

Phone Screen

		Center Number:	Partici	pant Number:		Participant'	's Initials: middle last
Phone So	creen						
ì	Give the caller a brief over Visit 1. Ask for verbal cons in order to determine eligi Fill in blanks and checl	ent to record personal bility. If the caller is eliq	informatio gible, sche	on over the pho	ne. Com	plete all phone	•
Verbal conser	nt given by respondent:	o No o	Interviev	wer's initials: $\frac{1}{6}$	irst middle last	-	
Date:/	//	Source:					Age:
Last name: _		First name:			DOB:	day /month	/
						-	
	:						
Height: ft	t in Weight: _	lbs BMI: _		Gender:	₁ Male		
Medical I	History						
•	Have you been diagnose or ever experienced the fo					Describe (being symptoms/type or	treated/how long f/family history)
Heart attack, h	neart-related chest pain, or o	other heart condition	O No	1 Yes →			
Abnormal hea	art rhythm		□ _o No	□ ₁ Yes →			
Cancer			□ _o No	□ ₁ Yes →			
Shortness of b	reath or other breathing p	roblem	□ ₀ No	□ ₁ Yes →			
Diabetes (med	s)		O No	1 Yes →			
High blood pro	essure (> 140/90)		O No	1 Yes →			
Anemia or oth	ner blood condition		O No	1 Yes →			
Thyroid or othe	er metabolic disorder such o	as phenylketonuria	O No	□ ₁ Yes →			
Stomach or di	gestive disorders		□ ₀ No	1 Yes →			
Immunologic c	disorder or AIDS		O No	1 Yes →			
Depression or	any other psychiatric or n	eurologic disease	O No	1 Yes →			
Active liver dis	sease and/or gallstones		O No	□ ₁ Yes →			
Kidney or urol	logic disorders		□ ₀ No	Yes →			
Major abdomi	inal or chest surgery		O No	1 Yes →			
Weight loss or	gain of > 3 kg over the po	ast 6 months	O No	1 Yes →			
Known metalli	ic objects or implants in yo	ur body	O ₀ No	1 Yes →			
Anaphylaxis,	severe allergies, or asthmo	1	□ ₀ No	□ ₁ Yes →			



Phone Screen

	Center Number:	Participant Number:	Participant's Initials: First middle last
M	ledications		
1	Have you received medication for depression or any other psychiatric disease in the past year?	\square_0 No \square_1 Yes \rightarrow	
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: Specify medications:
3	Have you been treated with steroids in the last six months?	□₀ No □₁ Yes	
4	Have you been treated with steroids for more than a month in the past five years?	□ ₀ No □ ₁ Yes	
5	Do you currently use regular medications other than birth control pills?	\square_0 No \square_1 Yes \rightarrow	If Yes: Specify 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: Specify:
Pł	hysical Activity/Lifestyle		
1	Over the past year, have you engaged in a regular program of physical fitness involving heavy physical activity more than 5 times per week? (Examples of heavy physical activity include: jogging, running, riding fast on a bicycle for 30 minutes or more; heavy gardening or other chores for an hour or more; active games or sports such as handball or tennis for an hour or more.)	. □ ₀ No □ ₁ Yes →	If Yes: Specify type and frequency of activity:
2	Have you used drugs recreationally within the past two years?	No 1 Yes	
3	Have you smoked within the past twelve months?	□₀ No □₁ Yes	
4	Have you given blood in the last 30 days?	□₀ No □₁ Yes	
5	Are you currently participating in another interventional trial?	□₀ No □₁ Yes	
	Are you currently practicing a vegan dietary lifestyle?	□₀ No □₁ Yes	
7	Do you anticipate difficulties adhering to special diets and clinical visits over a two year period?	□ ₀ No □ ₁ Yes	
E	igibility Information To be completed by the intervie	ewer	
	eview above items marked "Yes" against Exclusion criteri		k the appropriate response below:
Eliç	gible: □ ₀ No → If No: Reason for not being eligible:		
	, Yes → If Yes: Is participant interested in participating?	? \square_0 No \square_1 Yes	
	On hold → If on hold: For what reason?		
	Contact to resume screening aft	ter being on hold:	y month year
Ori	ientation (screening visit 1) scheduled:		,
Co	mments:		



Screening Visit 1 Checklist

Participant's Initials: ___ __

	Center Number:	Participant Number:	Participant's Initials:
Screening Visit 1 Checklis	șt į		
1 Date of initial clinic visit for Screening	g Visit 1:/ _{month}	/	
Check completed items:	,		
2 Informed consent			
3 HIPAA authorization			
4 Study video			
5 Study brochure			
6 Weight and height measures, inc	luding BMI eligibility		
7 Demographic form			
8 Stanford Activity Assessment			
9 General Dietary Questionnaire			
10 Eating Inventory			
11 MAEDS			
12 SCID-II			
13 BDI-II			
14 Meeting with dietitian			
15 Meeting with study coordinator/	manager		
16 Schedule Assessment Calendar			
17 Inclusion/Exclusion criteria review	W		
Doesn't like the st Doesn't want to b Unwilling to be ro Lives too far away Needs help with a Refused with no e Other (specify):	eck all that apply): ty criterion study th time cts with work or school udy's procedures the involved in a research stute andomized ty/transportation problems thild care explanation	idy	
Yes → If Yes: Date of scheduled S	Screening Visit 2:	/	

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



	Center Number:	_ Participant Number:	Participant's Initials: first middle last
Clinic Weight			
Weight date and time:/	/	: to 23:59	Staff initials:
OR Not done → Specify reason (use co	delist below):		
Clinic weight (if the first two measurements	are more than 0.1 kg apo	rt, measure weight a third time	e):
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Height			
Height (if the first two measurements are m	ore than 0.1 cm apart, me	asure height a third time):	
1 First height:	cm		
2 Second height:	cm		
3 Third height:	cm		
Not Done Codelist: 1 Participant refused	2 Clinician unable to o	otain 3 Insufficient time	4 Instrument failure 5 Not required



	Center Number: Participant	f Number: Parti	cipant's Initials: first middle last
Date:/	Maintain completed form in parti	icipant file at site.	
aay monin year	Please print	_	
	1 10430 primi		
Demographic Questionno	iire		
Name:			
first name	middle initial	last name	
Street address:			
City:	State:	Zip:	
Telephone (Home): ()		<u></u>	
	Do you mind being called at worl Best time to call, and where:		
E-mail address:			
Do you use e-mail regularly? ☐₀ No			
Date of birth:/	Age:		
Social Security number:	,		
Occupation:			
Emergency Contact:			
Name:		last name	
Telephone: ()	Relationship	:	
Primary Care Physician			
-			
Name:		last name	
Street address:			
City:		Zip:	
Telephone: ()	Fax: (

CRF, page 5



		Center Number:	Participant Number:	Participant's Initials:	first middle last
D	emographics				msi middle ids
	emograpines				
ı	Date of birth:/				
		year			
2	Sex: Male				
	Female				
3	Ethnicity (check only one):1 Hispanic of	or Latino			
		nic or Latino			
		(not reporting ethnicity)			
4	Race (check only one):	an or Alaska Native			
~	Asian	all of Alaska Native			
	_ _	ian or other Pacific Isla	nder		
	□ ₃ Nanve Hawan		ildei		
	□ ₄ black of Affice	an American			
	☐ ₆ More than on	e race			
	Unknown	e race			
	,				
5	Marital status (check only one):1 Mai	ried	4 Widowed		
		orced	5 Separated		
	₃ Sing	le, never married	Not married, but living with partner		
6	Living situation: Where do you live (a	heck only one):, Hou	Jse		
	,	Apo			
		\square_3 She			
		□₄ Dor			
			ner (specify):		
7	Education: What is the highest level	of formal education t	hat you have completed (check only or	ne) ?	
	(Note: If you have any questions as to which ca	tegory you fall in, please co	ntact the study representative.)		
	6 Non-doctoral graduate degree				
)			
8	Family income: What is the total ann	ual income of your h	ousehold (check only one):, \$0-\$19	2,999	
	-	,			
			\$ \$80,000		
			3	than \$100,000	

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



		Center Number:	Participant Number:	Pai	rticipant's Initials:
Date complete	ed:/ _{month} /	year			
Stanford	Brief Physical <i>I</i>	Activity Survey			
a b	activity you usually perfor out perform work around	case check the box next to med while on this job this home regularly , indicate work, check box A and go	last year. If you are not that activity in this sect	gainfully emplo	
_					a tallian an tha
teleph	none, assembling small p	or standing. When I was a arts, or operating a machi ft or carry anything for mo	ne that takes very little e	exertion or streng	
work, machi	I did such things as delivines, house painting, or c	g or using my hands and c vering mail, patrolling on g perating a machine that re and carry things frequently	juard duty, mechanical v equires some moderate	work on automol	oiles or other large
work,	I did such things as stac	or carrying heavy objects of king cargo or inventory, ho dener who does most of th	andling parts or materia	ls, or I did work	
heavy	tools, or carrying heavy	nard physical labor. When loads (bricks, for example lso required me to do hard	e) to the place where the	ey are to be used	d. If I drove a truck or
	Leisure-Time Activity your leisure time during t	Please check the box next most of the last year.	to the one statement th	at best describe	s the way you spent
or pla game	ying cards. If I did anyth	ent without very much phy ing else, it was likely to be nly occasionally, no more active gardening.	light chores around the	house or yard,	or some easy-going
	exercise–going for walks,	rom work, I did few active playing a round of golf (v			
swimr difficu	ming or riding a bike—for	overage, I engaged in som 15-20 minutes or more. O or washing windows, mov	Or I spent 45 minutes to	an hour or more	e doing moderately
heavy fast or such a	physical activity at least a bicycle for 30 minute	past year, I engaged in a three times per week. Exa s or more; heavy gardenin an hour or more; or a regu	mples of heavy physical g or other chores for ar	activity are: jogen hour or more; c	ging, running or riding active games or sports
	the past year, I engaged did it almost daily —five o	in a regular program of p r more times per week.	hysical fitness along the	lines described	in the last paragraph (I)



	Center Number: Participant Number:	_ Participant's I	nitials:
Date o	completed:/OR Not done → Specify reason (use codelist below	w):	
Eati	ing 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.		o 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 quota of calories, I am usually good about not eating anymore.		o False
5	Dieting is so hard for me because I just get too hungry.	, True	o False
6	I deliberately take small helpings as a means of controlling my weight.	☐₁ True	o False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	₁ True	o 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	o False
10	Life is too short to worry about dieting.	, True	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	o False
14	I have a pretty good idea of the number of calories in common food.	, True	o False
15	Sometimes when I start eating, I just can't seem to stop.	☐₁ True	o False
16	It is not difficult for me to leave something on my plate.	, True	o False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	, True	o False
18	While on a diet, if I eat food that is not allowed, I consciously eat less fo a period of time to make up for it.	r, True	□₀ False



	Center Number: Participant Number:	Participant's In	first middle last
Eat	ing Inventory (continued)		
19	Being with someone who is eating often makes me hungry to eat also.	1 True	o False
20	When I feel blue, I often overeat.		o False
21	I enjoy eating too much to spoil it by counting calories or watching my weight.	, True	o False
22	When I see a real delicacy, I often get so hungry that I have to eat right away.		o False
23	I often stop eating when I am not really full as a conscious means of limiting the amount I eat.		o False
24	I get so hungry that my stomach often seems like a bottomless pit.	, True	o False
25	My weight has hardly changed at all in the last ten years.	, True	o False
26	I am always hungry so it is hard for me to stop eating before I finish the food on my plate.		o 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.		o 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.		o 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.		o 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.	, True	o False
35	I pay a great deal of attention to changes in my figure.	, 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.	, True	o False

calerie Phase 2

Screening

	Center Number:	Participant Number: Participant's Initials: First middle last
Eat	ing Inventory (continued)	
Plec	se check one answer that is most appropriate to you	for each question below.
37	How often are you dieting in a conscious effort to control your weight?	\square_0 Rarely \square_1 Sometimes \square_2 Usually \square_3 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\square_0 Rarely \square_1 Sometimes \square_2 Usually \square_3 Always
39	How often do you feel hungry?	\square_0 Rarely \square_1 Sometimes \square_2 Usually \square_3 Always
40	Do your feelings of guilt about overeating help you to control your food intake?	\square_{0} Rarely \square_{1} Sometimes \square_{2} Usually \square_{3} Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	□₀ Easy □₁ Slightly difficult □₃ Wery difficult
42	How conscious are you of what you are eating?	\square_0 Not at all \square_1 Slightly \square_2 Moderately \square_3 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐ ₀ Almost never ☐ ₁ Seldom ☐ ₂ Usually ☐ ₃ Almost always
44	How likely are you to shop for low calorie foods?	☐₀ Unlikely ☐₁ Slightly likely ☐₃ Moderately likely ☐₃ Very likely
45	Do you eat sensibly in front of others and splurge alone?	□₀ Never □₁ Rarely □₂ Often □₃ Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐₀ Unlikely ☐₁ Slightly likely ☐₂ Moderately likely ☐₃ Very likely
47	How frequently do you skip dessert because you are no longer hungry?	□₀ Almost never □₁ Seldom □₂ At least once a week □₃ Almost every day
48	How likely are you to consciously eat less than you want?	☐₀ Unlikely ☐₁ Slightly likely ☐₃ Woderately likely
49	Do you go on eating binges though you are not hungry?	□₀ Never □₁ Rarely □₃ At least once a week
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	☐₀ Not like me ☐₁ Little like me ☐₂ Pretty good description of me ☐₃ Describes me perfectly
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in"



		Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last
Do	ite completed:/ _{month} /	year								
M	ultiaxial Assessment of	Eating Disorder	r Sym _l	otom	S (MAE	DS)				
In	structions: Using the scale shown, plea	ase rate the following items	s on a sca	e from 1	to 7. Ple	ase ansv	ver as tru	uthfully	as possi	ble.
				Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1	Fasting is a good way to lose	e weight.				\square_3	4	5		
2	My sleep isn't as good as it t	used to be.				\square_3	\square_{4}	5		
3	I avoid eating for as long as	I can.					4	5		
4	Certain foods are "forbidder	n" for me to eat.					4	5		
5	I can't keep certain foods in my binge on them.	y house because I wil	l				4	5	6	
6	I can easily make myself von	nit.				\square_3	4	5	6	
7	I can feel that being fat is ter	rible.				\square_3	4	5		
8	I avoid greasy foods.					\square_3	4	5	6	
9	It's okay to binge and purge	once in a while.				\square_3	4	5	6	
10	I don't eat certain foods.					\square_3				
11	I think I am a good person.						4	5	6	
12	My eating is normal.					\square_3	\square_4	5	6	
13	I can't seem to concentrate l	ately.								
14	I try to diet by fasting.					\square_3	4	5	6	
15	I vomit to control my weight.									
16	Lately nothing seems enjoya	ble anymore.						5		
17	Laxatives help keep you slim	•					4	5		
18	I don't eat red meat.						4	5		
19	I eat so rapidly I can't even t	aste my food.					4	5	6	

Participant's Initials: first middle last



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



	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Assessment of	Eating Disorde	r Sympto	oms (MAEDS)				
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue	.				4	5	6	
40 I am obsessed with becoming	overweight.			\square_3		5	6	
41 I don't eat fried foods.				\square_3		5	6	
42 I skip meals.				3	4	5	6	
43 Fat people are unhappy.				\square_3	4	5	6	
44 People are too concerned with	n the way I eat.			3	4	5	6	7
45 I feel good when I skip meals.				3	4	5	6	7
46 I avoid foods with sugar.				\square_3	4	5	6	
47 I hate it when I feel fat.				\square_3		5	6	
48 I am too fat.				\square_3	4	5	6	
49 I eat until I am completely stul	fed.			3	4	5	6	
50 I hate to eat.					4	5		7
51 I feel guilty about a lot of thin	gs these days.			\square_3	4	5	6	
52 I'm very careful of what I eat.				\square_3	4	5	6	
53 I can "hold off" and not eat e	ven if I am hungry			\square_3		5	6	
54 I eat even when I am not hung	gry.			\square_3	4	5	6	
55 Fat people are disgusting.				\square_3		5	6	
56 I wouldn't mind gaining a few	pounds.							

Participant's Initials: first middle last



	Center Number: Participant Number: P	Participant's Initials:	first middle last
Date	e completed:/ _{month} /		
Str	uctured Clinical Interview for DSM-IV (SCID-II)		
1	Have you avoided jobs or tasks that involved having to deal with a lot of people?	O No	1 Yes
2	Do you avoid getting involved with people unless you are certain they will like you?	O No	1 Yes
3	Do you find it hard to be "open" even with people are you close to?	□ ₀ No	1 Yes
4	Do you often worry about being criticized or rejected in social situations?	□ ₀ No	1 Yes
5	Are you usually quiet when you meet new people?	□ ₀ No	1 Yes
6	Do you believe that you're not as good, as smart, or as attractive as most other people?	□ ₀ No	1 Yes
7	Are you afraid to try new things?	□ ₀ No	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?	O No	Yes
14	When a close relationship ends, do you feel you immediately have to find someone else to take care of you?	O No	
15	Do you worry a lot about being left alone to take care of yourself?	O No	1 Yes
16	Are you the kind of person who focuses on details, order, and organization or likes to make lists and schedules?	O No	1 Yes
17	Do you have trouble finishing jobs because you spend so much time trying to get things exactly right?	O No	1 Yes
18	Do you or other people feel that you are so devoted to work (or school) that you have n time left for anyone else or for just having fun?	No O	1 Yes
19	Do you have very high standards about what is right and what is wrong?	O No	1 Yes
20	Do you have trouble throwing things out because they might come in handy some day?	O 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?	O No	1 Yes
22	Is it hard for you to spend money on yourself and other people even when you have enough?	O No	1 Yes
23	Are you often so sure you are right that it doesn't matter what other people say?	O No	1 Yes
24	Have other people told you that you are stubborn or rigid?	O No	1 Yes

Participant's Initials: first middle last



	Center Number: Participant Number: Participant Number: Participant Number: Participant Number: Participant Number: Participant Number:	apant's Initials:	first middle last
Str	uctured Clinical Interview for DSM-IV (SCID-II) (continued)		
25	When someone asks you to do something that you don't want to do, do you say "yes" but then work slowly or do a bad job?	O No	
26	If you don't want to do something, do you often just "forget" to do it?	O No	
27	Do you often feel that other people don't understand you, or don't appreciate how much you do?	O No	1 Yes
28	Are you often grumpy and likely to get into arguments?	O No	
29	Have you found that most of your bosses, teachers, supervisors, doctors, and others who are supposed to know what they are doing really don't?	O No	
30	Do you often think that it's not fair that other people have more than you do?	No	
31	Do you often complain that more than your share of bad things have happened to you?	O No	
32	Do you often angrily refuse to do what others want and then later feel bad and apologize	?	
33	Do you usually feel unhappy or that life is no fun?	□ _o No	
34	Do you believe that you are basically an inadequate person and often don't feel good about yourself?	□ ₀ No	1 Yes
35	Do you often put yourself down?	O No	
36	Do you keep thinking about bad things that have happened in the past or worry about bad things that might happen in the future?	□ ₀ No	1 Yes
37	Do you often judge others harshly and easily find fault with them?	O No	
38	Do you think that most people are basically no good?	O No	
39	Do you almost always expect things to turn out badly?	O No	1 Yes
40	Do you often feel guilty about things you have or haven't done?	O No	
41	Do you often have to keep an eye out to stop people from using you or hurting you?	O No	
42	Do you spend a lot of time wondering if you can trust your friends or the people you work with?	O No	
43	Do you find that it is best not to let other people know much about you because they will use it against you?	□ ₀ No	
44	Do you often detect hidden threats or insults in things people say or do?	O No	
45	Are you the kind of person who holds grudges or takes a long time to forgive people who have insulted or slighted you?	□ ₀ No	
46	Are there many people you can't forgive because they did or said something to you a long time ago?	O No	1 Yes
47	Do you often get angry or lash out when someone criticizes or insults you in some way?	O No	
48	Have you often suspected that your spouse or partner has been unfaithful?	O No	



Calerie Phase 2_CRF_V7.0_26 SEP 2008

Screening

		Center Number:	Participant Number:	Participant's Initials:	first middle last
Str	uctured Clinical Inter	view for DSM-IV (SCID-II) (continued)		
49	When you are out in public an they are talking about you?	d see people talking, do yo	u often feel that	o No	Yes
50	Do you often get the feeling the are really meant to give you a		al meaning to most people	No	
51	When you are around people, or stared at?			□ _o No	
52	Have you ever felt that you cabout them?	ould make things happen	just by making a wish or thinkir	ng No	
53	Have you had personal expe			□ ₀ No	
54	Do you believe that you have know and predict things that	others can't?		□ _o No	
55	Does it often seem that object that noises are actually peop	le's voices?		□ ₀ No	
56	Have you had the sense that you cannot see anyone?	some person or force is a	round you, even though	□ ₀ No	Yes
57	Do you often see auras or en	ergy fields around people	?	□ ₀ No	Yes
58	Are there very few people th	at you're really close to o	utside of your immediate family	?	
59	Do you often feel nervous wl	nen you are with other pe	ople?	□ ₀ No	
60	Is it NOT important to you w	hether you have any close	relationships?	□ ₀ No	
61	Would you almost always ra	ther do things alone than	with other people?	O No	Yes
62	Could you be content withou	t ever being sexually invol	lved with anyone?	O No	Yes
63	Are there really very few thin	ngs that give you pleasure	?	O No	1 Yes
64	Does it NOT matter to you w	hat people think of you?		□ ₀ No	Yes
65	Do you find that nothing mak	ces you very happy or ver	y sad?	O No	1 Yes
66	Do you like to be the center of	of attention?		O No	Yes
67	Do you flirt a lot?			O No	1 Yes
68	Do you often find yourself "c	oming on" to people?		□ ₀ No	
69	Do you try to draw attention	to yourself by the way yo	u dress or look?	O No	
70	Do you often make a point o			₀ No	Yes
71	Do you often change your m or what you have just read o		g on the people you're with	O No	1 Yes
72	Do you have lots of friends th	nat you are very close to?		O No	



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



	Center	Number:	Participant Number:	Participant's Initials:	first middle last
Stru	uctured Clinical Interview fo	r DSM-IV (S	CID-II) (continued)		
99	Do you have a lot of sudden mood cho	inges?		O No	Yes
100	Do you often feel empty inside?			□ ₀ No	1 Yes
101	Do you often have temper outbursts or	get so angry th	at you lose control?	□ ₀ No	Yes
102	Do you hit people or throw things whe	n you get angry	?	□ ₀ No	1 Yes
103	Do even little things get you very angr	y?		O No	1 Yes
104	When you are under a lot of stress, do spaced out?	you get suspicio	ous of other people or feel esp	ecially No	1 Yes
105	Before you were 15, would you bully o	or threaten other	kids?	□ ₀ No	Yes
106	Before you were 15, would you start fi	ghts?		□ ₀ No	1 Yes
107	Before you were 15, did you hurt or th broken bottle, knife, or gun?	reaten someone	with a weapon, like a bat, br	ick, one No	
108	Before you were 15, did you deliberate and suffering?	ely torture some	one or cause someone physico	al pain No	
109	Before you were 15, did you torture or	hurt animals on	purpose?	o No	Yes
110	Before you were 15, did you rob, mug threatening him or her?	or forcibly take	something from someone by	□ _o No	
111	Before you were 15, did you force som of you, or to touch you sexually?	eone to have se	x with you, to get undressed i	n front No	Yes
112	Before you were 15, did you set fires?			o No	
113	Before you were 15, did you deliberate	ely destroy thing	s that weren't yours?	□ _o No	Yes
114	Before you were 15, did you break into	houses, other k	ouildings, or cars?	o No	
115	Before you were 15, did you lie a lot o	r "con" other pe	ople?	□ _o No	Yes
116	Before you were 15, did you sometime someone's signature?	s steal or shoplit	t things or forge	□ ₀ No	
117	Before you were 15, did you run away	from home and	stay away overnight?	o No	Yes
118	Before you were 13, did you often stay supposed to be home?	out very late, la	ong after the time you were	□ ₀ No	
119	Before you were 13, did you often skip	school?		□ _o No	



