clinician unable to obtain

5 Not required

Not Done Codelist: 1 Participant refused

Panel Items not Displayed here appear on p.211: HEPA, TD, PV ALL <xyes></xyes>				
Panel Items not Displayed here appear on	p.211:			
HEPVAC <tuhvac></tuhvac>				
1= HAVRIX				
2= VAQTA				
98= OTHER				
TETVAC <tutvac></tutvac>				
1= DECOVAC				
98= OTHER				
PNEUVAC <tupvac></tupvac>				
1= PNEUMOVAX	SEE PAGE 211			
98= OTHER				
HEPSPEC V:30				
TETSPEC V:30				
PNEUSPEC V:30				
HEPLOT V:20				
TETLOT V:20				
PNEULOT V:20				

calerie Phase 2

Baseline Submission 2 Visit 7

PAGEID = 90A

AGEID = 90A Cei	nter Number:	Participant Number	:	Participant's Initia	first middle last
Sex Hormone					
If Not Done → Specify reason (use codelist be	low):STUDYN	D DATEHD	R (TYPE 4)		
Continuedisculate in The Martin of Sinitials STUDYTM or SINITIALS NONE	None OR Ch	eck all that apply Oral contraceptive	· QUTĆI	ME2 (TYPE ORALSP < V.F	00> ntions page
Day 1	THER <xyes></xyes>	ate	Time	If Not Done, Reason (use codelist)	Staff Initials
Day 1 of menses (females enly)	MEN	SESDT			
Date and time of last meal (males only)	/_LME_	AL/DT	LMEALTM 		
Hormone level blood draw 1 (males only)	/_HDR	AWDT year	00:00 to 23:59		first middle last /INIT <v:3></v:3>
Hormone level blood draw 2 (fomales only) Progesterone level	HD	RAW2DT	HDRAW2TM	HDRAW2ND<7 HDW2I	TUND> NIT <v:3></v:3>
Day 2	De	ate	Time	If Not Done, Reason (use codelist)	Staff Initials
Date and time of last meal	LMEA	L2DT	LMEAL2TM		
Hermone level blood draw 3 (females enty) Progesterene level	HDRAV	V3DT	HDRAW3TM	HDRAW3ND<7 HD	UND> W3INIT <v:3< td=""></v:3<>
DXA Scan					
Has the participant taken a calcium suppling No		n the Subject Sca		N (TYPE 4) e QA Center.	1
□0 140 □1 162	E AS PAGE 35			uled DXA exam?	?
	ne area scanned s	, , ,		D D NA	
Date of scan:/	ay only WBDY W	BDYND REW Date of rescan:		R	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Area Scar Check all tha		
☐ Whole body			☐ Whole body		
Not Done Codelist: 1 Participant refused 2 C	linician unable to obtai	n 3 Insufficient t	ime 4 Instrument	failure 5 Not n	equired



PAGEID = 91 Participant's Initials: first middle last Center Number: ___ Participant Number: ___ _

Metabolic Rate Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
RMRVISIT <turmr> Resting Metal Polic Rate (RMR)—Visit 7</turmr>	RMRDT 	RMRND <tund> ———</tund>	RMRINIT
CARTID <tucart> 1=</tucart>	☐ Tufts-003 (623-002) ☐ WASH U-00	5= (623-003) PBRC-0 (623-004) 6 PBRC-0	016 (623-005) 017 (623-001)
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 8	/		first middle last
Cart ID	☐ Tufts-003 (623-002) ☐ WASH U-001 ☐ Tufts-006 (623-006) ☐ WASH U-001	· · —	016 (623-005) 017 (623-001)

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time

RMR (TYPE 4)PS

4 Instrument failure 5 Not required



Baseline Submission 2 Randomization

PAGEID = 92

	Center Number:	Participant Number: _	Participant's Initials:	first middle last
Randomization				
Date of randomization:/	/_RANDOMDT		RANDOM (TYPE 1)	
Treatment Group				
To which treatment group was the par		(B) (1.79)		
Intervention				
Did participant start intervention? □₀ No → Complete the Study con □₁ Yes → If Yes: Date intervention	npletion/Early Discontinua		on .	
Staff Signature NOTE: Signa	ature of staff that randomiz	ed participant		
Signature: NOT DATABAS	SED		Date: NOT DATABASED	



Month 1 Submission CR Visit Study Week 2

CRF, page 93

		Findings ECG (TY	r L 4)	
	Normal Normal, not clinical	lly significant (specify):		first middle last
/		OAFETY	ID (T)	(DE 4)
nonth	year 00:00 to	OATETT	LB (I)	(PE 4)
Samp	ole Complete?	(Use codelist below)	Staf	f Initials
□ ₀ No		LMEALTM_	1	AS PAGE
	month Samp	Abnormal, clinically s month year 00:00 to Sample Complete? Do not display	SAME AS PAG Abnormal, not clinically significant (specify): Abnormal, clinically significant (specify): Sample Complete? Sample Complete? Sample Complete	SAME AS PAGE 30 Normal SAME AS PAGE 30 Abnormal, not clinically significant (specify): Abnormal, clinically significant (specify): Abnormal, clinically significant (specify): SAFETYLB (T) Sample Complete? If Not Done, Reason (Use codelist below) SAME Do not display SAME



	Center Number: Participant Number:	Participant's Initials:
C	linic Weight	
	reight date and time:/	Staff initials: Tree Trick Tric
Cli	inic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time	e):
W	eight 1: kg SAME AS PAGE 4	
W	eight 2: kg	WEIGHT (TYPE 4)
W	eight 3: kg	
W	eight of gown: kg	
	ital Signs	
As	sessment date and time:/	
1	If waist measurement not done → Specify reason (use codelist below): Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third	VITALS (TYPE 3) Staff initials: first middle lost
	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, me umbilical point waist circumference a third time):	asure
	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:: OR Not d Specific	one → 'y reason (use codelist below):
	6b Blood pressure 2:/ mm Hg Time:: :	
	6c Blood pressure 3:/ mm Hg Time::: _:	
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time	4 Instrument failure 5 Not required



CRF, page 95

PAGEID = 95

Center	Number: Participant i	Number: rai	first middle last		
12-Lead ECG					
Date and Time		Findings ECG (TYP	Staff Initials		
DATEHDR (TYPE 4) ———————————————————————————————————		SAME AS PAG Ily significant (specify): ignificant (specify):	OTHERSP first girlello lost		
Safety Labs					
Date and time of last meal: /					
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Blood	□₀ No □₁ Yes	SAME AS PAGE	first middle Tost		
Urine	□ ₀ No □ ₁ Yes		first middle last		
Contraception					
If Not Done → Specify reason (use codelist below):	CNTRAND <tund></tund>				
Contraception method (females only):					
Not Done Codelist: 1 Participant refused 2 Clinici	ian unable to obtain 3 Insuff	ficient time A Instrument failu	ure 5 Not required		
Transpani relosed 2 Clinici	an onable to obtain 3 insun	icieni iiiie 🗕 iiisii uiileili Idii	ore 3 Nor required		

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

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



Month 3 Submission CR Visit Study Week 6

Center	Number: Participant	Number: Pa	rticipant's Initials:
12-Lead ECG			
Date and Time		Findings ECG (TY	(PE 4) Staff Initials
DATEHDR (TYPE 4)	Is ECG (check only one): 1 Normal 2 Abnormal, not clinical 3 Abnormal, clinically s	first middle last	
Safety Labs (Potassium Surveillance)			
Date and time of sample collection:/	year	SAFETY	LB (TYPE 4)
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□ ₀ No □ ₁ Yes		ME AS PAGE 93
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuf	ficient time 4 Instrument fail	ure 5 Not required



Month 3 Submission CR Visit Study Week 8

Center	Number: Participant	Number: Pa	rticipant's Ini	first middle last
12-Lead ECG				
Date and Time		Findings ECG (TY	'PE 4)	Staff Initials
DATEHDR (TYPE 4) ———————————————————————————————————		SAME AS PAGE : Illy significant (specify): significant (specify):		first middle last
Safety Labs (Potassium Surveillance)	Š.		*	
Date and time of sample collection:/	/	SAFETY	LB (T)	/PE 4)
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staf	f Initials
Blood	□ ₀ No □ ₁ Yes		ME AS F	PAGE 93
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuf	ficient time 4 Instrument fail	ure 5 No	t required