Screening Visit 2 Checklist

Participant's Initials: ___ __

		Center Number:	Participant Number:	Participant's Initials:
Screening Vi	sit 2 Checklis	t		
Did participant re □ No → If No:	eturn for Screening V Skip to question 15	isit 2?	:: / _{month} year	
Check completed it	tems:			
2 Fasting blood	d sample			
3 Urine sample)			
4 Vitals (temper	rature, pulse, blood pre	essure)		
5				
6 Medical and	medication history			
7 Concomitant	medications log			
8 Physical exar	mination			
9 Barriers inter	view			
10 Body morph	assessment			
11 Additional in	terviews (SCID-II and)	or IDED-IV)		
12 Meeting with	dietitian to review d	lietary screening questic	onnaire	
13 14-day food	record procedure rev	viewed		
14 Meeting with	study coordinator/n	nanager		
15 Is the participant	expected to return f	or Screening Visit 3?		
\square_0 No \rightarrow If No:	Provide reason (chec	ck all that apply):		
	Failed an eligibility			
	Lost interest in the	study		
	Will take too much	n time		
	Scheduling conflic	ts with work or school		
	Doesn't like the stu	dy's procedures		
	Doesn't want to be	e involved in a research stu	dy	
	Unwilling to be rar	ndomized		
	Lives too far away	transportation problems		
	Needs help with c	hild care		
	Refused with no ex	cplanation		
	Unable to contact			
	Other (specify): _			
\square_1 Yes \rightarrow If Yes:	Date of scheduled S	creening Visit 3:	//	

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



Baseline Submission 1 Screening

Center	Number: _	Pa	rticipant Number: Participant's Initials:
Date completed:/ _{month} / _{year}	_		
Screening Medical History			
List any clinically significant pre-existing conditio	n(s).		
Body System			Assessments
	No	Yes	If Yes, Specify Diagnosis
1 Head, Ears, Eyes, Nose, Throat	О	1→	
2 Dermatologic			
3 Cardiovascular	\square_{o}		
4 Respiratory		□,→	
5 Gastrointestinal		□1→	
6 Endocrine/Metabolic		□₁→	
7 Genitourinary		□1→	
8 Neurological	□₀	□₁→	
9 Blood/Lymphatic	□₀	□₁→	
10 Musculoskeletal	□₀	□₁→	
11 Hepatic	□₀	□₁→	
12 Drug Allergies	□₀	$\square_1 \rightarrow$	
13 Other Allergies			
14 Psychological/Psychiatric	□₀	□1→	
15 Other (including contraception methods, females only)	\Box_{o}		
Physician's Signature			
Signature:			



Baseline Submission 1 Screening

	Center Number:	Participant Number:	Participant's Initials: first middle last
Date completed:/	/		
Medication History			
Record any medications taken fr	rom 6 months prior through screen oal medications. Include any steroi		ounter and prescription drugs,
Medication	Start Date	Stop Date	Indication
1	day month year	or	
2	day month year	or1 Continuing	
3	day month year	or	
4	day month year	or	
5		or	
6	day month year	OR	
7	day month year	OR	
8	day month year	or	
9	day month year	or	
10	day month year	or	
11	day month year	or1 Continuing	
12	day month year	or	

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



	Center Nu	mber:	Participant N	Number: Participant's Initials:			
Physical Examination							
Date of examination:/ _{month}	/	OR Not do	one → Specif	y reason (use codelist below):			
		Assessments					
Body System	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain			
General appearance:		□₀→	₉₇ →				
2 Head, Ears, Eyes, Nose, Throat:		\square_{o} \rightarrow	₉₇ →				
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:		□ _o →	→				
Physician's Signature							
Signature: Date:/							
Not done at this examination OR Referre	d participant to	primary care p	hysician for e	xam.			
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 Checkli	st			
 Did participant return for Screening □₀ No → If No: Skip to question 5 □₁ Yes → If Yes: Date of initial clinic 	and provide reason.	3:/	-	
Check completed items:		,		
2 Reviewed all lab results (blood,	urine, and pregnancy test)			
3 Repeated blood sample, if need	ed			
4 🗌 14-day food record collected an	d reviewed			
Has the participant been contacted □₀ No, no additional visits → If No c	dditional visits: Provide	, , ,	udy	
Yes → If Yes: Additional visit sch		Serooning Visit 4:	/	
		Screening Visit 4:/	,	
	Date of scheduled Base	eline Visit:/	ear	

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



Screening Visit 4 Checklist

		Center Number:	Participant Number:	Participant's Initials: First middle last
S	creening Visit 4 Checkli	S † Optional—Submit :	this form only if Screening Vi	sit 4 was scheduled
1	Did participant return for Screening □₀ No → If No: Skip to question 4 □₁ Yes → If Yes: Date of initial clinic	Visit 4? and provide reason.		year
Ch	eck completed items:			
2	Reviewed all lab results (blood,	urine, and pregnancy test	t)	
3	14-day food record collected an	d reviewed (if needed)		
4	Has the participant been contacted	•	d with a Baseline Visit (check	only one)?
	\square_0 No \rightarrow If No: Provide reason (ch	eck all that apply):		
	Failed an eligibil	ity criterion		
	Lost interest in the	e study		
	Will take too mu	ch time		
	Scheduling confl	icts with work or school		
		tudy's procedures		
	Doesn't want to	be involved in a research	study	
	Unwilling to be r	andomized		
	Lives too far awa	y/transportation probler	ns	
	☐ Needs help with	child care		
	Refused with no	explanation		
	Unable to contact	ct		
	Other (specify):			
		Baseline Visit:/	<u>'</u>	
		day	month year	



		tirst r	niddle lasi
In	Informed Consent		
١.	W Del are a set of the second		
ı .	1 Did participant present for baseline visit?		
		on (participant no longer meets criteria)	
	Lost interest in the study		
		vork or school	
		ocedures	
	Open't want to be involved.	ed in a research study	
		ed	
		ortation problems	
		e (unanticipated child care needs)	
		ion	
	98 Other (specify):		
2	2 Date and time study baseline informed consent signed://	:	
	day month	year 00:00 to 23:59	

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



		Center Number:	Participant Number:	Participant's Initials:				
In	formed Consent Det	ail						
Tis	Tissue consent:							
			Check only one					
	Sample type	Participant consent given for future studies by Calerie and external investigators	Participant consent given for future studies by Calerie	Participant consent not given				
	1 Blood archive		\square_2	\square_3				
	2 Urine archive			\square_3				
	3 Muscle biopsy archive			\square_3				
	4 Fat biopsy archive			\square_3				



		Center Number:	Participant Number:	Participant's Initials:
C	linic Weight			
W	eight date and time:/ _{month}	/	::	Staff initials:
	R Not done → Specify reason (use Cod	•		first middle last
Cli	inic weight (if the first two measurements o	re more than 0.1	kg apart, measure weight a third time):	
W	eight 1:	_ kg		
W	eight 2:	_ kg		
W	eight 3:	_ kg		
W	eight of gown:	_ kg		
V	ital Signs			
As	sessment date and time:/	/	: 00:00 to 23:59	
	If waist measurement not done → Sp	ecify reason (use	codelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, mea	sure natural waist circumference a third time	Staff initials: first middle last
	Natural waist measurement 1:		cm	
	Natural waist measurement 2:		cm	
	Natural waist measurement 3:		cm	
2	Umbilical point waist measurement (if tumbilical point waist circumference a third tii		ements are more than 1.0 cm apart, measure	e
	Umbilical point waist measurement 1	:	cm	
	Umbilical point waist measurement 2	:	cm	
	Umbilical point waist measurement 3	:	cm	
3	Pulse: bpm OR Not do	ne → Specify red	ason (use codelist below):	Staff initials: $\frac{1}{first middle last}$
4	Temperature:°C C	OR Not done →	Specify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR	Not done → Sp	oecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):	Left arm Ri	ght arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time:: OR Not done Specify re	→ ason (use codelist below):
	6b Blood pressure 2:/	mm Hg		
	6¢ Blood pressure 3:/	mm Hg	Time::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unab	le to obtain 3 Insufficient time 4 Ins	trument failure 5 Not required



Ce	nter Number: Participant	Number: Part	ricipant's Initials: First middle last
12-Lead ECG			
Date and Time		Findings	Staff Initials
/	Abnormal, not clinica	ally significant (specify): significant (specify):	first middle last
Safety Labs			,
Date and time of last meal:	/	23:59	
Date and time of sample collection:/_		23:59	
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□₀ No □₁ Yes		first middle last
Urine	□₀ No □₁ Yes		first middle last
Not Done Codelist: 1 Participant refused 2 C	Clinician unable to obtain 3 Insul	ficient time 4 Instrument failu	re 5 Not required



Cente	er Number: _	Part	icipant Number: Participant's Initials:					
Date completed:/	Date completed: /							
Abbreviated Medical History	Abbreviated Medical History							
List any clinically significant changes occurring	since Screen	ing medica	history was completed.					
Body System			Assessments					
body system	No Change	Yes	If Yes, Specify Diagnosis					
1 Head, Ears, Eyes, Nose, Throat	По	□,→						
2 Dermatologic	\Box_{o}	□,→						
3 Cardiovascular	\Box_{o}	□₁→						
4 Respiratory	По	□₁→						
5 Gastrointestinal		□₁→						
6 Endocrine/Metabolic		□₁→						
7 Genitourinary	По	□₁→						
8 Neurological	По	□₁→						
9 Blood/Lymphatic		□₁→						
10 Musculoskeletal	\Box_{o}	□₁→						
11 Hepatic	\Box_{o}	□₁→						
12 Drug Allergies		□₁→						
13 Other Allergies	По	□,→						
14 Psychological/Psychiatric	По	□₁→						
15 Other	\Box_{o}	□1→						
Physician's Signature		· · · · · · · · · · · · · · · · · · ·						
Signature:								



	Center Nu	mber:	Participant Nu	mber: Participant's Initials:middle last			
Physical Examination							
Date of examination:/	_/	_		Staff initials:			
OR Not done → Specify reason (use co				first middle last			
Body System		Assessments	3	If Abnormal or Not Done: Explain			
body System	Normal	Abnormal	Not Done	II Abilot ilidi of Noi Boile. Explain			
General appearance:		□₀→	₉₇ →				
2 Head, Ears, Eyes, Nose, Throat:		□ _o →	□ ₉₇ →				
3 Neck:		□₀→	□ ₉₇ →				
4 Heart:		□ _o →	□ ₉₇ →				
5 Lungs:		□₀→	□ ₉₇ →				
6 Abdomen:		□ _o →	□ ₉₇ →				
7 Lymph nodes:		□ _o →	□ ₉₇ →				
8 Extremities/Skin:		□₀→	□ ₉₇ →				
9 Neurological:		□ _o →	□ ₉₇ →				
10 Musculoskeletal:		□₀→	□ ₉₇ →				
	Normal	Abnormal	Not Done*				
11 Genitourinary:		□₀→	□ ₉₇ →				
12 Breast:		\square_{o} \rightarrow	□ ₉₇ →				
Physician's Signature							
Investigator:	nvestigator: Date:/						
Physician's Signature		□₀→		Date:/			

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

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



	Center Number:	Participant Number:	Participant's Initials:
Clinic Weight			
Weight date and time:	/	00:00 to 23:59	Staff initials:
	y reason (use codelist below):		ilisi ililuule iusi
Clinic weight (if the two	measurements are more than 0.1 kg a	part, measure weight a third time)	:
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Pregnancy Tes	t		
Complete only for fe	males.		
	ave reproductive potential?		
\bigsqcup_0 No \bigsqcup_1 Yes \rightarrow If Yes: D	ate urine pregnancy test performe	d:/	
	esults:1 Negative	day month year	
	Positive		
Not Done Codelist: 1 F	articipant refused 2 Clinician unab	le to obtain 3 Insufficient time	4 Instrument failure 5 Not required



		Center Number:	Participant Number:	Participant's Initials:
D	oubly Labeled W	ater (DLW)		
1	Date and time of DLW do	sing:/ _{month}	year 00:00 to 23:59	Staff initials:
	OR Not done → Specify r	eason (use codelist below):	-	
2	DLW dose mixture ID and	bottle number:	– CA	
3	Exact weight of DLW mixt	rure: gra	ıms	
4	Urine samples:			
	Collection	Sample	Date and Time	Collected
	Pre dosing (PD)	PDa	/	:: 00:00 to 23:59
		PDb	/	:::::::
	Day 0 (Visit 2)	DOα	/	: : : : : : : : : : : : : : : : : : :
		DOP	day month year	00:00 to 23:59
	Day 7 (Visit 3)	D7a	day / month year	
		D7b	day month year	: 00:00 to 23:59
	Day 14 (Visit 4)	D14a	/	::::::::
		D14b	/	:::
5	Affix CRF page label(s) co	orresponding to this urine sam	pple set: Affix Label Here	

3 Insufficient time 4 Instrument failure

5 Not required

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



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

		first middle last			
DXA Scan					
 Has the participant taken a calcium supplement today? □₀ No □₁ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? □₀ No □₁ Yes 					
DXA Scan DXA Rescan OR					
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 2	Clinician unable to obtain	n 3 Insufficient time 4 Instrument failure 5 Not required			



	Center Number:	Participant N	Number:	Participant's I	nitials: first_middle last
Date completed:/ _{month} /	OR Not don	ne → Specify re	ason (use codelist be	olow):	
Profile of Mood States					
Instructions: Please describe how yo	u feel right now by cl	necking one bo	x for each of the w	ords listed below.	
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly					4
2 Tense	\square_{o}		\square_{2}	\square_3	
3 Angry				\square_3	4
4 Worn out				\square_3	4
5 Unhappy					4
6 Clear-headed	\square_{o}		\square_{2}	\square_3	
7 Lively				\square_3	4
8 Confused				\square_3	4
9 Sorry for things done					4
10 Shaky				\square_3	
11 Listless					4
12 Peeved	\square_{o}		\square_{2}	\square_3	4
13 Considerate					4
14 Sad				\square_3	4
15 Active					4
16 On edge					
17 Grouchy					
18 Blue					
19 Energetic					
20 Panicky				\square_3	
Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. / 950, North Tonawanda, NY 14120-0950. In Canada, 3770		л2Н 3М6.		ns Inc. All rights reserved.	In the U.S.A., P.O. Box
Not Done Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insuff	ficient time 4 Instru	ment failure 5 N Participant's I	ot required
				•	first middle last



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed				\square_3	4
23 Unworthy					4
24 Spiteful					4
25 Sympathetic					4
26 Uneasy				\square_3	4
27 Restless					4
28 Unable to concentrate				\square_3	4
29 Fatigued					4
30 Helpful			\square_{2}	\square_3	4
31 Annoyed					4
32 Discouraged	\square_{0}		\square_{2}	\square_3	4
33 Resentful					4
34 Nervous				\square_3	4
35 Lonely				\square_3	4
36 Miserable					4
37 Muddled					4
38 Cheerful					4
39 Bitter					4
40 Exhausted					4
41 Anxious					4
42 Ready to fight					4
43 Good-natured					4

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 Ave., Toronto, ON M2H 3M6.

Participant's Initials: first middle last



	Center Number: _	Participal	nt Number:	Participant's	first middle last
Profile of Mood States (ontinued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy				\square_3	
45 Desperate					4
46 Sluggish					4
47 Rebellious					4
48 Helpless					
49 Weary					4
50 Bewildered	\Box_{o}			\square_3	
51 Alert					4
52 Deceived	\Box_{o}			\square_3	
53 Furious					4
54 Efficient	\Box_{o}			\square_3	
55 Trusting	o				4
56 Full of pep				\square_3	
57 Bad-tempered	o				4
58 Worthless	\Box_{o}			\square_3	
59 Forgetful					4
60 Carefree				\square_3	
61 Terrified					4
62 Guilty				\square_3	
63 Vigorous					4
64 Uncertain about things				\square_3	4
65 Bushed					4

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 Ave., Toronto, ON M2H 3M6.

Participant's Initials: first middle last



		Center Number:	Participant Numb	er:		Participant'	's Initials:	first middle last
Da	te completed:day //	OR Not done =	→ Specify reasor	(use code	list below):			
P	erceived Stress Scale (PSS	5)						
Ins	structions: The questions in this scale indicate how often you fe	e ask you about your feeli elt or thought a certain wa		-				lease
				Never	Almost Never	Some- times	Fairly Often	Very Often
1	In the last month, how often unable to control the importa	•					\square_3	4
2	In the last month, how often your ability to handle your p	-	ent about				\square_3	4
3	In the last month, how often going your way?	have you felt that thi	ngs were				\square_3	
4	In the last month, how often piling up so high that you cou							
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obto	in 3 Insufficien	t time 4	Instrument f	failure 5	Not requi	red

Participant's Initials: first middle last



	Center Number: Participan	t Number:	Parti	cipant's Initials	first middle last
Da	te completed:/ OR Not done → Specify I	reason (use codel	ist below):		
Pi	ttsburgh Sleep Quality Index (PSQI)				
	structions: The following questions relate to your usual sleep habits duri the most accurate reply for the majority of days and nights in		-		
Du	ring the past month	i ine pasi monini	Ticase answe	ii dii qoosiid	
1	When have you usually gone to bed?:				
2	How long (in minutes) has it taken you to fall asleep each	night?	minu	tes	
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
	a Cannot get to sleep within 30 minutes	o		2	\square_3
	b Wake up in the middle of the night or early morning	o		\square_{2}	\square_3
	c Have to get up to use the bathroom				\square_3
	d Cannot breathe comfortably				\square_3
	e Cough or snore loudly				\square_3
	f Feel too cold				\square_3
	g Feel too hot				\square_3
	h Have bad dreams				\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_3
6	During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	o			
	89,with permission from Elsevier Science. of Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Inst	ufficient time 4	Instrument failure	e 5 Not re	auired



	Center Number: Particip	ant Number:	Parti	icipant's Initials	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (continued)				
		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?				
		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?				3
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?	\square_{o}			\square_3



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	OR Not done → Specify	reason (use codelist below):	_	

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.

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

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



Center	Number:	Po	ırticipant N	umber:		Par	ticipant's I	nitials:	st middle last
Derogatis Interview for Sexua	l Functi	on (DIS	F-SR) (F)	Female \	/ersion (c	ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone					4		6	7	8
2.2 Actively seek sexual satisfaction					4		6		
2.3 Feel sexually aroused with a partner					4	5	6	7	8
	Never	Rarely	Sometimes	Usually	Always				

Copyright © 1987 by Leonard R. Derogatis, PhD.

throughout sexual relations

2.5 Have normal lubrication

2.4 Have normal lubrication with

masturbation



Center Nu	mber:	Po	articipant N	lumber:		Po	irticipant'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	;								
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	o			\square_3	4	5			8
3.2 Masturbation	По			\square_3	□ ₄	5			□ ₈
3.3 Casual kissing and petting	По				□ ₄	5			□ ₈
3.4 Sexual foreplay	По				4	5	□ ₆		□ ₈
3.5 Sexual intercourse, oral sex, etc.				\square_3	4	5			8
Section 4—Orgasm									
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	О				4				
4.2 The intensity of your orgasm	По				4				
4.3 The ability to have multiple orgasms (if typical for you)					4				
4.4 Feelings of closeness and togetherness with your partner	О				4				
4.5 Your sense of control (timing) of your orgasm	О				4				
4.6 Feeling a sense of relaxation and well-being after orgasm									

Copyright © 1987 by Leonard R. Derogatis, PhD.



Co	enter Number:		Participant	Number:		P	articipant's	s Initials:	irst middle last
Derogatis Interview for Sex	ual Fund	tion (DISF-SR) (F) Female	Version	(continue	ed)		
Section 5—Drive and Relationship									
	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				3	4	5		7	
	Not at	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex	·3			3	4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	do			3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represe	nt								

Copyright © 1987 by Leonard R. Derogatis, PhD.

of your sexual functioning?

the best description of the quality



Baseline Submission 1

Calerie """	_				0.00			Vi	sit 2
Center N	Number:	_ Partic	pant Num	ber:		_ Partic	cipant's Ir	nitials:	t middle last
Date completed:/OR No	t done → Spec	cify reaso	on (use co	delist bel	low):				
Derogatis Interview for Sexual	Function	DISF-S	R) (M) N	Nale Ver	sion				
Instruction: Below you will find a brief set of que sections that ask about different aspects of your sewhile another inquires about the kinds of sexual sexual arousal and the quality of your orgasm relationship.	exual experien experiences	nces. One that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fante d about t	asies or the natu	daydre	ams, ur
On some questions you are asked to respond activities asked about in that section. Some freque frequency scales range from "0 = never" to "4 = co of a satisfaction scale. This type of scale tells how Some satisfaction scales range from "0 = could no "0 = not at all satisfied," to "4 = extremely satisfied. In every section of the inventory the scales reco	ency scales go to always." In the much you enjo of be worse" to ed."	from "O e case of oyed, or o "8 = co	= not at other qu were sati uld not b	all" to "i estions, ; sfied by e better.	8 = four you will the sexu " Other	or more be asked al activit satisfacti	times a I to resp y being on scale	day." Of ond in to asked a s go fro	ther erms bout. m
follow. Although it is brief, take your time with the describes your personal experience.									
If you have any questions, please ask the person	who gave you	the inve	ntory for	help.					
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last tim you filled out this inventory, how often have you had thoughts, dreams, or fantasies abou	all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4	5	6		8
1.2 Erotic parts of a woman's body (e.g.,	,								

Copyright © 1987 by Leonard R. Derogatis, PhD.

1.3 Erotic or romantic situations

1.4 Caressing, touching, undressing, or

1.5 Sexual intercourse, oral sex, touching

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

face, genitals, legs)

foreplay

to orgasm



	Center Number:	Par	ticipant Nu	mber:		Part	icipant's I	nitials:	st middle last
Derogatis Interview for Sex	kual Functi	on (DISI	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal									
During the past 30 days or since the la you filled out this inventory, how often you have the following experiences?	l dii	t 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	e			3	4	5	6		8
2.2 A full erection during a sexual fantasy or daydream				\square_3	4				8
2.3 A full erection while looking at sexually arousing person, move picture					4		6		8
2.4 A full erection during masturbo	ation						6		8
of a normal sexual response cy that is from undressing and for through intercourse and orgas	ycle, replay						6		8

Copyright © 1987 by Leonard R. Derogatis, PhD.

Participant's Initials: first middle last



Center Num	ber:	Par	ticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DIS	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 3—Sexual Behavior/Experiences									
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			8
3.2 Masturbation				\square_3	4	5	6		8
3.3 Casual kissing and petting	o			\square_3	4	5			8
3.4 Sexual foreplay				\square_3	4	5			
3.5 Sexual intercourse, oral sex, etc.					4	5		7	8
Section 4—Orgasm	•								
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					4				
4.2 The intensity of your orgasm				\square_3	4				
4.3 The length or duration of your orgasm	□ _o			\square_3	4				
4.4 The amount of seminal liquid that you ejaculate									
4.5 Your sense of control (timing) of your orgasm					4				
4.6 Feeling a sense of relaxation and well-being after orgasm									

Copyright © 1987 by Leonard R. Derogatis, PhD.