PAGEID = 101

	Center Number: Partiapant Number: Partiapant's Initials:
Cl	inic Weight
We	right date and time:/: Staff initials:
	Not done \rightarrow Specify reason (use Codelist below): DATEHDR (TYPE 4)
Cli	nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
	ight 1: SAME AS PAGE 4
We	ight 2: WEIGHT (TYPE 4)
We	ight 3: kg
We	ight of gown: kg
V	tal Signs
As	sessment date and time:/
Г	If waist measurement not done → Specify reason (use codelist below): VITALS (TYPE 3)
ı۱	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):
	Natural waist measurement 1:
	Natural waist measurement 2: SAME AS PAGE 29
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure
1	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
Ļ	Staff initials
3	Pulse: bpm OR Not done → Specify reason (use codelist below): Staff initials:
4	Temperature: °C OR Not done → Specify reason (use codelist below): Staff initials:
5	Respirations: per minute OR Not done → Specify reason (use codelist below): Staff initials: Staff initials:
6	Blood pressure (check only one): 1 Left arm 2 Right arm Staff initials: 1 Tent middle lost
	6a Blood pressure 1: / mm Hg Time:: OR Not done \rightarrow Specify reason (use codelist below):
	6b Blood pressure 2: / mm Hg
	6¢ Blood pressure 3:/ mm Hg Time:::
Ļ	
No	t Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

ham NC 27705



PAGEID = 102

Center	Number:	rariidpani i	Number: _	Par	ticipant's ini	first middle last
12-Lead ECG						
Date and Time			Findin	95 ECG (TYP	E 4)	Staff Initials
DATEHDR (TYPE 4)	Is ECG (check only one): SAME AS PAGE 30 Abnormal, not clinically significant (specify): Abnormal, clinically significant (specify):					first middle last
Safety Labs						
	/	: : : : : : : : : : : : : : : : : : :		SAFETYLE	3 (TYPI	E 4)
Sample	Sample	Complete?		Done, Reason codelist below)	Staf	i Initials
Blood	□₀ No □₁ Yes			SAME AS		niddle last
Urine	□₀ No □₁ Yes				first	middle fast
Outcomes Labs						
Date and time of last meal: Date and time sample collection started: day day	// 	/	00:00 to 23:	OUTCME SAME AS		
Sample		Sample Com	plete?	If Not Done, Reason (Use codelist below		iff Initials
OTCMSAMP <tuotcm> Blood Display only item 2= Blood</tuotcm>		□₀ No □₁ Yes			fi	rst middle last
If a sample is not obtained, indicate with a Not Done.						
Contraception						
If Not Done → Specify reason (use codelist below):	:					
Contraception method (females only): SAME AS PAGE 95	☐ None O		ceptive →	Specify: Record on Concom	nitant Medi	cations page
		∐ Other → Sp	oecify (e.g	g., barrier, IUD):		

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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

am NC 27705

5 Not required



calerie Phase 2

AGEID = 106			ər:		Partici	pant's Ini	tials:	middle last	
Date completed:	SAME AS PAGE : _/OR Not done → Specify	36 reason	DAT (use code	EHDF elist belov	R (TYF v):	PE 4)			
MAEDS (TYPE 4)PS Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)									
Instructions: Using the	e scale shown, please rate the following items on a sca	le from 1	to 7. Ple	ase ansv	wer as tr	uthfully	as possi	ble.	
	SAME AS PAGE 65	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always	
1 Fasting is a go	od way to lose weight.			З	□₄		□ ₆		
2 My sleep isn't	as good as it used to be.			\square_3			6		
3 I avoid eating	for as long as I can.			З			□ ₆		
4 Certain foods	are "forbidden" for me to eat.			З		□₅	□₀		
5 I can't keep cer binge on them.	tain foods in my house because I will			Пз	□₄		□6		
6 I can easily mo	ake myself vomit.			\square_3			6		
7 I can feel that	being fat is terrible.			\square_3			6		
8 I avoid greasy	foods.			З			□,		
9 It's okay to bir	nge and purge once in a while.								
10 don't eat cert	rain foods.			З			□,		
11 I think I am a g	good person.			\square_3			6		
12 My eating is no	ormal.			З			6		
13 I can't seem to	concentrate lately.			3	4		6		
14 I try to diet by	fasting.			З		\square_{5}	6		
15 I vomit to contr	rol my weight.			3	4		6		
16 Lately nothing	seems enjoyable anymore.			\square_3	\square_{4}	\square_5	6		
17 Laxatives help	keep you slim.			З	4		6		
18 I don't eat red	meat.			\square_3			6		
19 I eat so rapidly	/ I can't even taste my food.			З			□6		
Not Done Codelist: 1	Participant refused 2 Clinician unable to obtain 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	d	
	CALERIE PHASE2 ANNOTATION V8.0 2	24FEB	2012		Partici	pant's In	itials:	t middle last	



PAGEID = 107

MAEDS (TYPE 4)PS

Center Number: Po	riicipani iv	umber: _		Pai	rtiapants	initials:	irst middle last
Multiaxial Assessment of Eating Disorder S	ympto	ms (MAEDS)	continue	d)		
SAME AS PAGE 66	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being overweight.			Пз			□ ₆	
21 When I feel bloated, I must do something to rid myself of that feeling.					5		
22 I overeat too frequently.			_3			□ ₆	
23 It's okay to be overweight.			Пз			□,	
24 Recently I have felt that I am a worthless person.						6	
25 I would be very upset if I gained 2 pounds.			Пз			□,	
26 I crave sweets and carbohydrates.			3			□,	
27 I lose control when I eat.			З			□,	
28 Being fat would be terrible.			3			□ ₆	
29 I have thought seriously about suicide lately.			\square_3			6	
30 I don't have any energy anymore.			_3			6	
31 I eat small portions to control my weight.			\square_3		_5	6	
32 I eat 3 meals a day.			\square_3	4	5	6	
33 Lately I have been easily irritated.			□₃		5	6	
34 Some foods should be totally avoided.			3			6	
35 I use laxatives to control my weight.]3			□,	
36 I am terrified by the thought of being overweight.			З		5	□ ₆	
37 Purging is a good way to lose weight.			\square_3			□6	
38 I avoid fatty foods.			З		5	6	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: First middle last



PAGEID = 108

MAEDS (TYPE 4)PS

	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Ass	essment of Eating Disorder	Sympto	oms (MAEDS)	(continue	d)		
	SAME AS PAGE 67	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have	e felt pretty blue.			Пз				
40 I am obsessed	with becoming overweight.			Пз			□6	
41 I don't eat fried	d foods.			Пз				
42 I skip meals.				Пз	□₄			
43 Fat people are	unhappy.						6	
44 People are too	concerned with the way I eat.			Пз			6	
45 I feel good wh	en I skip meals.			3	4		6	
46 I avoid foods w	ith sugar.			Пз			□,	
47 I hate it when I	feel fat.			3				
48 I am too fat.				Пз	□₄	\square_5	□ ₆	
49 l eat until l am	completely stuffed.			3			□ ₆	
50 I hate to eat.				Пз	4		□ ₆	
51 I feel guilty abo	out a lot of things these days.			3				
52 I'm very carefu	ul of what I eat.			3	□4		□ ₆	
53 I can "hold off	" and not eat even if I am hungry.			3			6	
54 I eat even whe	n I am not hungry.			Пз	□₄		□6	
55 Fat people are	disgusting.			3			□ ₆	
56 I wouldn't mind	d gaining a few pounds.			Пз				
	CALERIE PHASE2 ANNOTATION	V8.0 24F	EB201	2	Po	rticipant's	Initials:	first middle last

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



Month 6 Submission CR Visit Month 4

Date and Time	4)	Findings ECG (TY	PE 4) s	itaff Initi
DATEHDR (TYPE 2 lay / /	59	SAME AS PAGE 3		first middle la.
see codelist below):		significant (specify):		
afety Labs (Potassium Surveillance) the and time of sample collection:		:		DE 1)
afety Labs (Potassium Surveillance)			LB (TYI	PE 4)
afety Labs (Potassium Surveillance) Ite and time of sample collection:/		SAFETYI If Not Done, Reason (Use codelist below)	LB (TYI	Initials