Center	Number:		Participant	Number:		P	articipant's	s Initials:	irst middle last
Derogatis Interview for Sexua	l Fund	tion (DISF-SR) (M) Male \	/ersion (d	ontinue	d)		
Section 5—Drive and Relationship									
	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?				\square_3	□ ₄	5	□ ₆	_ ₇	□ ₈
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?					\square_4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_3	□4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?				\square_3	4				8

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number: Pa	rticipant Nun	nber:		Participar	nt's Initials:	first middle last
Da	te completed:/OR Not done → Sp	ecify reaso	on (use code	elist below)	:	_	
Fo	ood Cravings Questionnaire—Trait						
Ple	ase indicate the extent to which you agree with each statement be	ow, in gen	eral, by ch	ecking the	appropr	iate box.	
		Never OR NA	Rarely	Some- times	Often	Usually	Always
1	Being with someone who is eating often makes me hungry.			\square_3		5	
2	When I crave something, I know I won't be able to stop eating once I start.				4	5	6
3	If I eat what I am craving, I often lose control and eat too much.				4		6
4	I hate it when I give in to cravings.			$\square_{_3}$		5	6
5	Food cravings invariably make me think of ways to get what I want to eat.			\square_3			
6	I feel like I have food on my mind all the time.			\square_3	4	5	
7	I often feel guilty for craving certain foods.			\square_3			
8	I find myself preoccupied with food.			\square_3		5	6
9	I eat to feel better.			\square_3	4		
10	Sometimes, eating makes things seem just perfect.			\square_3	4		6
11	Thinking about my favorite foods makes my mouth water.				4	5	6
12	I crave foods when my stomach is empty.			\square_3		5	6
13	I feel as if my body asks for certain foods.			\square_3	4	5	
14	I get so hungry that my stomach seems like a bottomless pit.			3	4	5	
15	Eating what I crave makes me feel better.			\square_3	4	5	
16	When I satisfy a craving, I feel less depressed.			\square_3	4	5	6
17	When I eat what I am craving, I feel guilty about myself.				4		6
18	Whenever I have cravings, I find myself making plans to eat.						
19	Eating calms me down.			\square_3		5	6
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficie	nt time 4	Instrument	failure	5 Not requ	ired



Center Number: Participant Number: P						Participant's Initials: First middle last			
Food Cravings Questionnaire—Trait (continued	귀)								
	Never OR NA	Rarely	Some- times	Often	Usually	Always			
20 I crave foods when I am bored, angry, or sad.			\square_3		5				
21 I feel less anxious after I eat.					5	6			
22 If I get what I am craving, I cannot stop myself from eating it.	n				5	6			
23 When I crave certain foods, I usually try to eat them a soon as I can.	as		\square_3	4					
24 When I eat what I crave, I feel great.			\square_3		5	6			
25 I have no will power to resist my food crave.				4	5	6			
26 Once I start eating, I have trouble stopping.				4	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.					5				
29 If I give in to a food craving, all control is lost.				4	5				
30 When I'm stressed out, I crave food.				4	5				
31 I daydream about food.			3	4	5	6			
32 Whenever I have a food craving, I keep on thinking about eating until I actually eat the food.	g								
33 If I am craving something, thoughts of eating it consume me.				4	5				
34 My emotions often make me want to eat.			3	4	5	6			
35 Whenever I go to a buffet, I end up eating more than what I needed.			3	4	5	6			
36 It is hard for me to resist the temptation to eat appetizing foods that are in my reach.				4					
37 When I am with someone who is overeating, I usually overeat too.						6			
38 When I eat food, I feel comforted.				4	5	6			
39 I crave foods when I'm upset.									



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/ _{month} /	OR Not done -	Specify reason (use codelist below):		

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.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I have an intense desire to eat [one or more specific foods].			\square_3	4	5
2	I'm craving [one or more specific foods].		\square_2	\square_3	\square_{4}	5
3	I have an urge for [one or more specific foods]			\square_3	4	
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3		5
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3		
6	Eating [one or more specific foods] would feel wonderful.			\square_3		5
7	If I ate something, I wouldn't feel so sluggish and lethargic.				4	
8	Satisfying my craving would make me feel less grouchy and irritable.			\square_3		5
9	I would feel more alert if I could satisfy my craving.			\square_3		
10	If I had [one or more specific foods], I could not stop eating it.			\square_3	\square_{4}	
11	My desire to eat [one or more specific foods] seems overpowering.			\square_3	4	
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			\square_3	\square_{4}	
13	I am hungry.			\square_3		
14	If I ate right now, my stomach wouldn't feel as empty.			\square_3		
15	I feel weak because of not eating.			\square_3		



	Center Numbe	r: Po	rticipant Number:		Participant's Initials: First middle last			
Date completed:/ _{month}	_/ OR N	Not done → S _l	pecify reason (us	se codelist below):			
Food Craving Invento								
For each of the foods listed below		· -						
Note: A craving is defined as an in Over the past month, I		me a particulo	1	ype that is diffi	cult to resist.	Always/Almost		
have you experienced a c		Never	Rarely (once or twice)	Sometimes	Often	Every Day		
1 Cake				\square_3	4			
2 Pizza				$\qquad \qquad \square_3$	4			
3 Fried chicken								
4 Gravy								
5 Sandwich bread					4			
6 Sausage								
7 French fries								
8 Cinnamon rolls								
9 Rice								
10 Hot dog								
11 Hamburger								
12 Biscuits								
13 Ice cream								
14 Pasta								
15 Fried fish								
16 Cookies								
17 Chocolate								
18 Pancakes or waffles								
19 Corn bread								
20 Chips								
21 Rolls								
22 Cereal								
23 Donuts								
24 Candy								
25 Brownies								
26 Bacon								
27 Steak								
28 Baked potato								
Not Done Codelist: 1 Participant re	efused 2 Clinician und	able to obtain	3 Insufficient tim	ne 4 Instrumen	t failure 5 N	lot required		
					Participant's	Initials:		



		Center Number:	Participant Number:	Participant's I	nitials:
Date c	ompleted:/ _{month} /	OR Not done →	Specify reason (use codelist below)	·	
Eati	ng Inventory				
1	When I smell a sizzling ste difficult to keep from eatin	ak or see a juicy pie g, even if I have just	ece of meat, I find it very finished a meal.	☐₁ True	□₀ False
2	I usually eat too much at s	ocial occasions, like	parties and picnics.	1 True	o False
3	I am usually so hungry the	it I eat more than th	ree times a day.	, True	o False
4	When I have eaten my que not eating anymore.	ota of calories, I am	usually good about	, True	o False
5	Dieting is so hard for me b	ecause I just get too	hungry.	1 True	o False
6	I deliberately take small he	elpings as a means o	of controlling my weight.	, True	o False
7	Sometimes things just taste I am no longer hungry.	so good that I keep	o on eating even when	, True	o False
8	Since I am often hungry, I expert would tell me that I something more to eat.			, True	□₀ False
9	When I feel anxious, I find	myself eating.		☐₁ True	o False
10	Life is too short to worry a	bout dieting.			o False
11	Since my weight goes up o more than once.	ınd down, I have go	one on reducing diets	☐₁ True	□₀ False
12	I often feel so hungry that	I just have to eat so	mething.	1 True	o False
13	When I am with someone	who is overeating, I	usually overeat too.	☐₁ True	o False
14	I have a pretty good idea	of the number of ca	lories in common food.	, True	☐₀ False
15	Sometimes when I start ea	ting, I just can't seer	m to stop.	₁ True	o False
16	It is not difficult for me to le	eave something on I	my plate.	, True	o False
17	At certain times of the day to eating then.	, I get hungry becau	use I have gotten used	, True	□₀ False
18	While on a diet, if I eat foo for a period of time to mal		d, I consciously eat less	, True	□₀ False
Not D	one Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time 4 Instrumen	t failure 5 N	ot required



Baseline Submission 1

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

calerie Phase 2

Baseline Submission 1 Visit 2

	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.						
37	How often are you dieting in a conscious effort to control your weight?	☐₁ Rarely ☐₂ Sometimes	□ ₃ Usually □ ₄ Always					
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\square_1 Rarely \square_2 Sometimes	□ ₃ Usually □ ₄ Always					
39	How often do you feel hungry?		□₃ Usually □₄ Always					
40	Do your feelings of guilt about overeating help you to control your food intake?	☐₁ Rarely ☐₂ Sometimes	□ ₃ Usually □ ₄ Always					
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₃ Moderately difficult	□₂ Slightly difficult□₄ Very difficult					
42	How conscious are you of what you are eating?	□₁ Not at all□₃ Moderately	□₂ Slightly □₄ Extremely					
43	How frequently do you avoid "stocking up" on tempting foods?	☐₁ Almost never ☐₃ Usually	□₂ Seldom □₄ Almost always					
44	How likely are you to shop for low calorie foods?	☐₁ Unlikely ☐₃ Moderately likely	□₂ Slightly 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 □₃ Moderately likely	□₂ Slightly likely □₄ Very likely					
47	How frequently do you skip dessert because you are no longer hungry?	☐₁ Almost never ☐₃ At least once a week	□₂ Seldom □₄ Almost every day					
48	How likely are you to consciously eat less than you want?	☐₁ Unlikely ☐₃ Moderately likely	Slightly likely Very likely					
49	Do you go on eating binges though you are not hungry?	☐₁ Never ☐₃ Sometimes	☐₂ Rarely ☐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."	Not like me Little like me specifies 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?	Eat whatever you want, whenever you want it Usually eat whatever you want, whenever you want, whenever you want, whenever you want, whenever you want, often eat whatever you want, whenever you want, often eat whatever you want, whenever you want it want, all usually limit food intake, but often "give in" Usually limit food intake, rarely "give in" Constantly limiting food intake, never "giving in"						

Participant's Initials: first middle last



		Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed: _	/	OR Not done →	Specify reason (use codelist below):		

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

I a	I am confident that:		Not confident at all that you can resist the desire to eat						Very confident that you can resist the desire to eat					
		0	1	2	3	4	5	6	7	8	9			
1	I can resist eating when I am anxious (nervous).					4	5	6		8	9			
2	I can control my eating on the weekends.				\square_3	4	5	6		8	9			
3	I can resist eating even when I have to say "no" to others.				\square_3	4	5	6		8	9			
4	I can resist eating when I feel physically run down.				\square_3		5	6		8	9			
5	I can resist eating when I am watching TV.					4	5	6		8	9			
6	I can resist eating when I am depressed (or down).				\square_3	4	5	6		8	9			
7	I can resist eating when there are many different kinds of food available.					4	5			8	9			
8	I can resist eating even when I feel it is impolite to refuse a second helping.					4	5			8	9			
9	I can resist eating even when I have a headache.							6		8	9			
N	ot Done Codelist: 1 Participant refused 2 Clinician unable	to obta	in 3	Insufficie	ent time	4 Ins	trument	failure	5 Not	require	Ь			

Participant's Initials:



Center Number:		Partici	pant Nui	mber:			Particip	oant's Ini	first	middle last
Weight Efficacy Lifestyle Questionna	iire (v	VEL) (co	ontinue	d)						
I am confident that:	Not confident at all that you can resist the desire to eat								onfide i e desire	
	0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am reading.				\square_3			6			
11 can resist eating when I am angry (or irritable).							6		8	
12 I can resist eating even when I am at a party.				\square_3			6			9
13 I can resist eating even when others are pressuring me to eat.					4				8	9
14 I can resist eating when I am in pain.				$\square_{_3}$		5	6		8	
15 I can resist eating just before going to bed.					4		6		8	
16 I can resist eating when I have experienced failure.					4		6		8	
17 I can resist eating when high-calorie foods are available.							6		8	9
18 I can resist eating even when I think others will be upset if I don't eat.									8	9
19 I can resist eating when I feel uncomfortable.					4		6		8	
20 I can resist eating when I am happy.										



		Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last
Da	te completed:/ _{month} /	OR Not done	• Specify	reason	(use code	elist belov	v):			
M	ultiaxial Assessment of	Eating Disorder	Sym	otom	S (MAE	DS)				
Ins	structions: Using the scale shown, plea	se rate the following items	on a sca							
				Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1	Fasting is a good way to lose	e weight.				\square_3		5		
2	My sleep isn't as good as it u	used to be.				\square_3			6	
3	I avoid eating for as long as	I can.				\square_3		5		
4	Certain foods are "forbidden	" for me to eat.				\square_3	4	5	6	
5	I can't keep certain foods in my binge on them.	house because I will				\square_3	4	5	6	
6	I can easily make myself von	nit.				\square_3	4		6	
7	I can feel that being fat is ter	rible.				3		5		
8	I avoid greasy foods.					\square_{3}		5	6	
9	It's okay to binge and purge	once in a while.				\square_3	4	5		
10	I don't eat certain foods.					\square_3		5		
11	I think I am a good person.					\square_3		5		
12	My eating is normal.					\square_3		5		
13	I can't seem to concentrate lo	itely.				\square_3		5		
14	I try to diet by fasting.					\square_3	4	5		
15	I vomit to control my weight.					\square_3	4	5		
16	Lately nothing seems enjoyal	ole anymore.						5		
17	Laxatives help keep you slim	•						5		
18	I don't eat red meat.					\square_3		5		
19	I eat so rapidly I can't even t	aste my food.				\square_3		5		
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obta	in 3 In:	sufficient	time 4	Instrume	nt failure	5 No	t require	ed

Participant's Initials: first middle last



	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	oms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.				4	5		
21 When I feel bloated, I must do so of that feeling.	something to rid myse	elf		\square_3	4	5	6	
22 I overeat too frequently.				\square_3	4	5		
23 It's okay to be overweight.					4	5	6	
24 Recently I have felt that I am	a worthless person.			\square_3	4	5		
25 I would be very upset if I gain	ned 2 pounds.				4	5	6	
26 I crave sweets and carbohyde	rates.			3	4	5		
27 I lose control when I eat.				3	4	5	6	7
28 Being fat would be terrible.				\square_3	4	5		
29 I have thought seriously abou	ut suicide lately.			\square_3	4	5		7
30 I don't have any energy anymo	ore.			3	4	5		
31 I eat small portions to control	my weight.			3	4	5	6	7
32 I eat 3 meals a day.				3	4		6	
33 Lately I have been easily irrit	ated.			3	4	5	6	
34 Some foods should be totally	avoided.				4	5	6	7
35 I use laxatives to control my	weight.			3	4	5	6	7
36 I am terrified by the thought	of being overweight.			\square_3	4	5		
37 Purging is a good way to lose	e weight.				4	5	6	7
38 I avoid fatty foods.								



Center Number:	Participant N	lumber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of Eating Disord	er Sympto	oms (MAEDS)	(continue	d)		
	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.				4	5	6	
40 I am obsessed with becoming overweight.			\square_3	4	5		
41 I don't eat fried foods.			3	4	5	6	
42 I skip meals.			\square_3	4	5	6	
43 Fat people are unhappy.			\square_3	4	5	6	
44 People are too concerned with the way I eat.			\square_3	4	5	6	7
45 I feel good when I skip meals.			\square_3	4	5	6	
46 I avoid foods with sugar.			\square_3	4	5	6	
47 I hate it when I feel fat.			\square_3	4	5		
48 I am too fat.			\square_3	4	5	6	
49 I eat until I am completely stuffed.			\square_3	4	5	6	
50 I hate to eat.			\square_3	4	5	6	7
51 I feel guilty about a lot of things these days.			\square_3	4	5	6	
52 I'm very careful of what I eat.			\square_3	4	5	6	
53 I can "hold off" and not eat even if I am hungr	y. □₁			4	5		
54 I eat even when I am not hungry.					5		
55 Fat people are disgusting.					5		
56 I wouldn't mind gaining a few pounds.					5	6	



		Center Number: Parti	cipant Number:		Par	ticipant's I	nitials:	t middle last		
Dai	re completed:/ _{month} /	year OR Not done → Spe	cify reason (us	se codelist b	elow):					
В	ody Shape Questionnai	re (BSQ)								
	We would like to know how you have been feeling about your appearance over the past four weeks . Please read each question and check the box for the appropriate choice. Please answer all the questions.									
Ov	er the Past Four Weeks		Neve	Rarely	Some- times	Often	Very Often	Always		
1	Has feeling bored made you	brood about your shape	?		\square_3		5			
2	Have you been so worried a have been feeling that you o		J		\square_3	4	5	6		
3	Have you thought that your too large for the rest of you?		e		\square_3		5			
4	Have you been afraid that you fatter)?	ou might become fat (or			\square_3		5	6		
5	Have you worried about you enough?	ır flesh not being firm			3	4	5			
6	Has feeling full (e.g., after eating fat?	a large meal) made you feel			\square_3	4	5	6		
7	Have you felt so bad about y cried?	our shape that you have			\square_3	4	5			
8	Have you avoided running b wobble?	ecause your flesh might			\square_3	4	5	6		
9	Has being with thin women/ self-conscious about your sho				\square_3	4	5			
	Have you worried about you sitting down?		<u> </u>		\square_3	4	5	6		
11	Has eating even a small amo fat?	ount of food made you fe	el		\square_3	4	5	6		
	Have you noticed the shape felt that your own shape com	pared unfavorably?	d		\square_3	4	5	6		
13	Has thinking about your shape ability to concentrate (e.g., while to conversations)?				\square_3	4				
14	Has being naked, such as wheel fat?	nen taking a bath, made	you		\square_3	4	5	6		
15	Have you avoided wearing a particularly aware of the sho				\square_3	4	5			
16	Have you imagined cutting obody?	ff fleshy areas of your			3	4	5			
No	t Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient tim	ne 4 Instr	ument failı	ıre 5 N	lot require	ed .		



		Center Number:	Participant N	lumber: _		Pai	rticipant's	Initials:	rst middle last
Вс	ody Shape Questionnair	re (BSQ) (continued)							
Ov	er the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
17	Has eating sweets, cakes or a you feel fat?	other high calorie foo	od made				4		
18	Have you not gone out on sobecause you have felt bad ab		arties)			\square_3	4	5	6
19	Have you felt excessively larg	ge and rounded?				\square_3	4	5	
20	Have you felt ashamed of you	ur body?				\square_3	4	5	6
21	Has worry about your shape	made you diet?				\square_3		5	6
22	Have you felt happiest about stomach has been empty?	your shape when y	our			\square_3		5	6
23	Have you thought that you are because you lack self-control?		•			\square_3	4	5	
24	Have you worried about othe flesh around your waist or sto		s of			\square_3	4	5	6
25	Have you felt that it is not fair thinner than you?	r that other women/	men are			\square_3	4	5	6
26	Have you vomited in order to	feel thinner?			\square_{2}	\square_3	4	5	6
27	When in company, have you much room (e.g., sitting on a sofa or		g up too			\square_3	4	5	
28	Have you worried about you	r flesh being dimply	?			\square_3	4	5	6
29	Has seeing your reflection (e.g you feel bad about your shap		w) made			\square_3	4	5	
30	Have you pinched areas of you fat is there?	our body to see how	/ much			\square_{3}	4	5	
31	Have you avoided situations your body (e.g., communal changing						4	5	
32	Have you taken laxatives in c	order to feel thinner?	•				4	5	6
33	Have you been particularly so shape when in the company of		our/			\square_3	4	5	6
34	Has worry about your shape to exercise?	made you feel you	ought			\square_{3}	4	5	



Clinic Weight	
Weight date and time:/	raff initials:
OR Not done → Specify reason (use codelist below):	tirst middle last
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):	
Weight 1: kg	
Weight 2: kg	
Weight 3: kg	
Weight of gown: kg	

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

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

Participant's Initials:

Participant Number:

Center Number:

calerie Phase 2

Se	ven-L	Seven-Day Physical Activity Recall (PAR)	ctivity Reco	II (PAR)											
Tod	Today's date:	le:/		Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Speafy reason (use codelist below):	Mon Tue	se Med	Thurs	Fri So	at Sun	OR Not	done →	Speafy re	ason (use	sodelist bela	: (wo
_	Were yo	oyed	seven days?		°Z □	$\Box_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	stion 3	Ty Yes				Interv	Interviewer initials:		first middle last
7	If Yes: W	If Yes: Which days (check all that apply)?	المرام)ئ		Mon	Mon Tues Wed Thurs Fri	Med	Thurs	Ш	Sat	Sun				
6	Which d	Which days do you consider your weekend, or non-work, days?	our weekend, or r	10n-work, days	Mon	Tues [Wed Thurs		Fri	Sat	Sun				
Day	Jo vod		Slee	Sleep Time	Work Time	Time	Mor	Morning (in minutes)	iutes)	After	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
*	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
(yester-day)		day /	00:00 to 23:59	00:00 to 23:59											
9		day / /	00:00 to 23:59												
5			00:00 to 23:59			00:00 to 23:59									
4			00:00 to 23:59			00:00 to 23:59									
9			00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									
4		day / month year	00:00 to 23:59	00:00 to 23:59											
1 (1 week ago)		day month year	00:00 to 23:59	00:00 to 23:59	. :	00:00 to 23:59									

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

5 Not required

4 Instrument failure



		Center Number:	Participant Number:	Participant's Initials:	st middle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)? More Less About the same	over the past three mon	ths, was last week's physical c	ictivity more, less,	
In	terviewer: Please answer questions	below and note any co	mments on interview.		
5	Were there any problems with the S \square_0 No \square_1 Yes	even-Day PAR interview	?		
6	Do you think this was a valid Seven- one No no Yes	Day PAR interview?			
7	Were there any activities reported by Oo No	y the participant that yo	ou don't know how to classify?	•	



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

Compl	ete below OR Not done → Spe	ecify reason (use Codelist k	pelow): _	Staff	initials:
				Replacement Val	ues
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	/ _{month} /	Reliable Unreliable Unreliable Missing	8	/	Reliable Unreliable 3 Missing
2	/ _{month} /	Reliable Unreliable Unstance 3 Missing	9	/	Reliable Unreliable 3 Missing
3	/ _{month} /	Reliable Unreliable Unreliable Missing	10	/	Reliable Unreliable 3 Missing
4	/	Reliable Unreliable Missing	11	/	Reliable Unreliable 3 Missing
5	/	Reliable Unreliable Missing	12	/	Reliable Unreliable Unreliable Unreliable
6	/	Reliable Unreliable Missing	13	/	Reliable Unreliable Unreliable Unreliable



4 Instrument failure

5 Not required

	Center Number:	Participant Number:	Participant's Initials:
Clinia Waimbi			first middle last
Clinic Weight			
Weight date and time:	/	:	Staff initials:
OR Not done → Speci	fy reason (use codelist below):		
Clinic weight (if the two	measurements are more than 0.1 kg apo	art, measure weight a third time):	
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		

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

calerie Phase 2

Baseline Submission 2

Participant's Initials: _

Participant Number:

		e:/ _{month} /		(check only one):		es Wed → Skip to que				n OR N o	t done →	Specify re Interv	eason (use viewer ini	codelist bel	ow):
	-	Vhich days (check all that apply	-		Mon				Fri _	Sat	Sun				
3	Which d	lays do you consider your			? Mon	Tues	Wed	-	Fri		Sun				
Day	Day of	5.	Sleep	o Time	Work	Time	Mor	ning (in mi		Afte	rnoon (in n		Ever	ning (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	::	:::::::									
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	: 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									
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	00:00 to 23:59									
1 1 week ago)		/	00:00 to 23:59	00:00 to 23:59	:::	:::									

Center Number:



		Center Number:	Participant Number:	Participant's Initials:	first middle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)?	over the past three mont	hs, was last week's physica	l activity more, less,	
Int	erviewer: Please answer questions	below and note any cor	nments on interview.		
5	Were there any problems with the S No Yes	even-Day PAR interview	?		
6	Do you think this was a valid Seven- One No Tyes	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	u don't know how to classif	y? 	