Month 6 Submission **CR Visit Month 5**

PAGEID = 110

Date and Time		Findings ECG (TY	PE 4) Sto	aff Initia
DATEHDR (TYPE 2 day //	Normal Abnormal, not clinically	SAME AS PAGE 3		first middle last
Safety Labs (Potassium Surveillance)				
diely Labs (Foldssium Surveillance)				
Date and time of sample collection:		SAFETYL	_B (TYP	PE 4)
		SAFETYL If Not Done, Reason (Use codelist below)	_B (TYP	,
Pate and time of sample collection:/	month year 00:00 f	If Not Done, Reason (Use codelist below)		itials



		Center Number:	Participant Number:	Participant's Initials: first middle last
C	linic Weight			
W	reight date and time:/ _{month} /		0:00 to 23:59	Staff initials:
OF	R Not done → Specify reason (use Code	ist below):	_	DATEHDR (TYPE 4)
Cli	inic weight (if the first two measurements ar	e more than 0.1 kg	apart, measure weight a third time	e):
W	/eight 1:	kg	SAME AS PAGE 4	
W	'eight 2:	kg		WEIGHT (TYPE 4)
W	/eight 3:	kg		
W	eight of gown:	kg		
٧	ital Signs			
As	ssessment date and time:/ _{day} / _{month}	/	00:00 to 23:59	
	If waist measurement not done → Spe	cify reason (use co	delist below):	VITALS (TYPE 3)
1	Natural waist measurement (if the first two measurements are more than 1	.0 cm apart, measure	e natural waist circumference a third	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 umbilical point waist circumference a third time		ents are more than 1.0 cm apart, me	asure
	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 reasc	on (use codelist below):	Staff initials:
4	Temperature: °C OI	Not done → Sp	ecify reason (use codelist below):	Staff initials: middlelast
5	Respirations: per minute OR	Not done → Spec	ify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):1 Le	ft arm \square_2 Right	arm	Staff initials:
	6a Blood pressure 1:/	mm Hg Ti	ime:: OR Not d Specif	one → y reason (use codelist below):
	6b Blood pressure 2:systolic /dic	mm Hg T		
	6€ Blood pressure 3:/	mm Hg Ti	me: :	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable	to obtain 3 Insufficient time	4 Instrument failure 5 Not required



PAGEID = 112

	Center Number:	_ Participant N	lumber: Po	articipant's Initials: First middle last
12-Lead ECG				
Date and Time			Findings ECG (TYF	PE 4) Staff Initials
DATEHDR (TYPE 4) day / month / year 00:00 to 3 SAME AS PAGE 30 OR Not done → Specify reason (see codelist below): Safety Labs	23:59	rmal, not clinicall	SAME AS PAGE y significant (specify): gnificant (specify):	30 First middle last
			SAFEIYL	B (TYPE 4)
Sample	Sample (Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□ ₀ No □ ₁ Yes		SAME 	AS PAGE 30
Urine	□ ₀ No □ ₁ Yes			first middle lost
Contraception				
If Not Done → Specify reason (use codelist	below):			
Contraception method (females only): SAME AS PAGE 95	l l	Oral contrac	eptive → Specify:	mitant Medications page
Not Done Codelist: 1 Participant refused	2 Clinician unable to o	btain 3 Insuffi	cient time 4 Instrument fai	lure 5 Not required



Month 6 Submission CR Visit 2

Ce	enter Number:	Participant Number: Participant's Initials:	nidale last					
Clinic Weight								
Weight date and time:/ _{month} /	vegr 00:00 to 23:	Staff initials:						
OR Not done → Specify reason (use codelist l		DATEHDR (TYPE 4)						
Clinic weight (if the two measurements are more								
Weight 1: kg	S.F	AME AS PAGE 4						
Weight 2: kg	ı	WEIGHT (TYPE 4)						
Weight 3: kg	ı							
Weight of gown: kg								
Pregnancy Test								
Complete only for females.		PREGTEST (TYPE 4)						
Does participant have reproductive poter		CAME AS DAGE 22						
☐ ₁ Yes → If Yes: Date urine pregnancy t	est pertormed:							
Results: □ ₁ Negative □ ₂ Positive								
DXA Scan								
Has the participant taken a calcium supp □ ₀ No □ ₁ Yes → If Yes: Proceed with	scan and document in dioisotopes performed	DXASCAN (TYPE 4) In the Subject Scan Log to inform the QA Center. In the Weeks prior to the scheduled DXA exam? AS PAGE 35						
DXA Scan		DXA Rescan ORNA						
Date of scan:/	_	Date of rescan:/						
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply						
☐ Whole body		☐ Whole body						
Forearm		☐ Forearm						
Spine		☐ Spine						
☐ Hip		Hip						
Not Done Codelist: 1 Participant refused 20	Clinician unable to obtain	in 3 Insufficient time 4 Instrument failure 5 Not required						



Month 6 Submission CR Visit 2

PAGEID = 114

		Center Nomber.	Participant Number: Participant's Initials:
D	oubly Labeled V	Vater (DLW)	
1	Date and time of DLW d	osing:/ /	DLWHDR (TYPE 4)
		reason (use codelist below):	SAIVIE AS PAGE 34
2	DLW dose mixture ID an	d bottle number: =	CA
3	Exact weight of DLW mix	dure:	grams
4	Urine samples:		DLWCHT (TYPE 4)PS
	Collection	Sample	Date and Time Collected
	Pre dosing (PD)	_{PDa} SAME A	S PAGE 34//
		PDb	/
	Day 0 (Visit 2)	DOa	/
		DOP	//
	Day 7 (Visit 3)	D7a	/
		D7b	day month year 00:00 to 23:59
	Day 14 (Visit 5)	D14a	/
		D14b	/
		h di	DISPLAY DLWLBL2
5	Attix CRF page label(s) (corresponding to this urine s	ample set: Affix Affix Test Sample Retest Sample Label Here Label Here
			Labernere Labernere

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



PΔ	GFI	D = 1	121

٠٠.	-10 - 121	Center Number:	_ Participant N	lumber:	Participant's Ir	nitials:
Da	te completed:/ _{month} /	OR Not don	e → Specify red	ason (use codelist be	low):	T. (D.)
	rofile of Mood States	SAME A	S PAGE 36		DATEHDR (TYPE 4)
	structions: Please describe how you	J feel right now by ch	ecking one box	c for each of the wo	ords listed below.	
	Feeling	Not At All	A Little	Moderately	Quite A Bit	YPE 4)PS Extremely
1	Friendly	\square_{\circ}	SAME A	S PAGE ₂ 42	\square_3	4
2	Tense	\square_{o}	\square_1	\square_{2}	\square_3	\square_4
3	Angry	\Box_{o}			\square_3	4
4	Worn out	\square_{o}	\square_1	\square_{2}	\square_3	\square_4
5	Unhappy				\square_3	4
6	Clear-headed	\square_{o}	\square_1	\square_{2}	\square_3	4
7	Lively	\square_{o}			\square_3	4
8	Confused	\square_{o}	\square_1	\square_{2}	\square_3	4
9	Sorry for things done	\square_{o}			\square_3	4
10	Shaky	\square_{o}	\square_1	\square_{2}	\square_3	\square_{4}
11	Listless	\square_{o}			\square_3	4
12	Peeved	\square_{o}	\square_1	\square_{2}	\square_3	4
13	Considerate	\square_{o}			\square_3	4
14	Sad	\Box_{o}	\square_1	\square_{2}	\square_3	4
15	Active	\square_{o}			\square_3	4
16	On edge	\square_{o}	\square_1	\square_{2}	\square_3	\square_4
17	Grouchy	\square_{o}			\square_3	4
18	Blue	\square_{o}	\square_1	\square_{2}	\square_3	\square_{4}
19	Energetic				Пз	4
20	Panicky				Пз	4
	ight © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. M North Tonawanda, NY 14120-0950. In Canada, 3770			icense to Multi-Health System	ns Inc. All rights reserved.	In the U.S.A., P.O. Box
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to a	btain 3 Insuffi	cient time 4 Instru	ment failure 5 N	ot required