		Center Number	: Participant Num	ber: Part	icipant's Initials: first middle last					
Har	ndgrip Strength									
Date	and time of assessment:	/	: : : : : : : : : : : : : : : : : : :	Staff i	initials:					
OR N	ot done → Specify reaso	n (use codelist below):								
1 D	ynometer handle position	n:								
2 D	ominant hand (check only	one): 🔲 1 Left 🔠 2 Right	Ambidextrous							
3 Handgrip strength:										
	Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand					
	Test 1—peak force		kg	\Box_{o}	kg					
	Test 2—peak force	\square_{0}	kg	\square_{0}	kg					
	Test 3—peak force		kg	\square_{o}	kg					
Not D	Oone Codelist: 1 Participar	nt refused 2 Clinician una	ble to obtain 3 Insufficie	nt time 4 Instrument failui	re 5 Not required					



			Center Number:	Participant Number:	Particip	first middle las
Is	sometric/Isokine	tic Kne	e Extension and	l Flexion		
	ate and time of assessment R Not done → Specify rea			: 00:00 to 23:59	Staff ini	tials:
_	Decembration of the state of		□ N- □ V			
1	Recent injury or pain—rig					
2	1. 7 . 1					
3	Specify machine used (P	BRC only):				
	All values corrected	for gravi	ity effect torque	Right Leg	Left Leg	If Not Done, Specify Reason (Use codelist below)
3	60°/sec knee extension		peak torque	N.m	N.m	
			total work	N.m	N.m	
			average power	watts	watts	
4	60°/sec knee flexion		peak torque	N.m	N.m	
			total work	N.m	N.m	
			average power	watts	watts	
5	180°/sec knee extension		peak torque	N.m	N.m	
			total work	N.m	N.m	
			average power	watts	watts	
			work fatigue index	%	%	
6	180°/sec knee flexion		peak torque	N.m	N.m	
			total work	N.m	N.m	
			average power	watts	watts	
			work fatigue index	%	%	
7	Isometric knee extension	: trial 1	peak torque	N.m	N.m	
		trial 2	peak torque	N.m	N.m	
		trial 3	peak torque	N.m	N.m	
8	Isometric knee flexion:	trial 1	peak torque	N.m	N.m	
		trial 2	peak torque	N.m	N.m	
		trial 3	peak torque	N.m	N.m	
N	ot Done Codelist: 1 Particip	ant refused	2 Clinician unable to ob	stain 3 Insufficient time	4 Instrument failure	5 Not required



		Center Number:	Participant Number:	Participant's Initials: First middle last			
D	oubly Labeled V	Vater (DLW)					
1	-	osing:/ _{month} /	year 00:00 to 23:59	Staff initials: first middle last			
	OR Not done → Specify	reason (use codelist below): _	<u> </u>				
2	DLW dose mixture ID and bottle number:						
3	3 Exact weight of DLW mixture: grams						
4	Urine samples:						
	Collection	Sample	Date and Time C	ollected			
	Day 0 (Visit 4)	DOa	/	::			
		DOb	/	::			
	Day 7 (Visit 5)	D7α	/	00:00 to 23:59			
		D7b	/				
	Day 14 (Visit 7)	D14a	/				
		D14b	/				
5	Affix CRF page label(s) o	corresponding to this urine so	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



Clinic Weight						
Weight date and time:/						
OR Not done → Specify reason (see Codelist below):						
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):						
Weight 1: kg						
Weight 2: kg						
Weight 3: kg						
Weight of gown: kg						
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required						



5 Not required

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

	first middle last
V	O ₂ Max
1	Date and time of test:/
	OR Not done → Specify reason (use codelist below):
2	At what time was the participant's last meal/snack eaten?: =
3	Rest ECG: Rhythm (check only one):
4	Heart rate (HR) data: Resting heart rate:bpm Age-predicted heart rate:bpm Heart rate (max):bpm
5	Reason(s) for termination of testing (check all that apply): Symptom limited (dyspnea, fatigue) Angina/ischemia → Complete all that apply: HR when true cardiac angina occurred: bpm OR □ ₉₆ NA HR when ischemic ECG changes occurred: bpm OR □ ₉₆ NA Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress image study, complete ventricular episode report) Orthopedic/extremity complaints (pains/cramps) Other (specify):
6	Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min, bi/tri-geminy, NSVT [≥ 3 beats])? □₀ No □₁ Yes → If Yes: When did it occur (check all that apply)? □ During exercise □ During recovery
7	Peak VO₂: mL/kg/min L/min
8	Did the participant meet at least 2 of the 3 VO₂ max criteria (see box,right)? □₀ No □₁ Yes → If Yes: VO₂ max: mL/kg/min L/min □₁ The participant meet at least 2 of the 3 VO₂ max criteria (see box,right)? □₁ Achieve a plateau in VO₂ (change ≤ 150 mL) between the final two stages b RER ≥ 1.1 c HR max ± 5 bpm of age-predicted maximum
9	Exercise time: : seconds
10	Blood pressure at VO ₂ peak/VO ₂ max:/ mm Hg
11	Borg RPE score at VO ₂ peak/VO ₂ max: (6-20)
12	Peak RER:
13	VE at VO ₂ peak/VO ₂ max: L/min
14	VE/VO ₂ at VO ₂ peak/VO ₂ max L/min

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

2008 DCRI — Confidential

CRF, page 82

calerie Phase 2

Baseline Submission 2

						Center N	umber:	P	articipant I	Number: .		Po	ırticipant's	Initials:	rst middle last
Se	ven-[Day Physical Activ	vity Reca	[(PAR)											
Tod	ay's dat	e:/	Day	(check only one):	Mon Tu	es Wed	Thurs	Fri S	Sat Sui	n OR No	ot done →	Specify re	∋ason (use	codelist bel	low):
		ou employed in the last seve				→ Skip to que						Interv	iewer ini	itials:	middle last
2	If Yes: V	Which days (check all that apply)?	?		Mon	Tues	Wed	Thurs	Fri	Sat	Sun				
3	Which c	lays do you consider your v		-			Wed	Thurs			Sun				
Day	Day of	Date	Slee	p Time	Work	Time	Mor	ning (in m		Afte	rnoon (in n		Ever	ning (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									
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		/	00:00 to 23:59	00:00 to 23:59	::00:00 to 23:59	: 00:00 to 23:59									
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	: 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										



		Center Number:	Participant Number:	Participant's Initials:	first middle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)?	over the past three mont	hs, was last week's physica	l activity more, less,	
Int	erviewer: Please answer questions	below and note any cor	nments on interview.		
5	Were there any problems with the S No Yes	even-Day PAR interview	?		
6	Do you think this was a valid Seven- One No Tyes	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	u don't know how to classif	y? 	



5 Not required

		Center Number:	Partio	ipant Number: Po	articipant's Initials:			
6-D	ay Food Record							
Comp	olete below OR Not done → Speci	ify reason (use Codelist b	pelow): _	Staf	f initials: first middle last			
			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	/	☐ Reliable ☐ Unreliable ☐ Missing			
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	☐ Reliable ☐ Unreliable ☐ Missing			
3	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10	/	☐ Reliable ☐ Unreliable ☐ Missing			
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	☐ Reliable ☐ Unreliable ☐ Missing			
5	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12	/ _{month} / year	☐ Reliable ☐ Unreliable ☐ Missing			
6	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	13	/	☐ Reliable ☐ Unreliable ☐ Missing			
		·						

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



		Center N	umber:	Participant Num	ber:	Participant's Init	first middle la	
D	elayed-type Hypeı	rsensitivity	(DTH)					
1	Was the DTH worksheet con \square_0 No \square_1 Yes \rightarrow If Yes: Were any				test administer test.			
2	Date of injection:/	/	OR Not done	→ Specify reas	on (use codelist below)	:		
3	Injection by (initials):							
4	Arm injected: 1 Right	2 Left						
	Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. A = Largest diameter B = Second diameter perpendicular to A							
	Antigen		Hour (@Visit 7)	n In .		Hour (@Visit 8)	D. d.D.	
	1 Normal saline	A (diameter) mm	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:	
	2 Tetanus toxoid (∏)	mm	mm	first middle last	mm	mm	first middle last	
	3 Candida	mm	mm	(initials)	mm	mm	(initials)	
	4 Trichophyton	mm	mm		mm .	mm		

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

5 Not required



	Cen	ter Number: _	Participant Number:	Participant's Initials: first middle last
Cl	Clinic Weight			
	Veight date and time:/ _{month} / OR Not done → Specify reason (use Codelist b			Staff initials:
Cli	linic weight (if the first two measurements are mo	ore than 0.1 k	g apart, measure weight a third time):	
We	Veight 1: kg			
We	Veight 2: kg			
We	Veight 3: kg			
We	Veight of gown:kg			
V	/ital Signs			
As	ssessment date and time:/	/	:::::	
1	(if the first two measurements are more than 1.0 conclusions) Natural waist measurement 1:	m apart, measi	ure natural waist circumference a third time	Staff initials: first middle lost
	Natural waist measurement 2:	·	cm	
	Natural waist measurement 3:	·	cm	
2	Umbilical point waist measurement (if the first umbilical point waist circumference a third time):	t two measurer	ments are more than 1.0 cm apart, measu	re
	Umbilical point waist measurement 1:	·	cm	
	Umbilical point waist measurement 2:	·	cm	
	Umbilical point waist measurement 3:		cm	
3	5 Pulse: bpm OR Not done →	Specify reas	son (use codelist below):	Staff initials:
4	Temperature:°C OR N	lot done → S	specify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR Not	done → Spe	ecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):	rm \square_{2} Rig	ht arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time::_O0:00 to 23:59 OR Not done Specify re	eason (use codelist below):
	6b Blood pressure 2:/	mm Hg		. ,
	6c Blood pressure 3:/	_ mm Hg	Time:::	
No	lot Done Codelist: 1 Participant refused 2 C	linician unable	e to obtain 3 Insufficient time 4 In	strument failure 5 Not required



	Center Number:	Participant Number:	Participant's Initials:
Pregnancy	r Test		
Complete only	for females.		
□ _o No	Yes: Date urine pregnancy test performed: Results: 1 Negative 2 Positive	/	
Core Temp	erature	ŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢŢ	
Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sampl Collection/Procee	Reason
	Start Date:/	Start Time:00:00 to 23:59	
first middle last	Stop Date:	Stop Time:00:00 to 23:59	
Inpatient A	Admission and Discharge		
1 Inpatient adr	mission date and time:/ _{month} /_		
2 Inpatient disc	charge date and time:/ _{month} /_	year 00:00 to 23:59	
Not Done Codeli	ist: 1 Participant refused 2 Clinician unable to	o obtain 3 Insufficient time 4 Instrun	ment failure 5 Not required

calerie Phase 2

Baseline Submission 2

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

									-					fi	rst middle last
Se	ven-L	Day Physical Activ	vity Reca	II (PAR)											
Tod	ay's dat	e:/	Day	(check only one):	Mon Tu	es Wed	Thurs	Fri S	at Su	n OR No	t done →	Specify re	eason (use	codelist bel	ow):
1	1 Were you employed in the last seven days? □ ₀ No → Skip to question 3 □ ₁ Yes Interviewer initials: _{first middle lost}														
2	2 If Yes: Which days (check all that apply)?														
3	Which days do you consider your weekend, or non-work, days?														
Day	Day of	_	Slee	o Time	Work	Time	Mor	ning (in mi		Afte	noon (in n		Ever	ning (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									
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									
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									



	Center Number: Participant Number: Participant's Initials:	first middle last
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)?	
	□ ₁ More	
	Less 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?	
	□ ₀ No	
	∐ ₁ Yes	
6	Do you think this was a valid Seven-Day PAR interview?	
	□ ₀ No	
l _		
7	Were there any activities reported by the participant that you don't know how to classify?	
	□ ₀ No □ ₁ Yes	



		Center Number:	_ Participant Number: _	Particip	pant's Initials:	
Outcomes Labs						
Date and time of last mea				5 9		
	Sample		Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials	
Cate	echolamines		o No		first middle last	
	Blood		□ ₀ No □ ₁ Yes		first middle last	
Oral glucose	tolerance test	11 11 11 1	□ ₀ No □ ₁ Yes		first middle last	
If a sample is not obtained, i	indicate with a N	Not Done.				
Biopsy Labs						
Sample		Date of (Collection	If Not Done, Reason (Use codelist below)	Staff Initials	
Muscle biops	у	/month	/		first middle last	
Fat biopsy		/month	/		first middle last	
24-hour Urine C	ollection					
Total Volume Collected	_	Date of le Collection	Time of Sample Collectio	If Not Don Reason (Use codelist be	Staff Initials	
	/	rart Date:	Start Time::0:00 to 23:59			
mL	Stop Date:		Stop Time:		first middle last	
	day m	onth year	00:00 to 23:59			
Not Done Codelist: 1 Part	icipant refused	2 Clinician unable to o	btain 3 Insufficient time	4 Instrument failure	5 Not required	



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

					tirst middle lasi		
Sex Hormone							
If Not Done → Specify reason (use codelist belo	w):						
Contraception method (females only):		None OR Check all that apply: Oral contraceptive → Specify: Record on Concomitant Medications page Other → Specify (e.g., barrier, IUD):					
Day 1		ate	Time	If Not Done, Reason (use codelist)	Staff Initials		
Day 1 of menses (females only)							
Date and time of last meal (males only)	/month	/	00:00 to 23:59				
Hormone level blood draw 1 (males only)	/month	/	:: 00:00 to 23:59		first middle last		
Hormone level blood draw 2 (females enly) Progesterone level							
Day 2	De	ate	Time	If Not Done, Reason (use codelist)	Staff Initials		
Date and time of last meal							
Hormone level blood draw 3 (females only) Progesterone level							
DXA Scan							
 Has the participant taken a calcium supple □ No □ Yes → If Yes: Proceed with s Were any studies involving barium or radi □ No □ Yes 	can and document in				?		
DXA Scan		1	DXA Rescan O	RNA			
Date of scan:/	Date of rescan:	day month	/				
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Area Sca Check all the				
☐ Whole body			Whole body				
Not Done Codelist: 1 Participant refused 2 Cli	nician unable to obtai	n 3 Insufficient tim	ne 4 Instrument	failure 5 Not re	equired		



	Center Number: Participant Number	Particip	ant's Initials:			
Metabolic Rate						
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials			
Resting Metabolic Rate (RMR)—Visit 7			first middle last			
Cart ID	☐ Tufts-003 (623-002) ☐ WASH U-001 (623-003) ☐ PBRC-016 (623-004) ☐ Tufts-006 (623-006) ☐ WASH U-002 (623-004) ☐ PBRC-017 (623-004)					
Sample	Date of Collection If Not Done, Reas (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-002	_	016 (623-005) 017 (623-001)			
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Insufficient ti	me 4 Instrument failure	5 Not required			



Baseline Submission 2 Randomization

	Center Number:	Participant Number:	Participant's Initials:	first middle last
Randomization				
Date of randomization:/ _{month}	/			
Treatment Group				
To which treatment group was the parting a CR-calorie restricted a AL-ab libitum (control)	i cipant assigned (check	c only one):		
Intervention				
Did participant start intervention? □₀ № → Complete the Study com □₁ Yes → If Yes: Date intervention				
Staff Signature NOTE: Signat	ure of staff that rando	omized participant		
Signature:		Dat	e: /	_

calerie Phase 2

Month 1 Submission

	Center Number: Participant Number:	Participant's Initials: first middle las
C	inic Weight	
We	eight date and time:/	Staff initials:
	Not done → Specify reason (use Codelist below):	first middle lost
Cli	nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):	
We	eight 1: kg	
We	e ight 2: kg	
We	 kg	
We	eight of gown: kg	
V	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 time):	Staff initials:
	Natural waist measurement 1: cm	
	Natural waist measurement 2: cm	
	Natural waist measurement 3: cm	
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):	
	Umbilical point waist measurement 1: cm	
	Umbilical point waist measurement 2: cm	
	Umbilical point waist measurement 3: cm	
3	Pulse: bpm OR Not done → Specify reason (use codelist below):	Staff initials:
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): Left arm Right arm	Staff initials:
	6a Blood pressure 1:/ mm Hg Time:: OR Not done - Specify reas	on (use codelist below):
	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 Instru	ment failure 5 Not required



	Center Num	ımber: Participant Number: F		Participant's Initials:				
12-Lead ECG								
Date and Time			Findings		Staff Initials			
/		Is ECG (check only one): 1 Normal 2 Abnormal, not clinica 3 Abnormal, clinically s		first middle last				
Safety Labs								
Date and time of last meal: //								
do	y month	year 00:00 to	23:59					
Sample		Sample Complete?	If Not Done, Reason (Use codelist below)	Staff	Initials			
Blood	l _	o No Yes		first n	niddle last			
Urine		o No o No		first n	niddle last			
Contraception								
If Not Done → Specify reason (use code	list below):							
Contraception method (females only): □ None OR Check all that apply: □ Oral contraceptive → Specify: □ Record on Concomitant Medications page □ Other → Specify (e.g., barrier, IUD): □ One OR Check all that apply: □ Oral contraceptive → Specify: □ Other → Specify (e.g., barrier, IUD): □ Other → Specify (e.g., barrier, IUD):								
Not Done Codelist: 1 Participant refused	2 Clinician	unable to obtain 3 Insuff	icient time 4 Instrument fr	gilure 5 Not	required			



		Center Number:	Participant Number:	Participant's Initials:
Cl	inic Weight			
	eight date and time:/			Staff initials:
Cli	nic weight (if the first two measurements	are more than 0.1 k	ra apart measure weight a third time!	
	eight 1:		g apari, measore weight a third time,	
	eight 2:			
	eight 3:			
	eight of gown:			
	ital Signs			
	sessment date and time:/	/	:	
1	If waist measurement not done → S Natural waist measurement (if the first two measurements are more than Natural waist measurement 1:	-	ure natural waist circumference a third time):	Staff initials:
	Natural waist measurement 2:		cm	
	Natural waist measurement 3:		cm	
2	Umbilical point waist measurement (if umbilical point waist circumference a third t		ments are more than 1.0 cm apart, measure	
	Umbilical point waist measurement	l:	cm	
	Umbilical point waist measurement 2	2:	cm	
	Umbilical point waist measurement 3	B:	cm	
3	Pulse: bpm OR Not do	ne → Specify rea	son (use codelist below):	Staff initials:
4	Temperature:°C	OR Not done → S	Specify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR	Not done → Sp	ecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):1	Left arm Rig	ht arm	Staff initials:
	6a Blood pressure 1:/	mm Hg diastolic	Time:: OR Not done = Specify reas	→ son (use codelist below):
	6b Blood pressure 2:/_	mm Hg	Time: : : : : : : : : : : : : : : : : : :	
	6c Blood pressure 3:/	mm Hg diastolic	Time: : : : : : : : : : : : : : : : : : :	
No	at Done Codelist: 1 Participant refused	2 Clinician unabl	e to obtain 3 Insufficient time 4 Instru	ument failure 5 Not required



Center	Number:	Participant	Number: _	Partic	cipant's Initials:	
12-Lead ECG						
Date and Time			Findin	gs	Staff Initials	
/	□ ₁ No □ ₂ Abı	Is ECG (check only one):				
Safety Labs						
Date and time of last meal: /	/	ear 00:00 to	23:59			
Date and time of sample collection:/	/	ear 00:00 to	23:59			
Sample	Sample	Complete?		Done, Reason codelist below)	Staff Initials	
Blood	□ ₀ No □ ₁ Yes				first middle last	
Urine	□ ₀ No □ ₁ Yes				first middle last	
Outcomes Labs						
Date and time of last meal:	_// month	/	00:00 to 23:			
-		/				
Sample		Sample Com	plete?	If Not Done, Reason (Use codelist below)	Staff Initials	
Blood		□ ₀ No □ ₁ Yes			first middle last	
If a sample is not obtained, indicate with a Not Done.						
Contraception						
If Not Done → Specify reason (use codelist below)):					
Contraception method (females only): □ None OR Check all that apply: □ Oral contraceptive → Specify: ■ Record on Concomitant Medications page □ Other → Specify (e.g., barrier, IUD): ■						
Not Done Codelist: 1 Participant refused 2 Clinic	.: 11 :	-handa Ol f	G _ : : · ·	A landon of the		



	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	middle last
Date completed:/	OR Not done =	Specify	reason	(use code	elist belov	v):			
Multiaxial Assessment of	Eating Disorder	Sym	otom	S (MAE	DS)				
Instructions: Using the scale shown, pleas	e rate the following items	on a scal	e from 1	to 7. Ple	ase ansv	ver as tru	uthfully	as possi	ble.
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	weight.				\square_3		5	6	
2 My sleep isn't as good as it us	sed to be.				\square_{3}	4	5	6	
3 I avoid eating for as long as I	can.				\square_3	4	5	6	
4 Certain foods are "forbidden"	for me to eat.				\square_3	4	5	6	
5 I can't keep certain foods in my binge on them.	house because I will				\square_3	4			
6 I can easily make myself vom	it.				\square_{3}	4	5	6	
7 I can feel that being fat is terr	ible.				\square_3	4	5	6	
8 I avoid greasy foods.					\square_3	\square_4	5		
9 It's okay to binge and purge	once in a while.					4	5	6	
10 I don't eat certain foods.					\square_3	4	5	6	
11 I think I am a good person.						4	5	6	
12 My eating is normal.					\square_3	4	5	6	
13 I can't seem to concentrate la	ely.					4	5		
14 I try to diet by fasting.					\square_3	4	5		
15 I vomit to control my weight.						4	5	6	
16 Lately nothing seems enjoyab	le anymore.				\square_3		5	6	
17 Laxatives help keep you slim.						4	5		
18 I don't eat red meat.					\square_3	4	5		
19 I eat so rapidly I can't even to	ste my food.				\square_3	4	5		
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required									



Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	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.			3	4	5	6		
21 When I feel bloated, I must do something to rid myse of that feeling.	elf			4	5			
22 I overeat too frequently.				4	5			
23 It's okay to be overweight.			\square_3	4	5			
24 Recently I have felt that I am a worthless person.				4	5			
25 I would be very upset if I gained 2 pounds.			\square_3	4	5	6		
26 I crave sweets and carbohydrates.			\square_3	4	5			
27 I lose control when I eat.			\square_3	4	5			
28 Being fat would be terrible.			\square_3	4	5			
29 I have thought seriously about suicide lately.			\square_3	4	5			
30 I don't have any energy anymore.			\square_3	4	5			
31 I eat small portions to control my weight.			\square_3	4	5			
32 I eat 3 meals a day.			\square_3	4	5	6		
33 Lately I have been easily irritated.			\square_3	4	5			
34 Some foods should be totally avoided.			\square_3	4	5	6		
35 I use laxatives to control my weight.			\square_3	4	5			
36 I am terrified by the thought of being overweight.			\square_3	4	5	6		
37 Purging is a good way to lose weight.				4	5	6		
38 I avoid fatty foods.			\square_3					

CRF, page 107



	Center Number:	Participant No	umber: _		Pai	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blu	e.			3	4	5		
40 I am obsessed with becoming	g overweight.			\square_3	4	5		
41 I don't eat fried foods.				\square_3	4	5		
42 I skip meals.				3	4	5	6	
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			3	4	5	6	
45 I feel good when I skip meals	5.			\square_3	4	5		
46 I avoid foods with sugar.				\square_3	4	5	6	
47 I hate it when I feel fat.				\square_3	4	5		
48 I am too fat.				\square_3	4	5	6	
49 I eat until I am completely stu	iffed.			\square_3	4	5		
50 I hate to eat.				3	4	5	6	
51 I feel guilty about a lot of thir	ngs these days.			\square_3	4	5		
52 I'm very careful of what I eat	•			\square_3	4	5	6	
53 I can "hold off" and not eat e	even if I am hungry.			\square_3	4	5		
54 I eat even when I am not hun	gry.			\square_3	4	5	6	
55 Fat people are disgusting.				\square_3	4	5		
56 I wouldn't mind gaining a fev	v pounds.			\square_3	4	5		



	Center Number: Participant Number: Participant's Initials:
Cl	nic Weight
	Ight date and time: ${day} / {month} / {year} = {00:00 \text{ to } 23:59}$ Not done \rightarrow Specify reason (use Codelist below): ${first \text{ middle } last}$
	ic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
	ght 1: kg
	ght 2: kg
	ght 3: kg
	<u> </u>
	tal Signs
As	essment 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 time): Staff initials:
	Natural waist measurement 1: cm
	Natural waist measurement 2: cm
	Natural waist measurement 3: cm
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):
	Umbilical point waist measurement 1: cm
	Umbilical point waist measurement 2: cm
	Umbilical point waist measurement 3: cm
3	Pulse: bpm OR Not done → Specify reason (use codelist below): Staff initials: 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
	6a Blood pressure 1:/ mm Hg
	6b Blood pressure 2:/ mm Hg Time:: ::
	6c Blood pressure 3:/ mm Hg
No	Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



Ce	nter Number:	_ Participant N	lumber:	Participant's Ini	first middle last			
12-Lead ECG								
Date and Time			Findings		Staff Initials			
/		Is ECG (check only one): Normal Abnormal, not clinically significant (specify):						
Safety Labs								
Date and time of last meal://								
Sample	Sample (Complete?	If Not Done, Reason (Use codelist below)	1 Staf	f Initials			
Blood	□ ₀ No □ ₁ Yes			first	middle last			
Urine	□ ₀ No □ ₁ Yes			first	middle last			
Contraception								
If Not Done → Specify reason (use codelist be	low):							
Contraception method (females only): □ None OR Check all that apply: □ Oral contraceptive → Specify:								
Not Done Codelist: 1 Participant refused 2 C	Clinician unable to c	btain 3 Insuff	icient time 4 Instrument	failure 5 No	t required			



Month 6 Submission CR Visit 2

Ce	enter Number:	Participant Number:	Participant's Initials:						
Clinic Weight									
Weight date and time:/ _{month} /		50	Staff initials:						
OR Not done → Specify reason (use codelist l		J7							
Clinic weight (if the two measurements are more	than 0.1 kg apart, meas	sure weight a third time):							
Weight 1: kg	I								
Weight 2: kg	I								
Weight 3: kg	1								
Weight of gown: kg	1								
Pregnancy Test									
Complete only for females.									
□ ₀ No □ ₁ Yes → If Yes: Date urine pregnancy t Results: □ ₁ Negative □ ₂ Positive	☐ ₁ Yes → If Yes: Date urine pregnancy test performed:/								
DXA Scan									
 Has the participant taken a calcium supp □ No □ Yes → If Yes: Proceed with Were any studies involving barium or range of No □ Yes 	scan and document in	n the Subject Scan Log to inform t I within 4 weeks prior to the sche							
DXA Scan		DXA Rescan	OR ₉₆ NA						
Date of scan:/	_	Date of rescan:/	/						
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Sc Check all t							
☐ Whole body		☐ Whole body	1						
Forearm		Forearm							
Spine		Spine							
□ Нір		ПНір							

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

5 Not required



Month 6 Submission CR Visit 2

		Center Number:	Participant Number:	Participant's Initials:					
D	oubly Labeled W	/ater (DLW)							
1	Date and time of DLW do	osing:/	:::	Staff initials:					
	OR Not done → Specify	reason (use codelist below):							
2	DLW dose mixture ID and	d bottle number:	CA						
3	Exact weight of DLW mix	ture: grams							
4	Urine samples:								
	Collection	Sample	Date and Time	Collected					
	Pre dosing (PD)	PDa	/	:: 00:00 to 23:59					
		PDb	/	:::					
	Day 0 (Visit 2)	D0a	/	00:00 to 23:59					
		рор	/	:					
	Day 7 (Visit 3)	D7a	/	00:00 to 23:59					
		D7b	/	: 00:00 to 23:59					
	Day 14 (Visit 5)	D14a	/ _{month} / _{year}	00:00 to 23:59					
		D14b	/	::: _					
_									
5	AITIX CKr page label(s) c	orresponding to this urine sample s	Affix Test Sample Ret	Affix est Sample					
			Label Here La	ıbel Here					

3 Insufficient time

4 Instrument failure

5 Not required

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



	Center Number:	Participant I	Participant's I	nitials:	
Date completed:/	OR Not do	one → Specify re	ason (use codelist be	low):	
Profile of Mood St	ates				
Instructions: Please describe	e how you feel right now by	checking one bo	x for each of the wo	ords listed below.	
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly					4
2 Tense	\square_{o}		\square_{2}	\square_3	4
3 Angry				\square_3	4
4 Worn out			\square_{2}	\square_3	4
5 Unhappy				\square_3	4
6 Clear-headed				\square_3	
7 Lively				\square_3	4
8 Confused	\square_{o}		\square_{2}	\square_3	4
9 Sorry for things done	□ ₀			\square_3	4
10 Shaky					
11 Listless				\square_3	4
12 Peeved			\square_{2}	\square_3	4
13 Considerate				\square_3	4
14 Sad			\square_{2}	\square_3	4
15 Active					4
16 On edge				\square_3	
17 Grouchy					4
18 Blue					4
19 Energetic					4
20 Panicky					
Copyright © 2003, 2005 Maurice Lorr, Ph.D., 950, North Tonawanda, NY 14120-0950. In C	Canada, 3770 Victoria Park Ave., Toronto, ON	I M2H 3M6.			
Not Done Codelist: 1 Participa	ant refused 2 Clinician unable to	o obtain 3 Insuti	ficient time 4 Instru	ment failure 5 N	lot required nitials:
			_	-	first middle last



		Participai	nt Number:	Participant's	first middle last
Profile of Mood States (d	ontinued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed	\square_{o}			\square_3	4
23 Unworthy	\square_{o}			\square_3	4
24 Spiteful	\square_{o}		\square_{2}	\square_3	4
25 Sympathetic				\square_3	4
26 Uneasy	\square_{o}		\square_{2}	\square_3	4
27 Restless				\square_3	4
28 Unable to concentrate	\square_{o}			\square_3	4
29 Fatigued				\square_3	4
30 Helpful	\square_{o}		\square_{2}	\square_3	4
31 Annoyed	\square_{o}			\square_3	4
32 Discouraged	\square_{o}		\square_{2}	\square_3	4
33 Resentful	\square_{o}			\square_3	4
34 Nervous	\square_{o}		\square_{2}	\square_3	4
35 Lonely				\square_3	4
36 Miserable	o			\square_3	4
37 Muddled	\square_{o}				4
38 Cheerful	o			\square_3	4
39 Bitter	\square_{o}				4
40 Exhausted				\square_3	4
41 Anxious					4
42 Ready to fight					4
43 Good-natured					4

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 Ave., Toronto, ON M2H 3M6.



	Center Number: _	Participa	nt Number:	Participant's	Initials:
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy				\square_3	4
45 Desperate				\square_3	4
46 Sluggish				\square_3	
47 Rebellious				\square_3	4
48 Helpless					4
49 Weary					4
50 Bewildered				\square_3	
51 Alert					
52 Deceived					
53 Furious					
54 Efficient				\square_3	
55 Trusting				\square_3	
56 Full of pep				\square_3	
57 Bad-tempered				\square_3	
58 Worthless				\square_3	
59 Forgetful					
60 Carefree				\square_3	
61 Terrified					4
62 Guilty					
63 Vigorous					4
64 Uncertain about things					
65 Bushed					4

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 Ave., Toronto, ON M2H 3M6.



c	enter Number:	Participant Number	er:		Participant'	s Initials:	irst middle last
Date completed:/	OR Not done →	Specify reason	(use codel	ist below):			
Perceived Stress Scale (PSS)							
Instructions: The questions in this scale ask indicate how often you felt or				ease			
			Never	Almost Never	Some- times	Fairly Often	Very Often
In the last month, how often have unable to control the important to	•						
2 In the last month, how often have your ability to handle your person	-	nt about	\square_{o}		\square_{2}	\square_3	4
3 In the last month, how often have going your way?	ve you felt that thin	ngs were				\square_3	
4 In the last month, how often hav piling up so high that you could	-					\square_3	
Not Done Codelist: 1 Participant refused 2	Clinician unable to obtai	n 3 Insufficient	time 4	Instrument f	ailure 5	Not requir	red

Participant's Initials: first middle last



		Center Number:	Participant Number:	Partici	Participant's Initials: first middle last				
Da	te completed:day / _{month} /	year OR Not done →	Specify reason (use c	odelist below):					
Pi	ttsburgh Sleep Quality	Index (PSQI)							
		elate to your usual sleep ho or the majority of days and		-					
Du	ring the past month								
1	When have you usually gone	e to bed?::							
2	How long (in minutes) has it	taken you to fall aslee	ep each night? _	minutes					
3	When have you usually gotte	en up in the morning?	00:00 to 23:59						
4	How many hours of actual slee (This may be different than the number of hou	. ,	hours						
5	During the past month, how a sleeping because you (check	•	the pas	t once	Once or twice a week	3 or more times a week			
	a Cannot get to sleep within	30 minutes				\square_3			
	b Wake up in the middle of	the night or early mor	rning			\square_3			
	c Have to get up to use the	bathroom				\square_3			
	d Cannot breathe comfortab	bly				\square_3			
	e Cough or snore loudly				2	\square_3			
	f Feel too cold				\square_{2}	\square_3			
	g Feel too hot					\square_3			
	h Have bad dreams					\square_3			
	i Have pain					\square_3			
	i Other reason(s), please de you have had trouble slee reason(s):	•	often		$\square_{_{2}}$	\square_3			
6	During the past month, how a medicine (prescribed or "over the co	~	o?			\square_3			
	89,with permission from Elsevier Science. 1 Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient time	4 Instrument failure	5 Not re	quired			



	Center Number: Participal	nt Number:	Parti	cipant's Initials:	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (continued)				
		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?				
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?				\square_3



				CI	V 1311	2/0		01 V I	311 2
Center Nu	mber:	Partici	pant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed: — day /— month /— year OR Not of	lone → Spec	cify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Sexual	Function	(DISF-S	R) (F) Fe	male Ve	rsion				
Instruction: Below you will find a brief set of quest sections that ask about different aspects of your sex while another inquires about the kinds of sexual esexual arousal and the quality of your orgasm. relationship.	ual experien	that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fanto d about t	asies or the natu	daydre re of you	ams, ur
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 ollow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best lescribes your personal experience.									
If you have any questions, please ask the person who gave you the inventory for help.									
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4	5			8
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)				\square_3	4	5	6		
1.3 Erotic or romantic situations				\square_3	4	5	6		
1.4 Caressing, touching, undressing, or foreplay				\square_3	4	5	6		
1.5 Sexual intercourse, oral sex, touching to orgasm				\square_3	4	5			8
Copyright © 1987 by Leonard R. Derogatis, PhD.									

5 Not required

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused



Co	enter Number:	umber: Participant Number:			Par	Participant's Initials:			
Derogatis Interview for Sex	ual Functi	on (DIS	F-SR) (F)	Female \	/ersion (c	ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how a did you have the following experiences:	ften 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 alo	one				4	□ ₅	6	7	8
2.2 Actively seek sexual satisfaction				3	4	₅	6	7	8
2.3 Feel sexually aroused with a partner					4		6	7	8
	Never	Rarely	Sometimes	Usually	Always		•		
2.4 Have normal lubrication with masturbation					4				
2.5 Have normal lubrication throughout sexual relations					4				

Copyright © 1987 by Leonard R. Derogatis, PhD.



Center Nu	mber:	Po	articipant N	lumber:		Po	ırticipant'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	;								
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	По				4	5	□ ₆	\square_{7}	8
3.2 Masturbation	По				4	5	□ ₆		□ ₈
3.3 Casual kissing and petting	По				4	5			8
3.4 Sexual foreplay	О				4	5			8
3.5 Sexual intercourse, oral sex, etc.					4	5			8
Section 4—Orgasm									
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	О				4				
4.2 The intensity of your orgasm	o				4				
4.3 The ability to have multiple orgasms (if typical for you)	o			\square_3	4				
4.4 Feelings of closeness and togetherness with your partner	o				4				
4.5 Your sense of control (timing) of your orgasm					4				
4.6 Feeling a sense of relaxation and well-being after orgasm	o				4				

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number:		Participant	Number:		P	Participant's Initials: initials: last			
Derogatis Interview for S	exual Fun	ction (DISF-SR) (F) Female	Version	(continue	ed)			
Section 5—Drive and Relationshi	р									
	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 chowhat would be your ideal frequency of sexual intercou				3	4	5		7	8	
	Not at	Slightly	Moderately	Highly	Extremely					
5.2 During this period, how interested have you been in	sex?			3	4					
5.3 During this period, how satis have you been with your personal relationship with your sexual partner?										
	Could not be worse	poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better	
5.4 In general, what would repretent the best description of the quot of your sexual functioning?				3			6	7	8	

Copyright © 1987 by Leonard R. Derogatis, PhD.



				CR	Visit	2/C	ontr	ol Vi	sit 2
Center Numb	er:	Partici	pant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed:/OR Not dor	ne → Spec	ify reaso	on (use co	delist bel	low):				
Derogatis Interview for Sexual Fu	nction	(DISF-S	R) (M) N	lale Ver	sion				
Instruction: Below you will find a brief set of question sections that ask about different aspects of your sexual while another inquires about the kinds of sexual expsexual arousal and the quality of your orgasm. The relationship.	l experien eriences	that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fant d about t	asies or the natu	daydre re of you	ams, ur
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 inve	ntory for	help.					
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person				\square_3		5			8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)						5	6		8
1.3 Erotic or romantic situations						5	6		8
1.4 Caressing, touching, undressing, or foreplay	□₀			\square_3	4	5	□ ₆		8
1.5 Sexual intercourse, oral sex, touching to orgasm					4	5			8
Copyright © 1987 by Leonard R. Derogatis, PhD.									

5 Not required

4 Instrument failure

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused

3 Insufficient time



	Center Numb	er:	Part	icipant Nu	mber:		Part	icipant's I	nitials:	st middle last
Derogatis Interview for Se	exual Fu	ınctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal										
During the past 30 days or since the you filled out this inventory, how often 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	ng	□ _o				4		6	7	8
2.2 A full erection during a sexual fantasy or daydream	ıl	□ _o				4	5			8
2.3 A full erection while looking a sexually arousing person, map picture		□ _o				4	5	6	7	8
2.4 A full erection during masturk	oation	□ _o				4	5	6		
2.5 A full erection throughout the of a normal sexual response that is from undressing and for through intercourse and organical erections.	cycle, oreplay					4	₅			\square_8

Copyright © 1987 by Leonard R. Derogatis, PhD.



Center Num	ber:	Par	ticipant Nu	mber:		Pa	rticipant's	Initials:	rst middle last			
Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)												
Section 3—Sexual Behavior/Experiences												
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	l 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_{2}	\square_3	4	5	6					
3.3 Casual kissing and petting	o				4	5	6	7	8			
3.4 Sexual foreplay	o		\square_2	\square_3	4	5	6		8			
3.5 Sexual intercourse, oral sex, etc.					4	5	6		8			
Section 4—Orgasm												
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					4							
4.2 The intensity of your orgasm			\square_2	\square_3	4							
4.3 The length or duration of your orgasm					4							
4.4 The amount of seminal liquid that you ejaculate	□ _o				4							
4.5 Your sense of control (timing) of your orgasm					4							
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3					_			

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number:		Participant	Number:		P	Participant's Initials:						
Derogatis Interview for Se	xual Fund	tion (DISF-SR) (M) Male \	/ersion (d	ontinue	d)						
Section 5—Drive and Relationship													
	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 intercours							□ ₆		□ ₈				
	Not at all	Slightly	Moderately	Highly	Extremely								
5.2 During this period, how interest have you been in sex?	ested				\square_4								
5.3 During this period, how satisf have you been with your personal relationship with you sexual partner?				\square_3	□ ₄								
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better				
5.4 In general, what would repre the best description of the que of your sexual functioning?				3	4	5	□ ₆						

Copyright © 1987 by Leonard R. Derogatis, PhD.

Participant's Initials: first middle last



					_,							
	Center Number	: Participant	Number:		Participa	nt's Initials:	first middle last					
Da	te completed:/ _{month} / _{year} OR N	ot done → Specify r	eason (use d	codelist belov	w):	_						
Fc	Food Cravings Questionnaire—State (FCQ—S)											
hov	ow is a list of comments made by people about their w much you agree with the comment right now, at t ile others refer to one or more specific foods. Please i	his very moment.	Notice that	some quest	tions refer t							
			Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree					
1	I have an intense desire to eat [one or mospecific foods].	ore				4	5					
2	I'm craving [one or more specific foods].				\square_3		5					
3	I have an urge for [one or more specific f	oods]			\square_3	4	5					
4	Eating [one or more specific foods] would seem just perfect.	l make things										
5	If I were to eat what I am craving, I am so would improve.	ure my mood				4						
6	Eating [one or more specific foods] would wonderful.	l feel			\square_3		5					
7	If I ate something, I wouldn't feel so sluggand lethargic.	jish				4	5					
8	Satisfying my craving would make me fee and irritable.	el less grouchy				4	5					
9	I would feel more alert if I could satisfy m	y craving.				4	5					
10	If I had [one or more specific foods], I coueating it.	ıld not stop				4	5					
11	My desire to eat [one or more specific foo seems overpowering.	ods]				4	5					
12	I know I'm going to keep on thinking abo more specific foods] until I actually have i				\square_3	4						
13	I am hungry.											
14	If I ate right now, my stomach wouldn't fe	eel as empty.				4	5					
15	I feel weak because of not eating.											

Participant's Initials: first middle last

5 Not required

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused



Center Numb	oer: Pa	rticipant Number:		Participant's	Initials:
Date completed:/OR	Not done → Sp	ecify reason (us	se codelist below	·):	
Food Craving Inventory (FCI-II)					
For each of the foods listed below, please check the a	ppropriate box.				
Note: A craving is defined as an intense desire to cons	sume a particula	1	ype that is diff	icult to resist.	
Over the past month, how often have you experienced a craving for	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake			\square_3	4	5
2 Pizza			\square_3	4	5
3 Fried chicken			\square_3		5
4 Gravy					
5 Sandwich bread				4	
6 Sausage				4	
7 French fries					
8 Cinnamon rolls					
9 Rice					
10 Hot dog					
11 Hamburger				4	
12 Biscuits				4	
13 Ice cream				4	
14 Pasta			\square_3	4	
15 Fried fish				4	
16 Cookies			\square_3	4	
17 Chocolate				4	
18 Pancakes or waffles			\square_3	4	
19 Corn bread			\square_3	4	
20 Chips			\square_3	4	
21 Rolls			\square_3	4	
22 Cereal			\square_3	4	
23 Donuts			\square_3	4	
24 Candy			\square_3	4	
25 Brownies			\square_3	4	
26 Bacon			\square_3		
27 Steak				4	
28 Baked potato			\square_3	4	5
Not Done Codelist: 1 Participant refused 2 Clinician u	ınable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	Not required
				Participant's	Initials:



	Center Number: Participant Number:	Participant's i	first middle last
Date o	completed:/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.	, True	□₀ False
2	I usually eat too much at social occasions, like parties and picnics.	, True	o False
3	I am usually so hungry that I eat more than three times a day.	, True	o False
4	When I have eaten my quota of calories, I am usually good about not eating anymore.		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.	, True	o False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	, True	o 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.		o False
9	When I feel anxious, I find myself eating.	, True	o False
10	Life is too short to worry about dieting.	, True	o False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	, True	□₀ False
12	I often feel so hungry that I just have to eat something.	, True	o False
13	When I am with someone who is overeating, I usually overeat too.	, True	o False
14	I have a pretty good idea of the number of calories in common food.	, True	o False
15	Sometimes when I start eating, I just can't seem to stop.	1 True	o False
16	It is not difficult for me to leave something on my plate.	, True	o False
17	At certain times of the day, I get hungry because I have gotten used to eating then.	₁ True	o False
18	While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	, True	□₀ False
Not D	One Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrumer	t failure 5 N	lot required

Participant's Initials: first middle last



		Center Number:	Participant Number:	Participant's In	first middle last
Eat	ing Inventory (continued)				
19	Being with someone who is e	ating often makes	me hungry to eat also.	1 True	o False
20	When I feel blue, I often over	eat.		, True	o False
21	I enjoy eating too much to spe my weight.	oil it by counting c	alories or watching	, True	o False
22	When I see a real delicacy, I dright away.	often get so hungr	ry that I have to eat		o False
23	I often stop eating when I am limiting the amount I eat.	not really full as	a conscious means of		False
24	I get so hungry that my stome	ach often seems lil	ke a bottomless pit.	, True	o False
25	My weight has hardly change	ed at all in the last	ten years.	, True	o False
26	I am always hungry so it is ho the food on my plate.	ard for me to stop	eating before I finish	, True	o False
27	When I feel lonely, I console i	nyself by eating.		, True	o False
28	I consciously hold back at me	als in order not to	gain weight.	, True	o False
29	I sometimes get very hungry	late in the evening	g or at night.	☐₁ True	□₀ False
30	I eat anything I want, any tim	e I want.		, True	o False
31	Without even thinking about i	t, I take a long tim	ne to eat.	☐₁ True	□₀ False
32	I count calories as a conscious	s means of control	lling my weight.	, True	o False
33	I do not eat some foods beca	use they make me	fat.	, True	o False
34	I am always hungry enough t	o eat at any time.		, True	o False
35	I pay a great deal of attention	n to changes in my	y figure.	, True	o False
36	While on a diet, if I eat a food eat other high calorie foods.	d that is not allowe	ed, I often splurge and	, True	o False

calerie Phase 2

Month 6 Submission CR Visit 2/Control Visit 2

		Center Number:	Participant Number:	Participant's Initials:
Eat	ing Inventory (continued)			
	se check one answer that is most	appropriate to you	for each question below.	
37	How often are you dieting in effort to control your weight?		☐₁ Rarely ☐₂ Sometime	es 🔲 3 Usually 🔲 4 Always
38	Would a weight fluctuation o affect the way you live your		☐₁ Rarely ☐₂ Sometime	es 🔲 3 Usually 🔲 4 Always
39	How often do you feel hungr	y?	☐₁ Rarely ☐₂ Sometime	es 🔲 3 Usually 🖂 4 Always
40	Do your feelings of guilt about help you to control your food		\square_1 Rarely \square_2 Sometime	es □₃ Usually □₄ Always
41	How difficult would it be for yearing halfway through dinner for the next four hours?		☐₁ Easy ☐₃ Moderately difficult	☐₂ Slightly difficult ☐₄ Very difficult
42	How conscious are you of wheating?	nat you are	□₁ Not at all□₃ Moderately	□₂ Slightly □₄ Extremely
43	How frequently do you avoid on tempting foods?	d "stocking up"	☐₁ Almost never ☐₃ Usually	□₂ Seldom □₄ Almost always
44	How likely are you to shop for calorie foods?	or low	☐₁ Unlikely ☐₃ Moderately likely	☐₂ Slightly likely ☐₄ Very likely
45	Do you eat sensibly in front of splurge alone?	of others and		
46	How likely are you to conscion order to cut down on how		☐₁ Unlikely ☐₃ Moderately likely	□₂ Slightly likely □₄ Very likely
47	How frequently do you skip or you are no longer hungry?	dessert because	☐₁ Almost never ☐₃ At least once a week	□₂ Seldom □₄ Almost every day
48	How likely are you to conscion than you want?	ously eat less	☐₁ Unlikely ☐₃ Moderately likely	Slightly likely Very likely
49	Do you go on eating binges t not hungry?	hough you are	Never Sometimes	☐₂ Rarely ☐₄ At least once a week
50	To what extent does this state your eating behavior? "I star morning, but because of any things that happen during the evening I have given up and want, promising myself to staggain tomorrow."	t dieting in the number of day, by eat what I	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good descriptio ☐₃ Describes me perfectly	
51	On a scale of 0 to 5, where 0 restraint in eating (eating who want, whenever you want it) total restraint (constantly limit intake and never "giving in") would you give yourself?	atever you and 5 means ting food	Often eat whatever yo often limit food intake usually limit food intake	ou want, whenever you want it u want, whenever you want it e, but often "give in"

Participant's Initials: first middle last



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/ _{month} /	OR Not done →	Specify reason (use codelist below):		

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

I am confident that:				e nt at a st the de		Very confident that you can resist the desire to eat						
		0	1	2	3	4	5	6	7	8	9	
1	I can resist eating when I am anxious (nervous).					4	5	6		8	9	
2	I can control my eating on the weekends.				\square_3	4		6		8	9	
3	I can resist eating even when I have to say "no" to others.				\square_3	4	5	6		8	9	
4	I can resist eating when I feel physically run down.				\square_3	4	5	6		8	9	
5	I can resist eating when I am watching TV.					4		6		8	9	
6	I can resist eating when I am depressed (or down).				\square_3	4		6		8	9	
7	I can resist eating when there are many different kinds of food available.					4		6		8	9	
8	I can resist eating even when I feel it is impolite to refuse a second helping.				\square_3	4		6		8	9	
9	I can resist eating even when I have a headache.					4		6		8	9	
N	ot Done Codelist: 1 Participant refused 2 Clinician unable	to obta	in 3	Insufficie	ent time	4 Ins	trument	failure	5 Not	require	d	



	nber:			mber:			Particip	oant's Init	first	middle last	
Weight Efficacy Lifestyle Questio	Note	onfide	e nt at a		yo	Very confident that you can resist the desire to ea					
	0	1	2	3	4	5	6	7	8	9	
10 I can resist eating when I am reading.				\square_3					8	9	
11 can resist eating when I am angry (or irritable).					4		6		8	9	
12 I can resist eating even when I am at a party.							6		8	9	
13 I can resist eating even when others are pressuring me to eat.	re						6		8	9	
14 I can resist eating when I am in pain.				\square_3			6			9	
15 I can resist eating just before going to bed.							6		8	9	
16 I can resist eating when I have experienced failure.							6		8	9	
17 I can resist eating when high-calorie fo are available.	ods				4		6		8	9	
18 I can resist eating even when I think others will be upset if I don't eat.							6		8	9	
19 I can resist eating when I feel uncomfortable.							6		8	9	
20 I can resist eating when I am happy.						5	6		8	9	