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



PA	GFI	$D \ge 1$	122

	Center Number: _	Participan	t Number:	Participant's I	nitials:
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					PS
22 Relaxed	□ ₀ SA	AME AS PAGE	∃ 43 □₂	\square_3	
23 Unworthy				3	4
24 Spiteful	\square_{\circ}			\square_3	\square_4
25 Sympathetic	\square_{\circ}			\square_3	
26 Uneasy	\square_{o}			\square_3	□4
27 Restless				\square_3	4
28 Unable to concentrate				3	4
29 Fatigued				□₃	4
30 Helpful]3	4
31 Annoyed				_3	4
32 Discouraged				\square_3	4
33 Resentful]3	4
34 Nervous				З	4
35 Lonely				3	4
36 Miserable	□₀			₃	4
37 Muddled				3	4
38 Cheerful]3	4
39 Bitter]3	4
40 Exhausted]3	
41 Anxious				□₃	\square_4
42 Ready to fight	\square_{o}			\square_3	4
43 Good-natured				\square_3	_4
C . (0 0000 0000 () . (0 0 0 0) . ()	14 24 - 01 0 4 01/0 //	1 , 010 / 1 .	to a 14 feat to a .	1 111 : 11	1 / 1/01 00 0

950, North Tonawanda, NY 14120-0950. In Canada, 3770 Victoria Park Ave., Toronto, ON M2H 3M6

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



	Λ.	\sim	_	_	40	-
$\mathbf{-}$	/\ 1	_	_	 _	11.	,

	Center Number: _	Participar	Participant's Initials:			
Profile of Mood States	continued)					
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely	
44 Gloomy					PS	
45 Desperate	□ ₀	AME AS PAGI	E 44 □₂	\square_3		
46 Sluggish	\square_{o}	\square_1	\square_{2}	\square_3	4	
47 Rebellious				\square_3	4	
48 Helpless				Пз		
49 Weary		□ ₁		\square_3		
50 Bewildered	\square_{o}	\square_1	\square_{2}	\square_3	\square_{4}	
51 Alert		□ ₁				
52 Deceived	\square_{o}	\square_1	\square_{2}	\square_3		
53 Furious		□ ₁				
54 Efficient				Пз		
55 Trusting		□ ₁			4	
56 Full of pep	\square_{o}	\square_1		\square_3		
57 Bad-tempered				\square_3	4	
58 Worthless	\square_{o}	\square_1	\square_{2}	\square_3	4	
59 Forgetful		\Box_1		\square_3	4	
60 Carefree	\square_{o}			\square_3	4	
61 Terrified				\square_3	4	
62 Guilty				Пз		
63 Vigorous	□₀			□ ₃	4	
64 Uncertain about things	\square_{o}	\square_1	\square_2	\square_3	4	
65 Bushed	\square_{o}			\square_3	4	
0	14 14 1 54 5 4 5145 14		. t		1 1 1101 00 0	

Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. McNair Ph.D., and JW P. Heuchert, Ph.D. under exclusive license to Multi-Health Systems Inc. All rights reserved. In the U.S.A., P.O. Box 950, North Tonawanda, NY 14120-0950. In Canada, 3770 Victoria Park Aye., Toronto, ON M2H 3M6. Participant's Initials: first middle last

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

rham NC 27705



	Center Number: I	Participant Number: _		Participant's In		s Initials: _	rst middle last	
Date completed:day //	year OR Not done	Specify reason (use AGE 36	codelis					
Perceived Stress Scale (PS	SS)							
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.								
	SAME AS PAGE 4	5 Ne	ever	Almost Never	Some- times	Fairly Often	Very Often	
I In the last month, how often unable to control the import	이 보고 있는데 이번 이번 시간에 보고 있는데 아이를 하는데 하는데 하는데 하는데 없다면 하는데 없었다.	were	□₀				□ ₄	
2 In the last month, how often your ability to handle your p	er and a mandred control . # 이번 있는데 아르네 요즘 아이를 맞았습니다. 하는데 하는데 아이를 다 되었습니다. 그리아 아르네 아이	t about	o			\square_3	\square_{4}	
3 In the last month, how often going your way?	have you felt that thin	gs were					□ ₄	
4 In the last month, how often piling up so high that you co								
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required								



ca	le	rī	e	Phase	2
----	----	----	---	-------	---

PAGEID = 125 Center Number: Participant	Number:	Partic	ipant's Initial	S:
Date completed: $\{day}$ / $\{month}$ / $\{year}$ OR Not done \rightarrow Specify reSAME AS PAGE 36	eason (use code	elist below): DATEH	DR (TY	PE 4)
Pittsburgh Sleep Quality Index (PSQI)			,	•
Instructions: The following questions relate to your usual sleep habits during the most accurate reply for the majority of days and nights in During the past month SAME AS PAGE	the past month	n. Please answe		ons.
1 When have you usually gone to bed?:				
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?	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
 Cannot get to sleep within 30 minutes 				\square_3
b Wake up in the middle of the night or early morning	\square_{0}	\square_1		\square_3
c Have to get up to use the bathroom				\square_3
d Cannot breathe comfortably	\square_{o}	\square_1		\square_3
e Cough or snore loudly	\square_{0}			\square_3
f Feel too cold	\square_{o}	\square_1		З
g Feel too hot	\Box_{0}			\square_3
h Have bad dreams	\square_{o}	\square_1		\square_3
i Have pain				\square_3
i Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):	\square_{o}	\square_1	\square_{2}	\square_3
6 During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	□₀			3
© 1989,with permission from Elsevier Science. Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time 4	Instrument failure	5 Not re	equired



PAGEID = 126

	Center Number: Participant	Number:	Parti	icipant's Initials	first middle last
Pi	ttsburgh 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?				\square_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?				Пз
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?	□.			Пз

CALERIE PHASE2 ANNOTATION V4.12JUN2008

Participant's Initials: first middle last



PAGEID =	127

	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed: $\{doy}$ / $\{porth}$ / $\{year}$	OR Not done → Specify	reason (use codelist below):	ATEHDR (T	YPE 4)

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

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

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

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience. SAME AS PAGE 48

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

DISFEM1 (TYPE 4)PS

Section 1—Sexual Cognition/Fantasy Not at Less 1 or 2 1 per 2 or 3 4 to 6 1 per 2 or 3 4 or During the past 30 days or since the last time all than 1 week per per per day per more you filled out this inventory, how often have month per week week day per you had thoughts, dreams, or fantasies about: month day 1.1 A sexually attractive person 1.2 Erotic parts of a man's body (e.g., face, shoulders, legs) 1.3 Erotic or romantic situations 1.4 Caressing, touching, undressing, or foreplay 1.5 Sexual intercourse, oral sex, touching to orgasm Copyright © 1987 by Leonard R. Derogatis, PhD. 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 = 128

	Center Number:	ımber: Participant Number:			Participant's Initials: first middle last				
Derogatis Interview for Se	xual Functi	on (DIS	F-SR) (F)	Female \	/ersion (ontinued)		
Section 2—Sexual Arousal SAME AS PAGE 49 DISFEM1 (TYPE 4)PS									PS
During the past 30 days or since the time you filled out this inventory, how did you have the following experience	v often 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 o	alone				4		□6		□,
2.2 Actively seek sexual satisfacti	on \square_{\circ}				□₄	\square_5	□。		□,
2.3 Feel sexually aroused with a partner					4	5	□6		□8
	Never	Rarely	Sometimes	Usually	Always	DISFE	M2 (ГҮРЕ	4)PS
2.4 Have normal lubrication with masturbation					□ ₄				
2.5 Have normal lubrication throughout sexual relations									

Copyright © 1987 by Leonard R. Derogatis, PhD.



PAGEID = 129

Center Nu	mber:	P	articipant N	umber: _		Po	rticipant's	Initials:	irst middle last
Derogatis Interview for Sexual	Functi	on (DIS	SF-SR) (F)	Female \	ersion (ontinue	d)		
Section 3—Sexual Behavior/Experiences	SAM	E AS F	AGE 50)	DIS	SFEM	1 (TYF	PE 4)F	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	□,				□ ₄	5	□6		□8
3.2 Masturbation	□,			\square_3	□4	\square_5	\Box_{6}	\square_{7}	□8
3.3 Casual kissing and petting				□₃				□ ₇	□8
3.4 Sexual foreplay	口。			□₃	□₄	□ ₅	□6	□ ₇	□,
3.5 Sexual intercourse, oral sex, etc.	□.	□,		\square_3	□4	\square_5	□6		□₃
Section 4—Orgasm					DIS	SFEM	3 (TYF	PE 4)F	PS
During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm				□₃	□ ₄				
4.2 The intensity of your orgasm	□,			□₃	□₄				
4.3 The ability to have multiple orgasms (if typical for you)				□₃					
4.4 Feelings of closeness and togetherness with your partner	□.	П		□₃	□₄				
4.5 Your sense of control (timing) of your orgasm	□。			Пз					
4.6 Feeling a sense of relaxation and well-being after orgasm	□,			□₃	□4				

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 Send to DCRI Forms Management · 2400 Pratt St. · Room 0311 Terrace Level · Durham NC 27705



PAGEID = 130

	Center Number:	er Number: Participant Number:				Participant's Initials: first middle last			
Derogatis Interview for Se	xual Fund	tion (DISF-SR) (F) Female	Version	(continue	ed)		
Section 5—Drive and Relationship	SAME	AS PA	GE 51	С	ISFE	M1 (T	YPE 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	l 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 intercours					4		□6		□.8
	Not at	Slightly	Moderately	Highly	Extremely	DISFE	EM3 (T	YPE 4	4)PS
5.2 During this period, how interested have you been in so	ex? □.				4				
5.3 During this period, how satisfice have you been with your personal relationship with you sexual partner?					□₄ DI	SFEN	14 (TY	PE 4)F	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 repre- the best description of the qua of your sexual functioning?									