		Center Number:	er: Participant Number: Pa						articipant's Initials:		
Date completed:	/	year OR Not done	→ Specify	reason	(use code	elist belov	v):				
Multiaxial As	sessment of	Eating Disorde	r Sym _l	otom:	5 (MAE	DS)					
Instructions: Using th	ne scale shown, plec	se rate the following item	s on a sca				I				
				Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always	
1 Fasting is a go	ood way to lose	e weight.				\square_3		5			
2 My sleep isn't	as good as it u	ised to be.				\square_{3}	4	5			
3 I avoid eating	for as long as	I can.				\square_3	4				
4 Certain foods	are "forbidden	" for me to eat.				\square_3		\square_5			
5 I can't keep cer binge on them	•	/ house because I wil	I			\square_3	4	5	6		
6 I can easily m	ake myself von	nit.				\square_3		5			
7 I can feel that	being fat is ter	rible.						5			
8 I avoid greasy	foods.										
9 It's okay to bi	nge and purge	once in a while.									
10 I don't eat cer	tain foods.					\square_3		5			
11 I think I am a	good person.							5			
12 My eating is n	ormal.					\square_3		5			
13 I can't seem to	o concentrate la	ıtely.					4	5			
14 I try to diet by	fasting.					\square_3		5			
15 I vomit to cont	trol my weight.					\square_3	4	5			
16 Lately nothing	ı seems enjoyal	ole anymore.				\square_3		5			
17 Laxatives help	keep you slim	•				\square_3		5			
18 I don't eat red	meat.					\square_3		5			
19 I eat so rapidl	y I can't even t	aste my food.				\square_3	4		6		
Not Done Codelist: 1	Participant refused	2 Clinician unable to obt	ain 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	ed	



	Center Number:	Participant N	umber: _		Pa	irst middle last		
Multiaxial Assessment of	Eating Disorder	Sympto	oms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.					5	6	
21 When I feel bloated, I must do of that feeling.	something to rid myse	elf		\square_3	4	5	6	
22 I overeat too frequently.				\square_3	4	5	6	
23 It's okay to be overweight.					4	5	6	7
24 Recently I have felt that I am	a worthless person.			\square_3	4		6	
25 I would be very upset if I gai	ned 2 pounds.			\square_3	4	5	6	7
26 I crave sweets and carbohyd	rates.				4	5	6	
27 I lose control when I eat.				\square_3	4	5	6	7
28 Being fat would be terrible.				\square_3		5	6	
29 I have thought seriously abou	ut suicide lately.			\square_3	4	5	6	7
30 I don't have any energy anymo	ore.			\square_3	4	5	6	
31 I eat small portions to control	my weight.			\square_3	4	5	6	7
32 I eat 3 meals a day.				\square_3	4	5	6	
33 Lately I have been easily irrit	ated.			\square_3	4	5	6	7
34 Some foods should be totally	avoided.			\square_3		5	6	
35 I use laxatives to control my	weight.				4	5	6	7
36 I am terrified by the thought	of being overweight.			\square_3	4	5	6	
37 Purging is a good way to los	e weight.			\square_3		5	6	
38 I avoid fatty foods.						5		

CRF, page 143



	Center Number:	Participant No	umber: _		Pai	Participant's Initials: middl				
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)				
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always		
39 Recently I have felt pretty blu	e.				4					
40 I am obsessed with becoming	g overweight.			\square_3	\square_4	5				
41 I don't eat fried foods.				\square_3	4	5				
42 I skip meals.				\square_3	4	5		7		
43 Fat people are unhappy.				\square_3	4	5				
44 People are too concerned wit	h the way I eat.			\square_3	4	5	6			
45 I feel good when I skip meals	5.			\square_3	4	5				
46 I avoid foods with sugar.				\square_3	4	5	6			
47 I hate it when I feel fat.				\square_3	4	5	6			
48 I am too fat.				\square_3	4	5	6			
49 I eat until I am completely stu	ffed.			\square_3	4	5				
50 I hate to eat.				\square_3	4	5	6	7		
51 I feel guilty about a lot of thir	ngs these days.			\square_3	4	5				
52 I'm very careful of what I eat	•			\square_3	4	5	6			
53 I can "hold off" and not eat e	even if I am hungry.			\square_3	4	5	6			
54 I eat even when I am not hun	gry.			\square_3	4	5	6			
55 Fat people are disgusting.				\square_3	4	5				
56 I wouldn't mind gaining a few	v pounds.			\square_3	4	5				

calerie Phase 2

Month 6 Submission CR Visit 2/Control Visit 2

		Center Number: Participant	Number: _		Par	ticipant's I	nitials:	t middle last
Date	e completed:/ _{month} / _{yec}	OR Not done → Specify re	ason (use	codelist be	elow):			
Во	dy Shape Questionnaire	(BSQ)						
	would like to know how you have beer se read each question and check the b							
Ove	r the Past Four Weeks		Never	Rarely	Some- times	Often	Very Often	Always
1 1	Has feeling bored made you b	rood about your shape?			\square_3	4	5	
	Have you been so worried abo nave been feeling that you oug				$\square_{_3}$	4	5	6
	Have you thought that your thi	ghs, hips, or bottom are			\square_3	4	5	
	Have you been afraid that you after)?	might become fat (or			\square_3	\square_{4}	5	6
	Have you worried about your fenough?	flesh not being firm			$\square_{_3}$	4	5	6
	Has feeling full (e.g., after eating a lotate.	arge meal) made you feel			\square_{3}		5	6
(Have you felt so bad about your cried?					4	5	
	Have you avoided running bed wobble?	ause your flesh might			\square_{3}		5	6
	Has being with thin women/me self-conscious about your shape					4	5	
	Have you worried about your t sitting down?	thighs spreading out when			$\square_{_3}$		5	6
	Has eating even a small amour at?	nt of food made you feel				4	5	6
f	Have you noticed the shape of elt that your own shape comp	ared unfavorably?			$\square_{_3}$		5	6
(Has thinking about your shape ability to concentrate (e.g., while wo conversations)?				\square_3	4		6
	Has being naked, such as whe eel fat?	n taking a bath, made you			$\square_{_3}$	\square_{4}	5	6
	Have you avoided wearing clo particularly aware of the shape				\square_3		5	6
	Have you imagined cutting off body?	fleshy areas of your				4	5	6
Not	Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Insuf	ficient time	4 Instru	ıment failu	re 5 N	lot require	ed
						ticipant's l	•	

Participant's Initials:



	Center Number: Participant N	Number: _		Pai	Participant's Initials: first middle						
Body Shape Questionnair	' e (BSQ) (continued)										
Over the Past Four Weeks		Never	Rarely	Some- times	Often	Very Often	Always				
17 Has eating sweets, cakes or o you feel fat?	ther high calorie food made				4		6				
18 Have you not gone out on soo because you have felt bad ab				\square_3	4	5	6				
19 Have you felt excessively larg	e and rounded?			3	4	5	6				
20 Have you felt ashamed of you	ur body?				4	5	6				
21 Has worry about your shape	made you diet?			\square_3	4	5	6				
22 Have you felt happiest about stomach has been empty?	your shape when your			\square_3	4	5	6				
23 Have you thought that you ar because you lack self-control?				\square_3	4	5	6				
24 Have you worried about othe flesh around your waist or sto				\square_3		5					
25 Have you felt that it is not fair thinner than you?	that other women/men are			\square_3	4	5	6				
26 Have you vomited in order to	feel thinner?			\square_3		5					
27 When in company, have you much room (e.g., sitting on a sofa or				\square_3	4	5	6				
28 Have you worried about your	flesh being dimply?			\square_3		5					
29 Has seeing your reflection (e.g. you feel bad about your shap				\square_3		5					
30 Have you pinched areas of you fat is there?	our body to see how much			\square_3	4	5	6				
31 Have you avoided situations vyour body (e.g., communal changing					4		6				
32 Have you taken laxatives in o	rder to feel thinner?					5	6				
33 Have you been particularly se shape when in the company of					4		6				
34 Has worry about your shape to exercise?	made you feel you ought			\square_3	4	5					



Month 6 Submission CR Visit 3

Participant's Initials:

	tirst middle last
Clinic Weight	
Weight date and time:/	Staff initials:
OR Not done → Specify reason (use codelist below):	
Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):	
Weight 1: kg	
Weight 2: kg	
Weight 3: kg	
Weight of gown: kg	

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

Center Number: ___ _ Participant Number: ___ _ _ _

CRF, page 148

calerie Phase 2

Month 6 Submission

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

CR Visit 3

														fil	rst middle last
Se	ven-D	Day Physical Activ	vity Reca	ll (PAR)											
Tod	ay's dat	re:/	Day	(check only one):	Mon Tu	es Wed	Thurs	Fri S	Sat Sui	OR No	ot done →	Specify re	eason (use	codelist bel	ow):
		ou employed in the last seve				→ Skip to que						Interv	riewer ini	tials:	middle last
2	If Yes: W	Which days (check all that apply)	?		Mon	Tues	Wed	Thurs [Fri _	Sat	Sun				
3	Which d	days do you consider your v		•							Sun				
Day	Day of	. .	Sleep	p Time	Work	Time	Mor	ning (in m		Afte	rnoon (in m		Ever	ning (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	00:00 to 23:59									
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									
3		/	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	:: _	:: _									



Month 6 Submission CR Visit 3

		Center Number:	Participant Number:	Participant's Initials: first middle las
S	even-Day Physical Acti	vity Recall (PAR)	(continued)	
4	Compared to your physical activity or about the same (check only one)? More Less About the same		nths, was last week's physical o	activity more, less,
Int	terviewer: Please answer question	s below and note any co	omments on interview.	
5	Were there any problems with the \square_0 No \square_1 Yes	Seven-Day PAR intervie	w?	
6	Do you think this was a valid Seve	n-Day PAR interview?		
7	Were there any activities reported No	by the participant that y	ou don't know how to classify	?



Month 6 Submission CR Visit 3

Comp	lete below OR Not done → Spe	cify reason (use Codelist b	pelow): _	Staff i	nitials:
				Replacement Valu	Jes
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	/ _{month} /year	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	8	daymonthyear	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
2	/ _{month} /year	Reliable One of the control of the	9	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
3	/ _{month} /year	Reliable One of the control of the	10	daymonthyear	n Reliable number under the large la
4	/	Reliable Unreliable Missing	11	daymonthyear	n Reliable number to the large state of the large s
5	/	Reliable D 2 Unreliable Missing	12	/	Reliable Unreliable Missing
6	/	Reliable Unreliable Missing	13	/	Reliable Unreliable Missing



		Center Number:	Partic	ipant Number: _	Particip	pant's Initials:					
Outcomes	Labs										
Date and time of	last meal:	/									
Date and fille 3a	imple concensition started.	/	year	00:00 to 23:	59						
	Sample		Sample	Complete?	If Not Done, Reason (Use codelist below)	Staff Initials					
	Blood		ONO			first middle last					
If a sample is not obtained, indicate with a Not Done.											
Core Temp	erature										
Staff Initials		de Date of ection/Procedure		Time Collecti	If Not Done, Reason (Use codelist below)						
		art Date:			tart Time : 0:00 to 23:59						
first middle last		op Date:/			top Time: 0:00 to 23:59						
Inpatient A	Admission and [Discharge									
1 Inpatient adn	nission date and time:	/	year	00:00 to 23:59	_						
2 Inpatient disc	harge date and time: _	/	year	::: 00:00 to 23:59	_						
Not Dono Codoli	st. 1 Participant refused	2 Clinician unable to	abtain 2	Insufficient time	A Instrument failure	E Niet we assisted					



Month 6 Submission CR Visit 5

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

	tirst middle last
Clinic Weight	
Weight date and time:/	Staff initials:
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third tin	ne):
Weight 1: kg	
Weight 2: kg	
Weight 3: kg	
Weight of gown: kg	
Pregnancy Test	
Complete only for females.	
Does participant have reproductive potential? □₀ No	
☐ ₁ Yes → If Yes: Date urine pregnancy test performed:day /month /yet	ar —
Results: 1 Negative 2 Positive	



Month 6 Submission CR Visit 5

CRF, page 153

	Center Number:	Participant Number	Particip	ant's Initials:							
DXA Scan											
 Has the participant taken a calcium supplement today? □ No □ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? □ No □ Yes 											
DXA Scan		DXA Rescan OR									
Date of scan:/	ar	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								
Metabolic Rate											
Sample	Date of Colle	ction	If Not Done, Reason (Use codelist below)	Staff Initials							
Resting Metabolic Rate (RMR)—Visit 5	/	year		first middle last							
Cart ID	Tufts-003 (623-002) Tufts-006 (623-006)	WASH U-001		016 (623-005) 017 (623-001)							
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n 3 Insufficient ti	me 4 Instrument failure	5 Not required							

CRF, page 154

calerie Phase 2

Month 6 Submission CR Visit 5

						Center IV	Jiliber:	r	ariicipanii i	Number: _		FC	iriicipani s	fir	st middle last	
Se	ven-D	Day Physical Activ	vity Recall	(PAR)												
Tod	ay's date	e:/	Day (c	heck only one):	Mon Tue	es Wed	Thurs _	Fri S	at Sur	OR No	t done →	Specify re	eason (use	codelist bel	ow):	
1	Were yo	ou employed in the last seve	en days?		□ _o No	→ Skip to que	estion 3	\square_1 Yes				Interv	iewer ini	tials:	middle last	
2	If Yes: W	/hich days (check all that apply)	?		Mon	Tues	Wed	Thurs	Fri	Sat	Sun					
3	Which d	ays do you consider your v	weekend, or nor	n-work, days?	Mon	Tues	Wed	Thurs	Fri	Sat	Sun					
Day	Day of		Sleep	Time	Work	Time	Mor	ning (in mi	nutes)	After	noon (in m	ninutes)	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	::::::::										
6		//	00:00 to 23:59 - : : : : : : : : : : : : : : : : : : :	: 00:00 to 23:59 : 00:00 to 23:59	: : 00:00 ю 23:59	00:00 to 23:59										
5		/	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	::	::										
3		///year	: : : : : : : : : : : : : : : : : : :	:	: 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	::										



Month 6 Submission CR Visit 5

		Center Number:	Participant Number:	Participant's Initials:	niddle last
S	even-Day Physical Activi	y Recall (PAR) (continued)		
4	Compared to your physical activity or or about the same (check only one)? 1 More 2 Less 3 About the same	er the past three mon	ths, was last week's physical a	ctivity more, less,	
In	terviewer: Please answer questions b	elow and note any co	mments on interview.		
5	Were there any problems with the Se	ven-Day PAR interview	/?		
6	Do you think this was a valid Seven-D One No One Test	ay PAR interview?			
7	Were there any activities reported by \square_0 No \square_1 Yes	the participant that yo	ou don't know how to classify?		

calerie Phase 2

Month 9 Submission

		Center Number: _	Participant Nur	nber: Pa	rticipant's Initials:
C	linic Weight				
W	eight date and time:/ _{month}	_/	::	Staf	f initials:
	R Not done → Specify reason (use C	•			first middle last
Cli	nic weight (if the first two measuremen	ts are more than 0.1 kg	g apart, measure weight	a third time):	
W	eight 1:				
We	eight 2:	kg			
W	eight 3:	kg			
W	eight of gown:	kg			
	ital Signs				
As	sessment date and time:/	month year	00:00 to 23:59		
1	If waist measurement not done → Natural waist measurement (if the first two measurements are more the			Staff in ence a third time):	itials:
	Natural waist measurement 1:	·	cm		
	Natural waist measurement 2:		cm		
	Natural waist measurement 3:	·	cm		
2	Umbilical point waist measurement umbilical point waist circumference a thir		ments are more than 1.0 ci	m apart, measure	
	Umbilical point waist measuremen	nt 1:	cm		
	Umbilical point waist measuremen	nt 2:	cm		
	Umbilical point waist measuremen	nt 3:	cm		
3	Pulse: bpm OR Not	done → Specify reas	son (use codelist below): _	Staff in	itials:
4	Temperature:°C	OR Not done → S	pecify reason (use codelist	below): Staff in	itials:
5	Respirations: per minute C	DR Not done → Spe	ecify reason (use codelist	below): Staff in	itials:
6	Blood pressure (check only one):				itials:
	6a Blood pressure 1:/	/ mm Hg	Time: : : : : : : : : : : : : : : : : : :	OR Not done → Specify reason (use co	odelist below):
	6b Blood pressure 2:	/ mm Hg	Time: : : : : : : : : : : : : : : : : : :		
	6c Blood pressure 3:/	mm Hg	Time: : : : : : : : : : : : : : : : : : :		
No	ot Done Codelist: 1 Participant refuse	d 2 Clinician unable	e to obtain 3 Insufficie	ent time 4 Instrument fail	ure 5 Not required



Month 9 Submission

	Center Number:	_ Participant	Number:	Participant's Ini	first middle last			
12-Lead ECG								
Date and Time			Findings		Staff Initials			
OR Not done → Specify reason (see codelist below):	23:59	Is ECG (check only one): Normal Abnormal, not clinically significant (specify):						
Safety Labs								
Date and time of last meal://								
Sample	Sample (Complete?	If Not Done, Reason (Use codelist below)	Staf	f Initials			
Blood	□ ₀ No □ ₁ Yes			first	middle last			
Urine	□ ₀ No □ ₁ Yes			first	middle last			
Contraception								
If Not Done → Specify reason (use codelise	st below):							
Contraception method (females only):	Thod (females only): □ None OR Check all that apply: □ Oral contraceptive → Specify: □ Record on Concomitant Medication □ Other → Specify (e.g., barrier, IUD): □ Other			ications page				
	•							
Not Done Codelist: 1 Participant refused	2 Clinician unable to o	btain 3 Insuf	ficient time 4 Instrument f	ailure 5 No	ot required			



		Center Number:	Participant Number:	Participant's Initials:
C	linic Weight			
W	eight date and time:/ _{month}	_/	·:	Staff initials:
	R Not done → Specify reason (use C		to 23:59	first middle last
Cli	nic weight (if the first two measurement	s are more than 0.1 kg apo	art, measure weight a third time):	
W	eight 1:	kg		
W	eight 2:	kg		
W	eight 3:	kg		
W	eight of gown:	kg		
V	ital Signs			
As	sessment date and time:/	/	00:00 to 23:59	
1	If waist measurement not done → Natural waist measurement	Specify reason (use codelis	it below):	Staff initials:
	(if the first two measurements are more th	an 1.0 cm apart, measure no	itural waist circumference a third time):	first middle last
	Natural waist measurement 1:	·	cm	
	Natural waist measurement 2:	·	cm	
	Natural waist measurement 3:	·	cm	
2	Umbilical point waist measurement umbilical point waist circumference a third		are more than 1.0 cm apart, measure	
	Umbilical point waist measuremen	t1:	cm	
	Umbilical point waist measuremen	t 2:	cm	
	Umbilical point waist measuremen	13:	cm	
3	Pulse: bpm OR Not o	lone → Specify reason (use codelist below):	Staff initials:
4	Temperature: °C	OR Not done → Specif	y reason (use codelist below):	Staff initials: First middle last
5	Respirations: per minute C	R Not done → Specify	reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):] ₁ Left arm	n	Staff initials: First middle last
	6a Blood pressure 1:/	mm Hg Time	OR Not done of Specify red	ason (use codelist below):
	6b Blood pressure 2:/	mm Hg Time	00:00 to 23:59	
	6c Blood pressure 3:/_systolic	mm Hg Time	::::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to a	btain 3 Insufficient time 4 Inst	rument failure 5 Not required



Center N	Number: Participant (Number: Par	first middle last			
12-Lead ECG						
Date and Time Findings						
Safety Labs	,					
Date and time of last meal:/	: th: 00:00 to	23:59				
Date and time of sample collection:/	: th: 00:00 to	23:59				
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials			
Blood	□₀ No □₁ Yes		first middle last			
Urine	□₀ No □₁ Yes		first middle last			
Pregnancy Test						
Complete only for females. Does participant have reproductive potential? □₀ No □₁ Yes → If Yes: Date urine pregnancy test por Results: □₁ Negative □₂ Positive		./year				
Not Done Codelist: 1 Participant refused 2 Clinici	an unable to obtain 3 Insuff	ricient time 4 Instrument failu	ure 5 Not required			



		Center Number:	Participant Number:	Participant's Initials: first middle las					
D	oubly Labeled V	Water (DLW)							
1	Date and time of DLW d	losing:/	: : : : : : : : : : : : : : : : : : :	Staff initials:					
	OR Not done → Specify	reason (use codelist below):							
2	DLW dose mixture ID ar	nd bottle number: –	CA						
3	Exact weight of DLW mi	xture: gran	ns						
4	Urine samples:								
	Collection	Sample	Date and Tim	ne Collected					
	Pre dosing (PD)	PDa	/	::::::					
		PDb	/	: : : : : : : : : : : : : : : : : : :					
	Day 0 (Visit 1)	D0a	/	ar 00:00 to 23:59					
		DOb	/	: : : : : : : : : : : : : : : : : : :					
	Day 7 (Visit 2)	D7a	/	gr 00:00 to 23:59					
		D7b	/	: : : : : : : : : : : : : : : : : : :					
	Day 14 (Visit 4)	D14a	/	: : : : : : : : : : : : : : : : : : :					
		D14b	/	00:00 to 23:59					
5	5 Affix CRF page label(s) corresponding to this urine sample set:								
	em page label(s)	consequence of the same same	Affix	Affix					
				etest Sample Label Here					
				-					

3 Insufficient time

4 Instrument failure

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

5 Not required



	Center Nu	mber:	Participant Nu	mber: Participant's Initials:					
Physical Examination									
Date of examination:/	Date of examination:/								
OR Not done → Specify reason (use codelist below):									
Assessments Body System If Abnormal or Not Done: Explain									
Body System	Normal	Abnormal	Not Done	ir Abnormal or Nor Done: Explain					
1 General appearance:		□₀→	₉₇ →						
2 Head, Ears, Eyes, Nose, Throat:	\square_1	□ _o →	₉₇ →						
3 Neck:		□₀→	₉₇ →						
4 Heart:	\square_1	\square_{o} \rightarrow	□ ₉₇ →						
5 Lungs:		□₀→	₉₇ →						
6 Abdomen:	\square_1	\square_{o} \rightarrow	□ ₉₇ →						
7 Lymph nodes:		□₀→	□ ₉₇ →						
8 Extremities/Skin:	\square_1	□₀→	₉₇ →						
9 Neurological:		□₀→	₉₇ →						
10 Musculoskeletal:	\square_1	□₀→	₉₇ →						
	Normal	Abnormal	Not Done*						
11 Genitourinary:		□₀→	□ ₉₇ →						
12 Breast:		\square_{o} \rightarrow	₉₇ →						
Physician's Signature									
Investigator:	signatu	ire		Date:/					

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

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



CRF, page 165

	Center Number:	Participant Number:	Participant's Initials:	first middle last
DXA Scan				
Has the participant taken a calcium s □ ₀ No □ ₁ Yes → If Yes: Proceed	• •	n the Subject Scan Log to inforn	n the QA Center.	
2 Were any studies involving barium or □ No □ Yes	or radioisotopes performed	d within 4 weeks prior to the sc	heduled DXA exam?	
DXA Scan		DXA Resca	OR OR NA	
Date of scan:/	ır	Date of rescan:/	/	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Scanned that apply	
☐ Whole body		☐ Whole bo	dy	
Forearm		Forearm		
Spine		Spine		
ПНір		☐ Hip		



	Center Number:	Participant I	Number:	Participant's In	nitials: first_middle last
Date completed:/	OR Not don	ne → Specify re	ason (use codelist be	:low):	
Profile of Mood States					
Instructions: Please describe how yo	u feel right now by cl	hecking one bo	x for each of the wo	ords listed below.	
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly					4
2 Tense	\square_{o}		\square_{2}	\square_3	4
3 Angry				\square_3	4
4 Worn out			\square_{2}	\square_3	4
5 Unhappy					4
6 Clear-headed					4
7 Lively					4
8 Confused			\square_2	\square_3	
9 Sorry for things done					4
10 Shaky					4
11 Listless					4
12 Peeved	\square_{o}		\square_{2}	\square_3	4
13 Considerate					4
14 Sad					4
15 Active					4
16 On edge					4
17 Grouchy					4
18 Blue			\square_{2}	\square_3	4
19 Energetic				\square_3	4
20 Panicky	\square_{o}		\square_{2}	\square_3	
Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. / 950, North Tonawanda, NY 14120-0950. In Canada, 3770	Victoria Park Ave., Toronto, ΟΝ Λ	Л2H 3M6.			
Not Done Codelist: 1 Participant refused	2 Clinician unable to a	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N Participant's II	ot required
				i di napani s n	first middle last



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed					4
23 Unworthy					4
24 Spiteful	\square_{o}		\square_{2}	\square_3	4
25 Sympathetic				\square_3	4
26 Uneasy	\square_{o}		\square_{2}	\square_3	4
27 Restless				\square_3	4
28 Unable to concentrate			\square_{2}	\square_3	4
29 Fatigued				\square_3	4
30 Helpful	\square_{o}			\square_3	4
31 Annoyed				\square_3	4
32 Discouraged	\square_{o}			\square_3	4
33 Resentful					4
34 Nervous					4
35 Lonely					4
36 Miserable					4
37 Muddled					4
38 Cheerful					4
39 Bitter					4
40 Exhausted					4
41 Anxious					4
42 Ready to fight					4
43 Good-natured				\square_3	4

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 Ave., Toronto, ON M2H 3M6.



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States (a	continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy				\square_3	4
45 Desperate					4
46 Sluggish	\square_{o}		\square_{2}	\square_3	4
47 Rebellious					4
48 Helpless				\square_3	4
49 Weary					4
50 Bewildered				\square_3	4
51 Alert					4
52 Deceived				\square_3	4
53 Furious					4
54 Efficient					4
55 Trusting					4
56 Full of pep					4
57 Bad-tempered					4
58 Worthless					
59 Forgetful	o				4
60 Carefree	\square_{o}				4
61 Terrified					4
62 Guilty				\square_3	4
63 Vigorous					4
64 Uncertain about things	\square_{o}			\square_3	4
65 Bushed					4

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 Ave., Toronto, ON M2H 3M6.



	Center Number:	Participant Number	r:		Participant'	s Initials:	irst middle last
Date completed:/ _{month} /	OR Not done →	Specify reason (use codel	ist below):			
Perceived Stress Scale (PSS)							
Instructions: The questions in this scale of indicate how often you felt	-	-	-			-	lease
			Never	Almost Never	Some- times	Fairly Often	Very Often
In the last month, how often he unable to control the important	•						4
2 In the last month, how often he your ability to handle your per	,	nt about	\Box_{o}		\square_{2}	\square_3	4
3 In the last month, how often he going your way?	ave you felt that thir	igs were				\square_3	4
4 In the last month, how often he piling up so high that you could	-						
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	a 3 Insufficient t	ime 4	Instrument f	ailure 5	Not requi	red

Participant's Initials: first middle last



	Center Nur	mber: Participant	Number:	Partic	ipant's Initials	first middle last
Do	te completed:/ _{month} / _{year} O	PR Not done → Specify r	r eason (use code	list below):		
Pi	ttsburgh Sleep Quality Index (F	PSQI)				
	structions: The following questions relate to you the most accurate reply for the major	r usual sleep habits duri	-	-		
Du	ring the past month					
1	When have you usually gone to bed?	00:00 to 23:59				
2	How long (in minutes) has it taken you	•		minutes		
3	When have you usually gotten up in the	ne morning?	23:59			
4	How many hours of actual sleep did you (This may be different than the number of hours you spend in	•				
5	During the past month, how often have sleeping because you (check only one and	•	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
	a Cannot get to sleep within 30 minut	es				\square_3
	b Wake up in the middle of the night	or early morning	o			\square_3
	c Have to get up to use the bathroom	ı				
	d Cannot breathe comfortably					\square_3
	e Cough or snore loudly					\square_3
	f Feel too cold		o			\square_3
	g Feel too hot		o			\square_3
	h Have bad dreams		o			\square_3
	i Have pain					\square_3
	i Other reason(s), please describe, in you have had trouble sleeping becoreason(s):	•	\square_{o}			\square_3
6	During the past month, how often have medicine (prescribed or "over the counter") to he	-				\square_3
	89,with permission from Elsevier Science. 1 Participant refused 2 Clinician	unable to obtain 3 Insu	officient time 4	Instrument failure	5 Not re	quired



	Center Number: Participal	mber: Participant Number:		Participant's Initials:		
Pittsburgh Sleep Quality Index (PSQI) (continued)						
		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?					
		Very good	Fairly good	Fairly bad	Very bad	
9	During the past month, how would you rate your sleep quality overall?					



Month 12 Submission

									SIT I
Center Nu	mber:	Partici	pant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed:doy / OR Not c	lone → Spec	ify reaso	on (use co	delist bel	low):				
Derogatis Interview for Sexual I	unction	(DISF-S	R) (F) Fe	male Ve	rsion				
Instruction: Below you will find a brief set of quest sections that ask about different aspects of your sex while another inquires about the kinds of sexual esexual arousal and the quality of your orgasm. Trelationship.	ual experien xperiences	that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fant e d about t	asies or the natu	daydre re of you	ams, ur
activities asked about in that section. Some frequency frequency scales range from "0 = never" to "4 = alvof a satisfaction scale. This type of scale tells how much some satisfaction scales range from "0 = could not be	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								
In every section of the inventory the scales requifollow. Although it is brief, take your time with the indescribes your personal experience.									
If you have any questions, please ask the person who gave you the inventory for help.									
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4	5	6		
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)					4	5	6		
1.3 Erotic or romantic situations				3	4	5	6		8
1.4 Caressing, touching, undressing, or foreplay					4	5	6		8
1.5 Sexual intercourse, oral sex, touching to orgasm	J				4	5	6	7	8
Copyright © 1987 by Leonard R. Derogatis, PhD.		•		•					

5 Not required

4 Instrument failure

3 Insufficient time

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



Cente	er Number:	Po	articipant N	umber: _		Par	ticipant's	Initials:	st middle last
Derogatis Interview for Sexu	al Functi	on (DIS	F-SR) (F)	Female \	Version (ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how offed did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone					4	5	6		
2.2 Actively seek sexual satisfaction				\square_3	4	5	6		8
2.3 Feel sexually aroused with a partner					4		6		8
	Never	Rarely	Sometimes	Usually	Always				
2.4 Have normal lubrication with masturbation					4				
2.5 Have normal lubrication									

Copyright © 1987 by Leonard R. Derogatis, PhD.

throughout sexual relations



Center Nu	mber:	Po	articipant N	lumber:		Po	ırticipant'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									
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				\square_3	4	5			8
3.2 Masturbation	По			3	□ 4	5			
3.3 Casual kissing and petting					4	5			8
3.4 Sexual foreplay					4	5			
3.5 Sexual intercourse, oral sex, etc.	o				4	5			8
Section 4—Orgasm			•						
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	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm	О				4				
4.2 The intensity of your orgasm	По			3	4				
4.3 The ability to have multiple orgasms (if typical for you)	o			\square_3	4				
4.4 Feelings of closeness and togetherness with your partner	o				4				
4.5 Your sense of control (timing) of your orgasm					4				
4.6 Feeling a sense of relaxation and well-being after orgasm				3					

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number:		Participant	Number:		Р	articipant's	Initials:	irst middle last
Derogatis Interview for Se	xual Func	tion (DISF-SR) (F) Female	Version (continue	ed)		
Section 5—Drive and Relationship									
	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 intercours					4	5		7	8
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in se	ex?				4				
5.3 During this period, how satisfice have you been with your personal relationship with you sexual partner?				\square_3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better

Copyright © 1987 by Leonard R. Derogatis, PhD.

5.4 In general, what would represent the best description of the quality

of your sexual functioning?



Center Numb	er:	Partici	pant Numl	ber:		_ Partic	cipant's Ir	nitials:	t middle last
Date completed:OR Not do	ne → Sped	cify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Sexual Fu	nction	DISF-S	R) (M) <i>N</i>	lale Ver	sion				
Instruction: Below you will find a brief set of question sections that ask about different aspects of your sexual while another inquires about the kinds of sexual exposexual arousal and the quality of your orgasm. The relationship.	l experier eriences	nces. One that you	section of have. You	asks abo ou are a	out sexu Iso aske	al fant d about 1	asies or the natu	daydre re of yo	ams, ur
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 requency 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 collow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best lescribes your personal experience. If you have any questions, please ask the person who gave you the inventory for help.									
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person				\square_3	\Box_4	5			8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)				\square_3	4	5	6		
1.3 Erotic or romantic situations				\square_3	4	5	6		8
1.4 Caressing, touching, undressing, or foreplay				\square_3	4	₅	6		
1.5 Sexual intercourse, oral sex, touching to orgasm					4	5			

5 Not required

4 Instrument failure

2 Clinician unable to obtain

Copyright © 1987 by Leonard R. Derogatis, PhD. Not Done Codelist: 1 Participant refused

3 Insufficient time



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Derogatis Interview fo	or Sexual Function (DISF-SR) (M) Male Version (continu	ed)	

Section 2—Sexual Arousal									
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				3	4	5	6		8
2.2 A full erection during a sexual fantasy or daydream				\square_3	4	5	6		8
2.3 A full erection while looking at a sexually arousing person, movie, or picture					4	5	6		8
2.4 A full erection during masturbation						5	6		8
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm				3		5			8

Copyright © 1987 by Leonard R. Derogatis, PhD.



Center Num	ber:	Pai	ticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DISI	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 3—Sexual Behavior/Experiences									
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	О			3	4	5	6		8
3.2 Masturbation	o			\square_3	4	5	6		
3.3 Casual kissing and petting	По			\square_3	4	5	6		
3.4 Sexual foreplay	o			\square_3	4	5	6		
3.5 Sexual intercourse, oral sex, etc.	□ _o			\square_3	4	5			8
Section 4—Orgasm									
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	□ _o				4				
4.2 The intensity of your orgasm	По			3	4				
4.3 The length or duration of your orgasm	По			3	4				
4.4 The amount of seminal liquid that you ejaculate	По			\square_3	4				
4.5 Your sense of control (timing) of your orgasm				\square_3	4				
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3	4				

Copyright © 1987 by Leonard R. Derogatis, PhD.



Cente	r Number:		Participant	Number:		P	articipant'	s Initials:	S:	
Derogatis Interview for Sexu	al Fund	tion (DISF-SR) (M) Male \	/ersion (d	ontinue	d)			
Section 5—Drive and Relationship										
	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?				\square_3		5	□ ₆		□ ₈	
	Not at	Slightly	Moderately	Highly	Extremely					
5.2 During this period, how interested have you been in sex?				\square_3	□4					
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	\square_0			\square_3	_4					
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better	
5.4 In general, what would represent the best description of the quality of your sexual functioning?						5	□ ₆			

Copyright © 1987 by Leonard R. Derogatis, PhD.



Food Cravings Questionna	ina State (500 c			
Date completed:/ _{month} /		Specify reason (use codelist below):		
	Center Number:	Participant Number:	Participant's Initials:	first middle last

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.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I have an intense desire to eat [one or more specific foods].					
2	I'm craving [one or more specific foods].					5
3	I have an urge for [one or more specific foods]			\square_{3}	4	5
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3	4	
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3		
6	Eating [one or more specific foods] would feel wonderful.			\square_3		5
7	If I ate something, I wouldn't feel so sluggish and lethargic.			\square_3		5
8	Satisfying my craving would make me feel less grouchy and irritable.			\square_3		
9	I would feel more alert if I could satisfy my craving.			\square_3		
10	If I had [one or more specific foods], I could not stop eating it.			\square_3		
11	My desire to eat [one or more specific foods] seems overpowering.			\square_3		5
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			\square_3	4	5
13	I am hungry.			\square_3		5
14	If I ate right now, my stomach wouldn't feel as empty.			\square_3	4	5
15	I feel weak because of not eating.			\square_3	4	5
N	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time	4 Instrume	ent failure	5 Not req	uired



	Center Number:	Participant Number:		Participant's I	Initials:
Date completed:/					
Food Craving Inventory (FC					
For each of the foods listed below, please					
Note: A craving is defined as an intense de Over the past month, how offe	an	Darroles			Always/Almost
have you experienced a craving	NAVA	(once or twice)	Sometimes	Often	Every Day
1 Cake			\square_3	4	
2 Pizza			\square_3	4	
3 Fried chicken					
4 Gravy			\square_3		
5 Sandwich bread					
6 Sausage					
7 French fries					
8 Cinnamon rolls			\square_3		
9 Rice					
10 Hot dog					
11 Hamburger				4	
12 Biscuits					
13 lce cream					
14 Pasta					
15 Fried fish					
16 Cookies					
17 Chocolate					
18 Pancakes or waffles					
19 Corn bread					
20 Chips					
21 Rolls					
22 Cereal					
23 Donuts					
24 Candy					
25 Brownies					
26 Bacon					
27 Steak					
28 Baked potato					
Not Done Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient tin	ne 4 Instrumer	nt failure 5 N	Not required
				Participant's	Initials:



		Center Number:	Participant Number:	Participant's I	nitials:
Date o	ompleted:/	year OR Not done —	Specify reason (use codelist below):		
Eati	ng Inventory				
1	When I smell a sizzling ste difficult to keep from eatin	ak or see a juicy pie g, even if I have just	ece of meat, I find it very t finished a meal.	☐, True	□₀ False
2	I usually eat too much at s	ocial occasions, like	parties and picnics.		o False
3	I am usually so hungry the	at I eat more than th	ree times a day.		o False
4	When I have eaten my que not eating anymore.	ota of calories, I am	usually good about	☐₁ True	□₀ False
5	Dieting is so hard for me b	pecause I just get too	o hungry.	, True	o False
6	I deliberately take small h	elpings as a means	of controlling my weight.	, True	o False
7	Sometimes things just taste I am no longer hungry.	e so good that I kee	p on eating even when	, True	☐₀ False
8	Since I am often hungry, I expert would tell me that something more to eat.				o False
9	When I feel anxious, I find	myself eating.		, True	o False
10	Life is too short to worry o	bout dieting.		, True	o False
11	Since my weight goes up of more than once.	and down, I have go	one on reducing diets	☐₁ True	□₀ False
12	I often feel so hungry that	I just have to eat so	omething.		o False
13	When I am with someone	who is overeating, I	usually overeat too.	, True	o False
14	I have a pretty good idea	of the number of ca	lories in common food.	, True	o False
15	Sometimes when I start ed	ıting, I just can't see	m to stop.	☐₁ True	o False
16	It is not difficult for me to I	eave something on	my plate.	, True	o False
17	At certain times of the day to eating then.	, I get hungry becau	use I have gotten used	, True	□ _o False
18	While on a diet, if I eat foo for a period of time to ma		d, I consciously eat less		o False
N: - =	C. J.P		9 1 (() 1 () 41 ()		
Not D	one Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time 4 Instrument	rallure 5 N	lot required



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

calerie Phase 2

Month 12 Submission Visit 1

	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.
37	How often are you dieting in a conscious effort to control your weight?	☐₁ Rarely ☐₂ Sometimes ☐₃ Usually ☐₄ Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 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?	\square_1 Not at all \square_2 Slightly \square_3 Moderately \square_4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	\square_1 Almost never \square_2 Seldom \square_3 Usually \square_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?	\square_1 Never \square_2 Rarely \square_3 Often \square_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 ☐₄ Describes me perfectly
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in"



		Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:	/		Specify reason (use codelist below):		

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

I am confident that:		Not confident at all that you can resist the desire to eat						Very confident that you can resist the desire to eat				
		0	1	2	3	4	5	6	7	8	9	
1	I can resist eating when I am anxious (nervous).					4	5	6		8	9	
2	I can control my eating on the weekends.				\square_3	4	5	6		8	9	
3	I can resist eating even when I have to say "no" to others.					4	5		7	8		
4	I can resist eating when I feel physically run down.	o				4		6		8	9	
5	I can resist eating when I am watching TV.					4	5			8	9	
6	I can resist eating when I am depressed (or down).	o				4	5	6		8	9	
7	I can resist eating when there are many different kinds of food available.					4	5	6		8	9	
8	I can resist eating even when I feel it is impolite to refuse a second helping.				\square_3	4				8	9	
9	I can resist eating even when I have a headache.				\square_3	4				8	9	
N	ot Done Codelist: 1 Participant refused 2 Clinician unable	to obta	in 3	Insufficie	ent time	4 Ins	trument	failure	5 Not	required	d	



Center Number:							Particip	oant's Init	first	middle last
Weight Efficacy Lifestyle Questionna Lam confident that:	Not confident at all that you can resist the desire to eat					yo		Very co		
	0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am reading.						5	6			9
11 can resist eating when I am angry (or irritable).							6		8	9
12 I can resist eating even when I am at a party.							6		8	9
13 I can resist eating even when others are pressuring me to eat.							6		8	9
14 I can resist eating when I am in pain.				\square_3		5	6		8	9
15 I can resist eating just before going to bed.					4		6		8	9
16 I can resist eating when I have experienced failure.					4		6		8	9
17 I can resist eating when high-calorie foods are available.					4		6		8	9
18 I can resist eating even when I think others will be upset if I don't eat.							6		8	9
19 I can resist eating when I feel uncomfortable.					4		6		8	9
20 I can resist eating when I am happy.							6		8	9



	Center Number:	Participa	rticipant Number:			Participant's Initials:			middle last
Date completed://	OR Not done →	Specify	reason	(use code	elist belov	v):			
Multiaxial Assessment of	Eating Disorder	Symp	otom	S (MAE	DS)				
Instructions: Using the scale shown, pleas	se rate the following items o	on a scal	e from 1	to 7. Ple	ase ansv	ver as tru	uthfully	as possi	ble.
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	weight.				\square_3	4	5		
2 My sleep isn't as good as it us	sed to be.				\square_{3}	4	5		
3 I avoid eating for as long as I	can.				\square_3	4	5	6	
4 Certain foods are "forbidden"	' for me to eat.				\square_3	4	5		
5 I can't keep certain foods in my binge on them.	house because I will				\square_3			6	
6 I can easily make myself vom	it.				\square_3	4	5	6	
7 I can feel that being fat is terr	ible.				\square_3	4	5	6	
8 I avoid greasy foods.					\square_3	\square_4	5	6	
9 It's okay to binge and purge	once in a while.				\square_3	4	5		
10 I don't eat certain foods.					\square_3		5		
11 I think I am a good person.					\square_3	4	5	6	
12 My eating is normal.					\square_3	\square_4	5		
13 I can't seem to concentrate la	tely.				\square_3	4	5		
14 I try to diet by fasting.					\square_3	4	5	6	
15 I vomit to control my weight.					\square_3	4	5		
16 Lately nothing seems enjoyab	le anymore.				\square_3	\square_4	5		
17 Laxatives help keep you slim.						4	5		
18 I don't eat red meat.					\square_3		5		
19 I eat so rapidly I can't even to	iste my food.				\square_3	4	5	6	
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n 3 Ins	sufficient	time 4	Instrume	nt failure	5 No	t require	d



	Center Number:	Participant N	Participant Number: Participant's Initials:						
Multiaxial Assessment of	Eating Disorder	Sympto	oms (MAEDS)					
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always	
20 I do everything I can to avoid	being overweight.					5			
21 When I feel bloated, I must do s of that feeling.	comething to rid myse	elf		\square_3	4	5	6		
22 I overeat too frequently.				\square_3	4	5			
23 It's okay to be overweight.				\square_3	4	5	6		
24 Recently I have felt that I am o	a worthless person.			\square_3	4	5			
25 I would be very upset if I gain	ned 2 pounds.			\square_3	4	5	6		
26 I crave sweets and carbohydr	ates.			\square_3	4	5	6		
27 I lose control when I eat.				З	4	5	6	7	
28 Being fat would be terrible.				\square_3	4	5			
29 I have thought seriously abou	t suicide lately.			\square_3	4	5	6		
30 I don't have any energy anymo	re.			\square_3	4	5	6		
31 I eat small portions to control	my weight.			\square_3	4	5	6		
32 I eat 3 meals a day.				\square_3	4	5			
33 Lately I have been easily irrito	ated.			\square_3		5			
34 Some foods should be totally	avoided.			\square_3	4	5			
35 I use laxatives to control my v	veight.			\square_3	4	5	6	7	
36 I am terrified by the thought o	of being overweight.			\square_3	4	5	6		
37 Purging is a good way to lose	weight.			\square_3		5			
38 I avoid fatty foods.									



	Center Number:	Participant No	umber: _		Pai	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blu	e.			\square_3	4	5	6	
40 I am obsessed with becoming	overweight.			\square_3	4	5	6	
41 I don't eat fried foods.				\square_3	4	5		
42 I skip meals.				\square_3	4	5		
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			\square_3	4	5	6	
45 I feel good when I skip meals	i.			\square_3	4	5		
46 I avoid foods with sugar.				\square_3	4	5	6	
47 I hate it when I feel fat.				\square_3	4	5		
48 I am too fat.				\square_3	4	5	6	
49 I eat until I am completely stu	ffed.			\square_3	4	5		
50 I hate to eat.				\square_3	4	5	6	
51 I feel guilty about a lot of thir	igs these days.			\square_3	4	5		
52 I'm very careful of what I eat				\square_3	4	5	6	
53 I can "hold off" and not eat e	even if I am hungry.			\square_3	4	5		
54 I eat even when I am not hun	gry.			\square_3	4	5		
55 Fat people are disgusting.				\square_3	4	5	6	
56 I wouldn't mind gaining a fev	v pounds.			\square_3	4	\square_5	6	

CRF, page 195



		Center Number: Participant	Number: _		Par	ticipant's I	nitials:	middle last				
Da	te completed:/ _{month} /	OR Not done → Specify re	ason (use	codelist b								
В	Body Shape Questionnaire (BSQ)											
	We would like to know how you have been feeling about your appearance over the past four weeks. Please read each question and check the box for the appropriate choice. Please answer all the questions.											
Ov	er the Past Four Weeks		Never	Rarely	Some- times	Often	Very Often	Always				
1	Has feeling bored made you	brood about your shape?			\square_3	4	5					
2	Have you been so worried all have been feeling that you or				\square_3	4	5	6				
3	Have you thought that your t too large for the rest of you?	highs, hips, or bottom are			\square_3	4	5	6				
4	Have you been afraid that you fatter)?	ou might become fat (or			\square_3		5					
5	Have you worried about you enough?	r flesh not being firm			$\square_{_{3}}$	4	5	6				
6	Has feeling full (e.g., after eating of fat?	a large meal) made you feel			\square_{3}	4	5					
7	Have you felt so bad about y cried?	our shape that you have			\square_{3}	4						
8	Have you avoided running be wobble?	ecause your flesh might			\square_3	4	5	6				
9	Has being with thin women/r self-conscious about your sha				\square_3	4	5					
10	Have you worried about you sitting down?	r thighs spreading out when			\square_3	4	5					
11	Has eating even a small amo fat?	unt of food made you feel			\square_3	4	5	6				
	Have you noticed the shape of felt that your own shape com	pared unfavorably?			\square_3	4	5					
13	Has thinking about your shap ability to concentrate (e.g., while to conversations)?				\square_3							
14	Has being naked, such as whe feel fat?	en taking a bath, made you			\square_3		5	6				
15	Have you avoided wearing c particularly aware of the sha					4	5					
16	Have you imagined cutting of body?	ff fleshy areas of your			\square_3	4	5					

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



		Center Number:	Participant N	lumber: _		Pai	rticipant's	Initials: _	rst middle last
Bod	ly Shape Questionnai	re (BSQ) (continued)							
Over	the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
	as eating sweets, cakes or c ou feel fat?	other high calorie foo	od made				4	5	
18 H	ave you not gone out on so ecause you have felt bad ab	cial occasions (e.g., po pout your shape?	ırties)			\square_3		5	
19 H	ave you felt excessively larç	ge and rounded?				\square_3	4	5	
20 H	ave you felt ashamed of yo	ur body?				3	4	5	6
21 H	as worry about your shape	made you diet?				$\square_{_3}$	4	5	6
	ave you felt happiest about omach has been empty?	your shape when y	our				4	5	6
	ave you thought that you a ecause you lack self-control?		•			\square_3	4	5	
	ave you worried about othe esh around your waist or sto		s of			\square_3	4	5	
	ave you felt that it is not fair ninner than you?	r that other women/	men are			\square_3	4	5	6
26 H	ave you vomited in order to	feel thinner?				\square_3		5	
	When in company, have you nuch room (e.g., sitting on a sofa or		g up too			\square_3	4	5	
28 H	ave you worried about you	r flesh being dimply	?			\square_3	4	5	
	las seeing your reflection (e.g ou feel bad about your shap		w) made			\square_3	4	5	6
	ave you pinched areas of your is there?	our body to see how	much			\square_3	4	5	6
	ave you avoided situations our body (e.g., communal changing						4	5	6
32 H	ave you taken laxatives in c	order to feel thinner?	•			\square_3	4	5	6
	ave you been particularly so nape when in the company		our				4	5	6
	as worry about your shape exercise?	made you feel you	ought					5	6