Copyright © 1987 by Leonard R. Derogatis, PhD.



DATEHDR (TYPE 4)

P

AGEID = 131	Center Number:	Participant Number:	Participant's Initials:	first middle last
	OD N - t - l > C ' C			

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

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

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

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

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

DISMALE1 (TYPE 4)PS

	SAME A	S DAG	E 52							
Section 1—Sexual Cognition/Fantasy										
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	l or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	l per day	2 or 3 per day	4 or more per day	
1.1 A sexually attractive person	□.		\square_2	\square_3	□₄	\square_5	□6		□8	
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	□。		\square_2	\square_3	□₄	\square_5		□7	□8	
1.3 Erotic or romantic situations	□.			\square_3	□ ₄	□ ₅			□8	
1.4 Caressing, touching, undressing, or foreplay	□₀		\square_2	\square_3	□4	\square_5			□8	
1.5 Sexual intercourse, oral sex, touching to orgasm	□.				□4					
Copyright © 1987 by Leonard R. Derogatis, PhD.										
Not Done Codelist: 1 Participant refused 2 Clinician und	able to ob	tain 3	Insufficier	nt time	4 Instrum	nent failure	9 5 No	ot require	d	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



		-	
\square	GF		400
PA		II) =	4.37

Center Number: Participant Number: Participant's Initials:									
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal SAME AS P.	AGE 53	3		DI	SMAL	.E1 (T`	YPE 4)PS	
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening	□₀				4		□6		□8
2.2 A full erection during a sexual fantasy or daydream	□,			Пз	□ ₄	\square_5	□。		□8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	□.				4		□₀		□₅
2.4 A full erection during masturbation	□.				□ ₄		□₀	□,	□.
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	□₀								

Copyright © 1987 by Leonard R. Derogatis, PhD.



PAGEID = **133**

Center Nu	mber:	Pa	rticipant Nu	ımber:		Participant's Initials: first middle last				
Derogatis Interview for Sexual I	unctio	n (DISI	F-SR) (M)	Male Ve	rsion (co	ntinued))			
Section 3—Sexual Behavior/Experiences	SAME	AS PA	GE 54	DI	SMAL	.E1 (T	YPE 4	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				Пз	□ ₄		□6		□8	
3.2 Masturbation				З	□₄		□6		□8	
3.3 Casual kissing and petting				3	_4		□ ₆		□8	
3.4 Sexual foreplay				\square_3			□6		□8	
3.5 Sexual intercourse, oral sex, etc.					_4	5			□ ₈	
Section 4—Orgasm					DIS	MALE	Ξ2 (Τ\	/PE 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				3	_4					
4.2 The intensity of your orgasm				\square_3						
4.3 The length or duration of your orgasm				\square_3	_4					
4.4 The amount of seminal liquid that you ejaculate				\square_3						
4.5 Your sense of control (timing) of your orgasm					_4					
4.6 Feeling a sense of relaxation and well-being after orgasm				Пз						

Copyright © 1987 by Leonard R. Dergantia Phil



PAGEID = 134

Center	Number:		Participant	Number:	Participant's Initials:				
Derogatis Interview for Sexua	l Func	tion (DISF-SR) (M) Male \	ersion (ontinue	4)		
Section 5—Drive and Relationship	SAME	AS PA	GE 55		DISN	//ALE	1 (TYP	PE 4)P	S
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?	□₀			\square_3	□₄		□₀		□,
	Not at all	Slightly	Moderately	Highly	Extremely	DISN	//ALE2	(TYP	E 4)PS
5.2 During this period, how interested have you been in sex?	□。			Пз	□₄				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	□。			\square_3	□₄	ISMA	LE3 (T	ΓΥΡΕ ⁴	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?	□。			Пз	□₄	5	□6		

Copyright © 1987 by Leonard R. Derogatis, PhD.



Month 6 Submission

PAGEID = 135	
PAGEID = 133	

AGEID = 135 Center Number: Partici		VISIT	•		
Date completed:/	pant Number: _ fygreason (use				
Food Cravings Questionnaire—State (FCQ-S)	. 30	U	ATERD	R(ITF	E 4)
Below is a list of comments made by people about their eating habits. Ple how much you agree with the comment right now, at this very mome while others refer to one or more specific foods. Please respond to each i					
SAME AS PAGE 58	Strongly Disagree	Disarros	Nevtral	Agree	Strongly Agree
I have an intense desire to eat [one or more specific foods].			\square_3		
2 I'm craving [one or more specific foods].			\square_3	\square_{4}	5
3 I have an urge for [one or more specific foods]			З		5
4 Eating [one or more specific foods] would make things seem just perfect.			\square_3		
5 If I were to eat what I am craving, I am sure my mood would improve.					5
6 Eating [one or more specific foods] would feel wonderful.			Пз		
7 If I ate something, I wouldn't feel so sluggish and lethargic.					5
8 Satisfying my craving would make me feel less grouch and irritable.	У П,				
9 I would feel more alert if I could satisfy my craving.					
10 If I had [one or more specific foods], I could not stop eating it.			Пз		
11 My desire to eat [one or more specific foods] seems overpowering.					
12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			Пз		
13 I am hungry.			\square_3		
14 If I ate right now, my stomach wouldn't feel as empty.					
15 I feel weak because of not eating.				4	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

2 Clinician unable to obtain

5 Not required

4 Instrument failure

Not Done Codelist: 1 Participant refused

3 Insufficient time



DAOEID	400	

Cer	nter Number: _	Par	ticipant Number:		first middle fast				
Date completed:day //	OR Not	done → Sp	ecify reason (us	e codelist below	T EHDR (TVPF 4)			
Food Craving Inventory (FCI-II				<u> </u>	(I E I I BIX	111 = 4)			
For each of the foods listed below, please che					· · · · · · · · · · · · · · · · · · ·	YPE 4)PS			
Note: A craving is defined as an intense desire Over the past month, how often	to consume	a particulai	_	ype that is diff	icult to resist.	Always/Almost			
have you experienced a craving for	•••	Never	Rarely (once or twice)	Sometimes	Often	Every Day			
1 Cake		SAME A	S PAGE 59	□₃	4	\square_5			
2 Pizza		\square_1	\square_{2}	□₃	□₄	\square_{5}			
3 Fried chicken				□₃	4	\square_5			
4 Gravy			\square_{2}	□₃	4	\square_5			
5 Sandwich bread				□₃	4	\square_5			
6 Sausage		\square_1	\square_{2}	□₃	\square_{4}	\square_5			
7 French fries				□₃	4	\square_5			
8 Cinnamon rolls		\square_1	\square_{2}	□₃	\square_4	\square_5			
9 Rice				□₃	4	\square_5			
10 Hot dog		\square_1		□₃	\square_4	\square_5			
11 Hamburger				□₃	4	5			
12 Biscuits		\square_1	\square_{2}	□₃	\square_{4}	\square_5			
13 Ice cream				₃	4	\square_5			
14 Pasta		\Box_1		\square_3		\square_5			
15 Fried fish				₃	4	_5			
16 Cookies		\square_1		□₃	4	\square_{5}			
17 Chocolate				₃	4	5			
18 Pancakes or waffles		\square_1		□₃	\square_{4}	\square_{5}			
19 Corn bread				₃	4	5			
20 Chips		\square_1		□₃	4	\square_{5}			
21 Rolls				□₃	4	\square_5			
22 Cereal		\square_1	\square_{2}	□₃	4	\square_5			
23 Donuts				□₃	4	\square_5			
24 Candy		\square_1		□₃	4	\square_5			
25 Brownies				□₃		\square_5			
26 Bacon				□₃	\square_4	\square_{5}			
27 Steak				□₃					
28 Baked potato		\square_1		□₃		\square_5			
	linician unable		3 Insufficient tim		nt failure 5 N	lot required			
CALERIE PH	ASE2 ANN	IOTATIO	N V8.0 24FE	B2012	Participant's I	nitials:			

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



			_		
Λ.	വ	_		-	_

		Center Number:	Participant Number:	Participant's I	nitials:
	ompleted:/ _{month} /	OR Not don	e → Specify reason (use codelist b AS PAGE 36	®AT EHD R (TYPE 4)
Eati	ng Inventory				
1	When I smell a sizzling difficult to keep from e	g steak or see a juicy ating, even if I have			
2	I usually eat too much	at social occasions, l	ike parties and picnics.	AME AS PAGE 	□₀ False
3	I am usually so hungry	that I eat more than	three times a day.	☐₁ True	o False
4	When I have eaten my not eating anymore.	quota of calories, I	am usually good about	□₁ True	□₀ False
5	Dieting is so hard for r	me because I just get	too hungry.	☐₁ True	□₀ False
6	I deliberately take smo	all helpings as a mea	ns of controlling my weight	t True	o False
7	Sometimes things just to I am no longer hungry		eep on eating even when	□₁ True	□₀ False
8	Since I am often hungs expert would tell me t something more to eat	hat I have had enoug	hat while I am eating, an h or that I can have	☐ ₁ True	□ _o False
9	When I feel anxious, I	find myself eating.		☐₁ True	□₀ False
10	Life is too short to wor	ry about dieting.		☐₁ True	o False
11	Since my weight goes more than once.	up and down, I have	gone on reducing diets	□₁ True	□₀ False
12	I often feel so hungry	that I just have to eat	something.	☐₁ True	o False
13	When I am with some	one who is overeating	g, I usually overeat too.	☐₁ True	□₀ False
14	I have a pretty good is	dea of the number of	calories in common food.	☐₁ True	o False
15	Sometimes when I star	rt eating, I just can't s	eem to stop.	☐₁ True	□₀ False
16	It is not difficult for me	to leave something o	on my plate.	☐₁ True	o False
17	At certain times of the to eating then.	day, I get hungry be	cause I have gotten used	□₁ True	□₀ False
18	While on a diet, if I ea for a period of time to		wed, I consciously eat less	□ ₁ True	□₀ False
Not D	one Codelist: 1 Participant refu	used 2 Clinician unable to	obtain 3 Insufficient time 4 Instr	rument failure 5 N	lot required
			TION V8.0 24FEB2012	Participant's I	

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



PAGEID = 138

		C	enter Number:	Participant Number:	Participant's I	nitials: middle last
Eat	ing Inventor	y (continued)				
19	Being with son	neone who is ed		tes me hungry to eat also. S PAGE 61	□₁ True	□₀ False
20	When I feel blo	ue, I often overe			TFEQA (T)	PE 4)PS Gralse
21	l enjoy eating my weight.	too much to spo	oil it by counting	g calories or watching	☐₁ True	□₀ False
22	When I see a r right away.	eal delicacy, I c	ften get so hur	ngry that I have to eat	□₁ True	□ _o False
23	I often stop ea limiting the am	•	not really full o	as a conscious means of	□ ₁ True	□₀ False
24	I get so hungry	y that my stoma	ch often seems	like a bottomless pit.	□ ₁ True	□₀ False
25	My weight has	hardly change	d at all in the l	ast ten years.	☐ ₁ True	□₀ False
26	I am always he the food on my		rd for me to sto	op eating before I finish	□ ₁ True	□₀ False
27	When I feel lo	nely, I console n	nyself by eating	g.	☐ ₁ True	□₀ False
28	I consciously h	old back at med	als in order not	to gain weight.	□ ₁ True	□₀ False
29	l sometimes ge	et very hungry l	ate in the even	ing or at night.	☐ ₁ True	□₀ False
30	I eat anything	l want, any time	e I want.		□ ₁ True	□₀ False
31	Without even t	hinking about it	, I take a long	time to eat.	☐ ₁ True	□₀ False
32	I count calorie	s as a conscious	means of cont	rolling my weight.	□₁ True	□₀ False
33	l do not eat so	me foods becau	use they make i	me fat.	□₁ True	□₀ False
34	I am always h	ungry enough t	o eat at any tim	ie.	□ ₁ True	□ _o False
35	l pay a great o	deal of attention	to changes in	my figure.	□₁ True	□₀ False
36	While on a die eat other high		that is not allo	owed, I often splurge and	□ ₁ True	o False
		CALERIE PH	ASE2 ANNOTA	TION V8.0 24FEB2012	Participant's I	nitials:



PAGEID = 139

	Center Number:	Participant Number: Participant's Initials:
Eat	ing Inventory (continued)	
Plea	se 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?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	SAME AS PAGE 62 $\square_{1} \text{ Rarely } \square_{2} \text{ Sometimes } \square_{3} \text{ Usually } \square_{4} \text{ Always}$
39	How often do you feel hungry?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	☐₁ Rarely ☐₂ Sometimes ☐₃ Usually ☐₄ Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult
42	How conscious are you of what you are eating?	☐₁ Not at all ☐₂ Slightly ☐₃ Moderately ☐₄ Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐₁ Almost never ☐₂ Seldom ☐₃ Usually ☐₄ Almost always
44	How likely are you to shop for low calorie foods?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
45	Do you eat sensibly in front of others and splurge alone?	□₁ Never □₂ Rarely □₃ Often □₄ Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
47	How frequently do you skip dessert because you are no longer hungry?	\square_1 Almost never \square_2 Seldom \square_3 At least once a week \square_4 Almost every day
48	How likely are you to consciously eat less than you want?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
49	Do you go on eating binges though you are not hungry?	☐₁ Never ☐₂ Rarely ☐₃ Sometimes ☐₄ At least once a week
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of me ☐₃ Describes me perfectly
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in"

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



P

C	EID = 140					•11		,,, _	, •••	0	,, ,,,	911 2
\G		Number:		Partici	oant Nur	mber: _			Particip	ant's Init	tials:	middle las
Do	ite completed:/	OR No	ot done –	→ Speci	fy reaso	on (use	codelist	below):	·	_		
	day month year		SAME	EAS	PAGE	36		DA	TEH	IDR	(TYF	2E 4
W	eight Efficacy Lifestyle Quest	ionn	aire (v	/EL)								
do	is form describes some typical eating situations. wn. The following are a number of situations re ting situations which you find the hardest to mo	elating t										
o	Read each situation listed below and decide he the difficult situations. In other words, pretend to your confident, choose ONE number that re	that you	are in th	e eatin	g situat	ion rigl	nt now.	On a s	cale fro	om 0 (no	ot confi	dent)
de	sire to eat. Check this number for each item.		SAME	AS P	AGE 6	3		WEL	.Q (T	YPE	4)PS	
Ie	ım confident that:				ent at a st the d		eat	yo			onfide e desire	
			0	1	2	3	4	5	6	7	8	9
1	I can resist eating when I am anxiou (nervous).	JS				Пз	4	5	□ ₆			□,
2	I can control my eating on the week	ends.	\square_{0}			\square_3	\square_{4}	\square_5	□ ₆			□,
3	I can resist eating even when I have say "no" to others.	to				Пз	4		□ ₆		□ ₈	
4	I can resist eating when I feel physic run down.	ally				\square_3	\square_4				8	□,
5	I can resist eating when I am watchi	ng TV.				Пз	4		□ ₆			
6	I can resist eating when I am depres	sed				Пз	4		□ ₆			□,
7	I can resist eating when there are modifferent kinds of food available.	any							□ ₆			□ ₉
8	I can resist eating even when I feel it impolite to refuse a second helping.	t is				Пз			□ ₆			
9	I can resist eating even when I have	а										

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

2 Clinician unable to obtain

5 Not required

4 Instrument failure

Not Done Codelist: 1 Participant refused

headache.

3 Insufficient time



PAGEID = 141

	Center Number: _	: Participant Number:					Participant's Initials:						
Weight Efficacy Lifestyle	Questionnai	re (w	/EL) (co	ntinue	l)								
I am confident that:				e nt at a st the d	ll that esire to			,					
SAME AS	PAGE 64	0	1	2	3	VV E 4	LQ (6	E 4)P	8	9		
10 I can resist eating when I am	reading.	\square_{0}			\square_3	\square_{4}	\square_5	6					
11 can resist eating when I am (or irritable).	angry				\square_3	_4	5	□ ₆		8	□ ₉		
12 I can resist eating even when a party.	I am at				Пз	4	\square_5			□ ₈			
13 I can resist eating even when pressuring me to eat.	others are	По			Пз	_4	5						
14 I can resist eating when I am	in pain.	□₀			Пз	□₄	\square_5	□ ₆		□ ₈	□ ₉		
15 I can resist eating just before bed.	going to	По			З	_4	5	6		8			
16 I can resist eating when I have experienced failure.	re	\Box_{0}			\square_3		\square_5	6			□ ₉		
17 I can resist eating when high- are available.	calorie foods	По			З	_4		6		8			
18 I can resist eating even when others will be upset if I don't		\square_{0}			\square_3		5	□ ₆		□ ₈			
19 I can resist eating when I fee uncomfortable.					3	4				□ ₈			
20 I can resist eating when I am	happy.				\square_3	4		6	□ ₇	8			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: First middle last



	വ			

	Center Number: Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last			
Da	te completed: $\{day}$ / $\{month}$ / $\{year}$ OR Not done \rightarrow Specify		DAT (use code	EHDF	R (TYF v): MAED	′					
	ultiaxial Assessment of Eating Disorder Sym	ptom	S (MAE		IALD	5 (11		7)1 3			
Ins	Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.										
	SAME AS PAGE 65	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always			
1	Fasting is a good way to lose weight.			З			□6				
2	My sleep isn't as good as it used to be.			\square_3			6	\square_{7}			
3	I avoid eating for as long as I can.			\square_3			6				
4	Certain foods are "forbidden" for me to eat.			\square_3	□₄	\square_{5}	□₀				
5	I can't keep certain foods in my house because I will binge on them.										
6	I can easily make myself vomit.			З			_6				
7	I can feel that being fat is terrible.			З			□ ₆				
8	I avoid greasy foods.			З	□₄		□,				
9	It's okay to binge and purge once in a while.			З			□ ₆				
10	I don't eat certain foods.			Пз		□₅	6				
11	I think I am a good person.			\square_3			6				
12	My eating is normal.			Пз			6				
13	I can't seem to concentrate lately.			\square_3	4		6				
14	I try to diet by fasting.			\square_3			6	\Box_{7}			
15	I vomit to control my weight.				4		6				
16	Lately nothing seems enjoyable anymore.			Пз			6				
17	Laxatives help keep you slim.			З			□ ₆				
18	I don't eat red meat.			\square_3	□₄		□,				
19	I eat so rapidly I can't even taste my food.			\square_3			□ ₆				
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	d			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PAGEID = 143

	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Assessr	nent of Eating Disorder	Sympto	oms (MAEDS)	(continue	ed)		
	SAME AS PAGE 66	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I car	n to avoid being overweight.				□₄		□₀	
21 When I feel bloated, of that feeling.	I must do something to rid myse	elf		□₃	□₄		□6	
22 I overeat too freque	ently.			3				
23 It's okay to be over	weight.			\square_3			6	
24 Recently I have felt	that I am a worthless person.					5	6	
25 I would be very ups	et if I gained 2 pounds.			\square_3			□6	
26 I crave sweets and o	carbohydrates.			З			□6	
27 I lose control when	l eat.			Пз			□,	
28 Being fat would be	terrible.			3			6	
29 I have thought serio	usly about suicide lately.			\square_3			□6	
30 I don't have any ener	rgy anymore.			3			6	
31 I eat small portions	to control my weight.			\square_3			□6	
32 I eat 3 meals a day.				3			6	
33 Lately I have been e	easily irritated.			Пз			□6	
34 Some foods should	be totally avoided.			З			□,	
35 I use laxatives to co	ntrol my weight.			Пз			6	
36 I am terrified by the	thought of being overweight.			Пз			□6	
37 Purging is a good w	ay to lose weight.			Пз	□₄		□,	
38 I avoid fatty foods.							□6	
	CALERIE PHASE2 ANNOTA	TION V8.	0 24FE	B2012	Pa	rticipant's	Initials:	irst midale last

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 Send to DCRI Forms Management · 2400 Pratt St. · Room 0311 Terrace Level · Durham NC 27705



		-	
$D\Delta$	GE	ב חו	- 144

Center Number: Par	ticipant N	umber: _		ra	rticipant's	initials:	irst middle last
Multiaxial Assessment of Eating Disorder Sy	mpto	ms (MAEDS)	continue	d)		
SAME AS PAGE 67	Never	Very Rarely	Rarely	Some- times	Often DS (T	Very Often	Always
39 Recently I have felt pretty blue.						□6	
40 I am obsessed with becoming overweight.			□3	□₄		□6	□ ₇
41 I don't eat fried foods.				□4		6	
42 I skip meals.	□₁		Пз	□₄		□6	
43 Fat people are unhappy.				4		6	
44 People are too concerned with the way I eat.	П		Пз	□4	□ ₅	□6	
45 I feel good when I skip meals.			3	□₄	□₅	□ ₆	
46 I avoid foods with sugar.			3	4		□6	
47 I hate it when I feel fat.				4			
48 I am too fat.	П		Пз	□₄		□,	
49 I eat until I am completely stuffed.			3	□₄		□6	
50 I hate to eat.			3	□ ₄		6	
51 I feel guilty about a lot of things these days.			3	□₄		□6	
52 I'm very careful of what I eat.			Пз	□₄	□ ₅	□6	
53 I can "hold off" and not eat even if I am hungry.				□ ₄		□,	
54 I eat even when I am not hungry.			Пз	□₄		6	
55 Fat people are disgusting.				4		6	
56 I wouldn't mind gaining a few pounds.			Пз	□₄			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 Porticipo



ca	leri	e	Phase	2
----	-------------	---	-------	---

PAGEID = 145 Center Number: Participant			-			
Date completed:/	eason (use					
Body Shape Questionnaire (BSQ)						
We would like to know how you have been feeling about your appearance of Please read each question and check the box for the appropriate choice. Please					(TYPE	∃ 4)P\$
Over the Past Four Weeks SAME AS PAGE 68	Never	Rarely	Some- times	Often	Very Often	Always
Has feeling bored made you brood about your shape?						
2 Have you been so worried about your shape that you have been feeling that you ought to diet?			3			
3 Have you thought that your thighs, hips, or bottom are too large for the rest of you?						
4 Have you been afraid that you might become fat (or fatter)?			\square_3		\square_{5}	□6
5 Have you worried about your flesh not being firm enough?						6
6 Has feeling full (e.g., after eating a large meal) made you feel fat?			Пз			□ ₆
7 Have you felt so bad about your shape that you have cried?						
8 Have you avoided running because your flesh might wobble?			Пз			□ ₆
9 Has being with thin women/men made you feel self-conscious about your shape?						□ ₆
10 Have you worried about your thighs spreading out when sitting down?			Пз			
11 Has eating even a small amount of food made you feel fat?						□ ₆
12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?						□ ₆
13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?				4		□ ₆
14 Has being naked, such as when taking a bath, made you feel fat?			З			
15 Have you avoided wearing clothes which make you particularly aware of the shape of your body?			З			□6
16 Have you imagined cutting off fleshy areas of your body?					\square_5	
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time	4 Instru	ument failt	ure 5 N	lot require	ed

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PAGEID = 146

Center Number: Participant N	lumber: _		Par	ticipant's	Initials:	rst middle last
Body Shape Questionnaire (BSQ) (continued)	240	2 %	ş	·S. 2		
Over the Past Four Weeks SAME AS PAGE 69	Never	Rarely	Some- times	Often (TVP	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?				□₄		□,
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?			\square_3		\square_5	□6
19 Have you felt excessively large and rounded?			□ ₃	_4		□6
20 Have you felt ashamed of your body?			Пз	□₄	□ ₅	□6
21 Has worry about your shape made you diet?			□₃	_4		
22 Have you felt happiest about your shape when your stomach has been empty?			□₃	□₄	\square_{5}	
23 Have you thought that you are the shape you are because you lack self-control?			□₃	_4	₅	
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?			\square_3	□₄	\square_5	□6
25 Have you felt that it is not fair that other women/men are thinner than you?			Пз	_4		
26 Have you vomited in order to feel thinner?			□₃	□₄	\square_{5}	
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?					5	
28 Have you worried about your flesh being dimply?			\square_3	□₄	\square_5	□6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?				_4		
30 Have you pinched areas of your body to see how much fat is there?			□3	□₄	\square_5	
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?						
32 Have you taken laxatives in order to feel thinner?			\square_3		\square_5	□6
33 Have you been particularly self-conscious about your shape when in the company of other people?			□₃		□ ₅	□6
34 Has worry about your shape made you feel you ought to exercise?			\square_3			

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

ham NC 27705



Month 6 Submission CR Visit 3

PAGEID = **147**

	Center Number	er: Participant Number:	Participant's Initials:
Clinic Weight			
Weight date and time:	day //	:	Staff initials: first middle lost
	ify reason (use codelist below):		DATEHDR (TYPE 4)
Clinic weight (if the first	two measurements are more than C).1 kg apart, measure weight a third ti	
Weight 1:	kg	SAME AS PAGE 4	
Weight 2:	, kg		WEIGHT (TYPE 4)
Weight 3:	, kg		,
Weight of gown:	kg		
Not Done Codelist: 1	Participant refused 2 Clinician un	able to obtain 3 Insufficient time	4 Instrument failure 5 Not required

ca	leri	e	Phase	2
----	------	---	-------	---

Month 6 Submission

CR Visit 3

PAGEID - 148		

Center Number: ___ Participant Number: ___ Participant's Initials: First middle last PARHDR (TYPE 4)

Se	Seven-Day Physical Activity Recall (PAR)														
Tode	Today's date: /														
1	Were you employed in the last seven days? □ ₀ No → Skip to question 3 □ ₁ Yes Interviewer initials: _{first middle last}														
2	If Yes: W	hich days (check all that apply)?	?		Mon	Tues	Wed _	Thurs	Fri 🗌	Sat	Sun				
3	3 Which days do you consider your weekend, or non-work, days?														
Day	Day of	Date		p Time	Work	Time		ning (in m	very		noon (in m	vinutes) Very		ning (in min	vites) Very
#	Week	Dule	In Bed	Up	Start	Stop	Mod.	Hard	Hard	Mod.	Hard	Hard	Mod.	Hard	Hard
7 (yester- day)		/	00:00 to 23:59 	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					PAI	RCHT	(TYPE	4)PS	
6			00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
5		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
4		/	00:00 to 23:59 : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59	:::			SAME .	AS PA(SE 71				
3		/	00:00 to 23:59 	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
2		/	00:00 to 23:59	00:00 to 23:59 	00:00 to 23:59	00:00 to 23:59									
1 (1 week ago)		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	: 00:00 to 23:59									



Month 6 Submission CR Visit 3

PAGEID = 149

	Center Number: Participant Number: Participant's Initials:
S	even-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) About the same SAME AS PAGE 72
In	nterviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? One No Types
6	Do you think this was a valid Seven-Day PAR interview? No Yes
7	Were there any activities reported by the participant that you don't know how to classify? No Yes



Month 6 Submission CR Visit 3

PAGEID = **150**

		ipant Number: Particip	oant's Initials:							
6-D	ay Food Record									
Com	Complete below OR Not done → Specify reason (use Codelist below): Staff initials:									
	SAME AS F	PAGE 73		Replacement Values						
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	FOODRCD (TYPE	Record Quality (check only one)					
1		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	8	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
2		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	9	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
з	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	10	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing					
4		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	11	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
5	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	12	/	1 Reliable 2 Unreliable 3 Missing					
6		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	13	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing					
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										
5		Unreliable In Reliable Unreliable Unreliable In Reliable Unreliable Unreliable In Reliable Unreliable Unreliable Unreliable Unreliable In Reliable Unreliable In Reliable Unreliable In Reliable Unreliable In Reliable Unreliable In Missing	11 12 13							



PAGEID = 151

		Center Number:	Partic	ipant Number: _	Particip	ant's Initials:			
Outcomes	Labs								
Date and time of			/	00:00 to 23:	OUTCMELB	(TYPE 4)PS			
Date and time sa	mple collection started:	/	GE 102						
	Sample		Sample	Complete?	If Not Done, Reason (Use codelist below)	Staff Initials			
	Blood		□₀ No □₁ Yes		first middle last				
If a sample is not o	btained, indicate with a No	of Done.							
Core Temp	erature								
Staff Provide Date of Initials Sample Collection/Proces				Time Collecti	If Not Done, Reason (Use codelist below)				
		art Date:			ADMIT (TYP tart Time SAME A	,			
first middle lost		op Date:			: -: 				
Inpatient Admission and Discharge									
1 Inpatient adn	nission date and time:	<u> </u>							
Not Done Codeli	st: 1 Participant refused	2 Clinician unable to	obtain 3	Insufficient time	4 Instrument failure	5 Not required			



Month 6 Submission CR Visit 5

Participant's Initials:

PAGEID = **152**

	first middle fast							
Clinic Weight								
Weight date and time:/	Staff initials:							
OR Not done → Specify reason (use codelist below):	DATEHDR (TYPE 4)							
Clinic weight (if the two measurements are more than 0.1 kg apart, measo	· · · · · · · · · · · · · · · · · · ·							
Weight 1: kg SA	ME 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)							
□₀ No	,							
\[\begin{align*} \begin{align*} \text{Tes: Date urine pregnancy test performed: } \(\frac{day}{day} \end{align*} \]	/SAME AS PAGE 33							
Results: 🔲 Negative								
$\square_{\!\scriptscriptstyle 2}$ Positive								



Month 6 Submission CR Visit 5

PAGEID = **153**

	Center Number:	Participant Number:	Participant's Initials:							
DXA Scan										
 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. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? 										
□ ₀ No □ ₁ Yes										
DXA Scan	DXA Scan DXA Rescan OR 🔲 96 NA									
Date of scan:/										
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply								
☐ Whole body		☐ Whol	e body							
Metabolic Rate										
Sample	Date of Colle	(Use co	one, Reason odelist below) Staff Initials							
Resting Metabolic Rate (RMR)—Visit 5 No Display 2 = RMR2	/	year	TYPE 4)PS							
RMRVISIT <turmr></turmr>	Tufts-003 (623-002) Tufts-006 (623-006)	WASH U-001 (623-003								
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 Insufficient time 4 In	strument failure 5 Not required							

ADD CARTID TO EXISTING RMR PANEL

CRF, page 154

calerie Phase 2

Month 6 Submission CR Visit 5

PA	GEID :	= 154				Center N	umber: _	P	articipant	Number: .	PA	RHDR	articipant's (TYP)	Initials: —	irst middle last
PAGEID = 154 Center Number: Participant Number: Participant's Initials: PARHDR (TYPE 4) Seven-Day Physical Activity Recall (PAR)															
Today's date:/															
		day month ye ou employed in the last seve		. , , .								Interv	iewer ini	tials:	·
	1 Were you employed in the last seven days?								middle tast						
Day	Day of		Slee	p Time	Work Time Mor				Afte	ernoon (in minutes)		Evening (in minutes			
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7 (yester- day)		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					PAI	RCHT	(TYPE	4)PS	
6			00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	: 00:00 to 23:59									
5			00:00 to 23:59 	00:00 to 23:59	00:00 to 23:59	: 00:00 to 23:59									
4		day /	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59			SAME	AS PAC	SE 71 				
3			00:00 to 23:59 : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
2		/	00:00 to 23:59 : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1 (7 week ago)		/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									



Month 6 Submission CR Visit 5

PAGEID = 155

	Center Number:	Participant Number:	Participant's Initials: middle last
Seven-Day Physical Act	rivity Recall (PAR) (continued)	
4 Compared to your physical activi		hs, was last week's physica	
or about the same (check only one); 		PARQ (TYPE 4)
☐ ₂ Less ☐ ₃ About the same	SAME AS P	AGE 72	
Interviewer: Please answer question	ons below and note any cor	mments on interview.	
5 Were there any problems with th □₀ No □₁ Yes	e Seven-Day PAR interview	·\$	
6 Do you think this was a valid Sev □ ₀ No □ ₁ Yes	ren-Day PAR interview?		
7 Were there any activities reporte □₀ No □₁ Yes	d by the participant that yo	ou don't know how to classi	fy?