		Center Number	: Participant Num	ber: Part	Participant's Initials: first middle last						
Har	ndgrip Strength										
Date	and time of assessment:	/	:::::	Staff	initials:						
OR N	ot done → Specify reaso	n (use codelist below):									
1 D	1 Dynometer handle position:										
2 D	2 Dominant hand (check only one): \square_1 Left \square_2 Right \square_3 Ambidextrous										
3 H	3 Handgrip strength:										
	Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand						
	Test 1—peak force		kg		kg						
	Test 2—peak force		kg	\square_{0}	kg						
	Test 3—peak force		kg	\square_{0}	kg						
Not D	Oone Codelist: 1 Participar	nt refused 2 Clinician una	ble to obtain 3 Insufficie	nt time 4 Instrument failui	re 5 Not required						



			Center Number:	Participant Nu	mber:	Particip	pant's Initials:	
ls	ometric/Isokineti	ic Knee	Extension and	Flexion				
	ate and time of assessment: R Not done → Specify reaso			:: 00:00 to 23:59		Staff initials:		
1 2 3	Recent injury or pain—right Recent injury or pain—left Specify machine used (PBF	knee?	O No O Yes					
	All values corrected f	or gravit	y effect torque	Right Le	eg	Left Leg	If Not Done, Specify Reason (Use codelist below)	
3	60°/sec knee extension		peak torque		V.m	N.m		
			total work		۷.m	N.m		
			average power		vatts	watts		
4	60°/sec knee flexion		peak torque		٧.m	N.m		
			total work		۷.m	N.m		
			average power		vatts	watts		
5	180°/sec knee extension		peak torque		۷.m	N.m		
			total work		V.m	N.m		
			average power		vatts	watts		
			work fatigue index	%	6	%		
6	180°/sec knee flexion		peak torque		۷.m	N.m		
			total work		V.m	N.m		
			average power		vatts	watts		
			work fatigue index	%	6	%		
7	Isometric knee extension:	trial 1	peak torque		V.m	N.m		
		trial 2	peak torque		٧.m	N.m		
		trial 3	peak torque		٧.m	N.m		
8	Isometric knee flexion:	trial 1	peak torque		۷.m	N.m		
		trial 2	peak torque		V.m	N.m		
		trial 3	peak torque		۷.m	N.m		
N/	ot Done Codelist: 1 Participa	int refused	2 Clinician unable to obt	rain 3 Insuffici	ent time	1 Instrument failure	5 Not required	



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

		tirst middle last
Clinic Weight		
Weight date and time:		Staff initials:
OR Not done → Specify	y reason (use codelist below):	
Clinic weight (if the two r	measurements are more than 0.1 kg apart, measure we	eight a third time):
Weight 1:	kg	
Weight 2:	kg	
Weight 3:	kg	
Weight of gown:	kg	

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

CRF, page 201

calerie

Phase 2

Month 12 Submission Visit 2

						Center N	umber: _	F	Participant	Number:		P	articipant's	Initials:	irst middle last
Se	ven-C	Day Physical Activ	vity Reca	(PAR)											
Tod	ay's date	e:/	Day	(check only one):	Mon Tu	es Wed	Thurs	Fri S	Sat Su	o OR No	ot done →	Specify re	eason (use	codelist be	ow):
		ou employed in the last seve				→ Skip to que							riewer ini	ı:l	middle last
2	If Yes: Which days (check all that apply)?				Mon	Tues	Wed	Thurs	Fri	Sat	Sun				
3	Which d	ays do you consider your v		on-work, days? o Time				Thurs [Sun rnoon (in n	-:	Evo	ning (in mi	
Day #	Day of Week	Date	In Bed	Up	Start	Time Stop	Mod.	Hard	Very	Mod.	Hard	Very	Mod.	Hard	Very
"	WCCK		III bea	ОР	Jidii	Зюр	mou.	Tidia	Hard	Mou.	Tidia	Hard	Mod.	Tidia	Hard
7 yester-		/	00:00 to 23:59	00:00 to 23:59	:: 00:00 to 23:59	:									
day)		,	00:00 to 23:59	00:00 to 23:59											
6		//	00:00 to 23:59	00:00 to 23:59	:	:									
		day month year	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	 :	 :									
		day month year	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	:	:									
		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
3		//	00:00 to 23:59	00:00 to 23:59	:	:									
		day month year	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									
		,	00:00 to 23:59	00:00 to 23:59	00.00 10 23.37	00.00 10 23.37									
1 1 week		/	00:00 to 23:59	00:00 to 23:59	:	:									
ago)		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									



		Center Number:	Participant Number:	Participant's Initials:	ddle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)? More Less	over the past three mon	ths, was last week's physical c	ictivity more, less,	
In	terviewer: Please answer questions	below and note any co	mments on interview.		
5	Were there any problems with the S No Yes	even-Day PAR interviev	v?		
6	Do you think this was a valid Seven-	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	ou don't know how to classify?	•	



Month 12 Submission

		Center Number:	Partic	cipant Number: Partic	ipant's Initials:				
6-D	ay Food Record								
Comp	olete below OR Not done → Speci	ify reason (use Codelist b	pelow): _	Staff in	itials: first middle last				
				Replacement Value	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	/	Reliable Deliable Deliable Deliable Deliable				
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	Reliable Deliable Deliable Deliable Deliable				
5	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12	/	Reliable Unreliable Missing				
6	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	13	/	Reliable Unreliable Missing				
Not D	Oone Codelist: 1 Participant refused	2 Clinician unable to ob	otain 3	Insufficient time 4 Instrument failure	s 5 Not required				



		Center Number:	Participant Number	r: Par	ticipant's Initials:
V	O ₂ Max				
1	Date and time of test:/	/	00:00 to 23:59	Staff	initials:
	OR Not done → Specify reason (use of	codelist below):			
2	At what time was the participant's la	st meal/snack eaten:	00:00 to 23:59		
3		1 Sin	us Atrial fibrill	ation \square_{98} Other \square_3 RBBB	
4	Heart rate (HR) data: Resting heart rate Age-predicted Heart rate (max	heart rate:	bpm		
5	Reason(s) for termination of testing (a ☐ Symptom limited (dyspnea, fatigue) ☐ Angina/ischemia → Complete all the	theck all that apply):	true cardiac angina o		
	Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress i Orthopedic/extremity complaints (pa Other (specify):	mage study, complete ins/cramps)	ventricular episode repo	s occurred:	bpm or
6	Did frequent ventricular ectopy occur ☐ No ☐ Yes → If Yes: When did it occur (c	-			
7	Peak VO ₂ : mL/kg/min	L/min			
8	Did the participant meet at least 2 of ☐ ₀ No ☐ ₁ Yes → If Yes: VO ₂ max:	_	.,.	a Achieve a plateau in between the final two b RER ≥ 1.1 c HR max ± 5 bpm of a	
9	Exercise time: : : seconds		_		
10	Blood pressure at VO ₂ peak/VO ₂ ma	X:/diastol	mm Hg		
11	Borg RPE score at VO_2 peak/ VO_2 ma	x: (6-20	0)		
12	Peak RER:				
13	VE at VO ₂ peak/VO ₂ max:	L/min			
14	VE/VO ₂ at VO ₂ peak/VO ₂ max	L/min			

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

5 Not required

4 Instrument failure



4 Instrument failure

5 Not required

	Center Number: I	Participant Number: Parti	cipant's Initials:
Core Tempe	erature		
Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason (Use codelist below)
	Start Date:	Start Time	
	//	00:00 to 23:59	
first middle last	Stop Date:	Stop Time	
	day month year	00:00 to 23:59	
Inpatient A	dmission and Discharge		
1 Inpatient admi	ission date and time:/ _{month} / _{year}	::	
2 Inpatient disch	parge date and time:/ _{month} / _{year}	:	

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



)e									
تد	layed-type Hype	rsensitivity	(DTH)						
	Was the DTH worksheet con No Yes → If Yes: Were any		-		test administer test.				
	Date of injection:/_	/	OR Not done	→ Specify reas	on (use codelist below):			
	Injection by (initials): First middle	last							
ı ,	Arm injected:	Left							
because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. A = Largest diameter B = Second diameter perpendicular to A									
	A = Largest diameter	perpendicular to A			48				
	A = Largest diameter	perpendicular to A		Read By:	48 A (diameter)	Hour (@ Visit 5) B (diameter)	Read By:		
	A = Largest diameter B = Second diameter	perpendicular to A	Hour (@ Visit 4)	Read By:		Hour (@ Visit 5)			
	A = Largest diameter B = Second diameter Antigen	perpendicular to A 24 A (diameter)	Hour (@ Visit 4) B (diameter)	Read By:	A (diameter)	Hour (@ Visit 5) B (diameter)	Read By:		
	A = Largest diameter B = Second diameter Antigen Normal saline	perpendicular to A 24 A (diameter) mm	B (diameter)	, , , , , , , , , , , , , , , , , , ,	A (diameter) mm	Hour (@ Visit 5) B (diameter) mm			

3 Insufficient time

4 Instrument failure

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

5 Not required



	Center Number:	Participant Number: _	Participo	ant's Initials: first middle last						
Clinic Weight										
Weight date and time: _	/	_ :	Staff initi	als:						
	reason (use codelist below):	0.10.25.37								
Clinic weight (if the two me	easurements are more than 0.1 kg apart,	measure weight a third time	e):							
Weight 1:	kg									
Weight 2:	kg									
Weight 3: kg										
Weight of gown:	kg									
Outcomes Labs										
Date and time of last me	al:/	: :								
Date and time sample collection started: / :										
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials						
Са	techolamines	□ ₀ No □ ₁ Yes		first middle last						
	Blood	□ ₀ No □ ₁ Yes		first middle last						
Oral glucos	e tolerance test (OGTT)	□ ₀ No □ ₁ Yes		first middle last						
If a sample is not obtained,										
24-hour Urine (Collection									
Total Volume Collected	Date of Sample Collection	Time of Sample Collection	If Not Done Reason (Use codelist bel	Staff Initials						
	Start Date:	Start Time:								
	/	00:00 to 23:59								
mL	Stop Date:	Stop Time:		first middle last						
	/ _{month} /year	: : : : : : : : : : : : : : : : : : :								

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



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

Sex Hormone					tirst middle last			
If Not Done → Specify reason (use code	list helow)							
Contraception method (females only):	iisi Belowy	None OR Check all that apply: ☐ Oral contraceptive → Specify: Record on Concomitant Medications page ☐ Other → Specify (e.g., barrier, IUD): ☐ Other → Specify (e.g., barrier, IUD):						
Day 1		Date	Time	If Not Done, Reason (use codelist)	Staff Initials			
Day 1 of menses (females only)								
Date and time of last meal (males only	r)	/	:					
Hormone level blood draw 1 (males o	nly)	/			first middle last			
Hormone level blood draw 2 (females of Progesterone level	o nly)							
Day 2		Date Time		If Not Done, Reason (use codelist)	Staff Initials			
Date and time of last meal								
Hormone level blood draw 3 (females of Progesterone level	only)							
Metabolic Rate								
Sample		Date of Collection	If Not Done, Ro (Use codelist be		f Initials			
Resting Metabolic Rate (RMR)—Visit 4		/		first	middle last			
Cart ID		-003 (623-002)		PBRC-016 (623- PBRC-017 (623-				
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	me 4 Instrument	failure 5 Not r	equired			

CRF, page 208

calerie Phase 2

Month 12 Submission Visit 4

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

														nrs	st middle last
Se	ven-C	Day Physical Activ	ity Recal	(PAR)											
Tod	oday's date:/														
		ou employed in the last seve				→ Skip to que						Interv	iewer ini	tials:	middle last
2	If Yes: Which days (check all that apply)?				Mon	Tues	Wed	Thurs	Fri _	Sat	Sun				
3	Which d	ays do you consider your w	eekend, or no	on-work, days?	Mon	Tues .	Wed	Thurs	Fri _	Sat	Sun				
Day	Day of		Sleep	Time	Work	Time	Mor	ning (in mi	inutes)	After	noon (in n	inutes) 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	:: 00:00 to 23:59	00:00 to 23:59									
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	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	:::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									
3		//	:: _	::: _	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	:::	:::									



		Center Number:	Participant Number:	Participant's Initials:	ddle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)? More Less	over the past three mon	ths, was last week's physical c	ictivity more, less,	
In	terviewer: Please answer questions	below and note any co	mments on interview.		
5	Were there any problems with the S No Yes	even-Day PAR interviev	v?		
6	Do you think this was a valid Seven-	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	ou don't know how to classify?	•	



	Center Number: Participant Number: _	Particip	pant's Initials:
Biopsy Labs			
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Muscle biopsy	/ _{month} /		first middle last
Fat biopsy	/		first middle last

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



Month 18 Submission Month 17 Visit

	Center Number:	Participant Numb	per: Partici	pant's Initials:
Clinic Weight				
Weight date and time:/ _{month}	/	:	Staff in	first middle last
OR Not done → Specify reason (use code	-	00 10 23.37		
Clinic weight (if the two measurements are r	more than 0.1 kg apart	, measure weight a thii	rd time):	
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			
Pregnancy Test				
Complete only for females.				
U ₀ No ☐ ₁ Yes → If Yes: Date urine pregnar Results: ☐ ₁ Negat ☐ ₂ Positive Outcomes Labs	ive	/ _{month} /	year	
Date and time sample collection started:	// day month	year 00:00	_ :) to 23:59	
Sample If a sample is not obtained, indicate with a N	Not Done.	ple Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□ ₀ No □ ₁ Yes			first middle last
Vaccine Adr NOTE: Before any vaccine is administe and protocol for po	ered, review the vaccine	e questionnaire	If Not Done, Reason (Use codelist below)	Staff Initials
Vaccine(s) given (check all that app		titis A us/diphtheria nococcal vaccine		first middle last
	,			·
Not Done Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insufficien	t time 4 Instrument failure	5 Not required



Month 18 Submission CR Visit 1/Control Visit

	Center Number: Participant Number: Participant's Initials:
C	inic Weight
	ight date and time: $\frac{1}{day} / \frac{1}{month} / \frac{1}{year} = \frac{1}{00:00 \text{ to } 23:59}$ Staff initials: $\frac{1}{first \text{ middle } last}$ Not done \rightarrow Specify reason (use Codelist below):
Cli	nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
We	ight 1: kg
We	ight 2: kg
We	ight 3: kg
We	ight of gown: kg
V	tal 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 time): Natural waist measurement 1: cm
	Natural waist measurement 2: cm
	Natural waist measurement 3: cm
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):
	Umbilical point waist measurement 1: cm
	Umbilical point waist measurement 2: cm
	Umbilical point waist measurement 3: cm
3	Pulse: bpm OR Not done → Specify reason (use codelist below): Staff initials: list
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: initials:
6	Blood pressure (check only one): 1 Left arm 2 Right arm Staff initials: 1 Init
	6a Blood pressure 1:/ mm Hg Time:: OR Not done → Specify reason (use codelist below):
	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



Month 18 Submission CR Visit 1/Control Visit

	Center Number:	Participant Number:	Particip	pant's Initials:
12-Lead ECG				
Date and Time		Findi	ngs	Staff Initials
/	□ ₁ No □ ₂ Ab	(check only one): ormal normal, not clinically signif normal, clinically significar		first middle last
Safety Labs				
Date and time of last meal:	_//	ear 00:00 to 23:59		
Date and time of sample collection:				
Sample	Sampl		of Done, Reason se codelist below)	Staff Initials
Blood	O No			first middle last
Urine	□ ₀ No □ ₁ Yes			first middle last
Outcomes Labs		'		
Date and time of last meal:	/	/ :_	22.50	
Date and time sample collection started:	/			
Sample		Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood		□₀ No □₁ Yes		first middle last
If a sample is not obtained, indicate with a No	ot Done.			

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



Month 18 Submission CR Visit 1

		Center Number:	Participant Number:	Participant's Initials: first middle las
Do	oubly Labeled V	Vater (DLW)		
1	Date and time of DLW d	osing:/ _{month} / _{year}	:::	Staff initials: First middle last
	OR Not done → Specify	reason (use codelist below):		
2	DLW dose mixture ID an	nd bottle number: –	CA	
3	Exact weight of DLW mix	xture: grams		
4	Urine samples:			
	Collection	Sample	Date and Ti	ime Collected
	Pre dosing (PD)	PDa	/	year 00:00 to 23:59
		PDb	///	year 00:00 to 23:59
	Day 0 (Visit 1)	D0a	/	year 00:00 to 23:59
		DOP	/	year 00:00 to 23:59
	Day 7 (Visit 2)	D7a	/	year 00:00 to 23:59
		D7b	/	year 00:00 to 23:59
	Day 14 (Visit 4)	D14a	/	year : : : : : : : : : : : : : : : : : : :
		D14b	/	year 00:00 to 23:59
_			,, ,	,
5	Attix CRF page label(s)	corresponding to this urine sample set	Attix	Affix
			Test Sample F	Retest Sample Label Here

3 Insufficient time

4 Instrument failure

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

5 Not required



Month 18 Submission CR Visit 1

Ce	nfer Number:	Participant Number:	Participant's Initials:
Pregnancy Test			
Complete only for females.			
Does participant have reproductive poter ☐ No ☐ Yes → If Yes: Date urine pregnancy to Results: ☐ Negative ☐ Positive		//	
DXA Scan			
 Has the participant taken a calcium supp □ No □ Yes → If Yes: Proceed with Were any studies involving barium or rad □ No □ Yes 	scan and document in		
DXA Scan		DXA Rescan O	RNA
Date of scan:/	_	Date of rescan:/	_/
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scar Check all tha	
☐ Whole body		☐ Whole body	
Forearm		Forearm	
Spine		Spine	
☐ Hip		ПНір	

3 Insufficient time 4 Instrument failure

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

5 Not required



Month 18 Submission CR Visit 2

C	enter Number:	Participant Number:	Participant's Initials: middle last
Clinic Weight			
Weight date and time:/ _{month} /_		:: :00 to 23:59	Staff initials: first middle last
OR Not done → Specify reason (use Codelis	t below):		
Clinic weight (if the first two measurements are	more than 0.1 kg c	part, measure weight a third time):	
Weight 1: k	g		
Weight 2: k	g		
Weight 3: k	9		
Weight of gown: k	9		
Contraception			
If Not Done → Specify reason (use codelist b	elow):		
Contraception method (females only):	☐ None C		n Concomitant Medications page
Not Done Codelist: 1 Participant refused 2	Clinician unable to	obtain 3 Insufficient time 4 Instru	ment failure 5 Not required

calerie Phase 2

Month 18 Submission CR Visit 2

						Center Nu	mber:	Po	articipant N	Number: _		Pa	rticipant's	Initials:	rst middle last
Se	ven-C	Day Physical Activ	vity Reca	(PAR)											
		e:/			Mon Tu	es Wed	Thurs	Fri S	Sat Su	OR No	t done →	Specify re	eason luse	codelist he	low).
				teneer only one,						OKINO	done	Interv	iewer ini	tials.	
	-	ou employed in the last seve	•		∐₀ No	→ Skip to que		_				illici v	icwei iiii	tials:	middle last
		Which days (check all that apply)?			Mon	Tues'	Wed	Thurs			Sun				
3	Which d	lays do you consider your w						Thurs			Sun /·		Even	ning (in mir	, 1
Day #	Day of Week	Date	In Bed	Time Up	Work		Mod.	ning (in m Hard	Very	Mod.	noon (in n	Very	Mod.		Very
#	vveek		in bea	ОР	Start	Stop	Moa.	пага	Hard	Mod.	Hard	Hard	Mod.	Hard	Hard
7		/ /	00:00 to 23:59	00:00 to 23:59											
'yester- day)		day month year	00:00 to 23:59	:: 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			::	::											
6		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
		day illollili yedi	00:00 to 23:59	00:00 to 23:59	00:00 16 23:39	00:00 16 23:39									
			00:00 to 23:59	:: 00:00 to 23:59											
5		day month year	:	:	00:00 to 23:59	00:00 to 23:59									
			00:00 to 23:59	00:00 to 23:59											
4		//	00:00 to 23:59	00:00 to 23:59	:	:									
-		day month year	:: 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			:	:											
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	00:00 to 23:59											
2		//	00:00 to 23:59	00:00 to 23:59	:	:									
_		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1			::	::											
1 week		/	00:00 to 23:59	00:00 to 23:59 :	00:00 to 23:59	00:00 to 23:59									
ago)			00:00 to 23:59	00:00 to 23:59											

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

4 Instrument failure

5 Not required



Month 18 Submission CR Visit 2

		Center Number:	Participant Number:	Participant's Initials:	ddle last
S	even-Day Physical Activi	ty Recall (PAR) (continued)		
4	Compared to your physical activity or about the same (check only one)?	ver the past three mon	ths, was last week's physical a	ctivity more, less,	
In	terviewer: Please answer questions b	elow and note any co	mments on interview.		
5	Were there any problems with the Se	even-Day PAR interview	v?		
6	Do you think this was a valid Seven-Do No	Day PAR interview?			
7	Were there any activities reported by \square_0 No \square_1 Yes	the participant that yo	ou don't know how to classify?		



Month 18 Submission **CR Visit 2**

		Center Number:	Partic	cipant Number: Partic	ipant's Initials:
6-D	ay Food Record				
Comp	olete below OR Not done → Speci	ify reason (use Codelist b	pelow): _	Staff in	itials: first middle last
				Replacement Value	es
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	/	Reliable Deliable Deliable Deliable Deliable
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	Reliable D ₂ Unreliable D ₃ Missing
3	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10	/	Reliable Description 1 Reliable Description 3 Missing
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	Reliable Deliable Deliable Deliable Deliable
5	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12	/	Reliable Unreliable Missing
6	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	13	/	Reliable Unreliable Missing
Not D	Oone Codelist: 1 Participant refused	2 Clinician unable to ob	otain 3	Insufficient time 4 Instrument failure	s 5 Not required



Month 18 Submission CR Visit 2/Control Visit

	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last
Date completed:/	year OR Not done —	→ Specify	/ reason	(use cod	lelist belo	w):			
Multiaxial Assessment of	Eating Disorder	Sym	otom	S (MAE	DS)				
Instructions: Using the scale shown, plea	se rate the following items	on a scal	e from 1	to 7. Ple		ver as tr			
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	e weight.				\square_3		5		
2 My sleep isn't as good as it u	used to be.				\square_3	4	5	6	
3 I avoid eating for as long as	l can.					4	5	6	
4 Certain foods are "forbidden	" for me to eat.				\square_3	\square_{4}	5		
5 I can't keep certain foods in my binge on them.	house because I will					4		6	
6 I can easily make myself von	nit.				\square_3	4	5	6	
7 I can feel that being fat is ter	rible.				\square_3	4	5	6	
8 I avoid greasy foods.					\square_3	\square_{4}	5		
9 It's okay to binge and purge	once in a while.					4	5		
10 I don't eat certain foods.						4	5	6	
11 I think I am a good person.							5		
12 My eating is normal.							5		
13 I can't seem to concentrate la	itely.						5		
14 I try to diet by fasting.							5		
15 I vomit to control my weight.					\square_3	4	5		
16 Lately nothing seems enjoyal	ole anymore.					\square_{4}	5		
17 Laxatives help keep you slim	•					4	5		
18 I don't eat red meat.					\square_3	\square_4	5		
19 I eat so rapidly I can't even t	aste my food.					4	5		
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 Ins	sufficient	time 4	Instrume	nt failure	5 No	t require	d



Month 18 Submission CR Visit 2/Control Visit

	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	oms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.					5	6	
21 When I feel bloated, I must do so of that feeling.	something to rid myse	If		\square_3	4	5	6	
22 I overeat too frequently.				\square_3		5		
23 It's okay to be overweight.				\square_3	4	5		
24 Recently I have felt that I am	a worthless person.			\square_3		5		
25 I would be very upset if I gain	ned 2 pounds.			\square_3		5	6	
26 I crave sweets and carbohyde	rates.			\square_3	4	5	6	
27 I lose control when I eat.				\square_3	4	5		
28 Being fat would be terrible.				\square_3	4	5		
29 I have thought seriously abou	ut suicide lately.			\square_3	4	5	6	
30 I don't have any energy anymo	ore.			\square_3		5		
31 I eat small portions to control	my weight.			\square_3		5	6	
32 I eat 3 meals a day.				\square_3		5		
33 Lately I have been easily irrite	ated.			\square_3	4	5		
34 Some foods should be totally	avoided.			\square_3	4	5		
35 I use laxatives to control my	weight.			\square_3	4	5		
36 I am terrified by the thought of	of being overweight.				4	5		
37 Purging is a good way to lose	e weight.			\square_3		5		
38 I avoid fatty foods.								



Month 18 Submission CR Visit 2/Control Visit

	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of	Eating Disorde	r Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blu	e.			3	4	5		
40 I am obsessed with becoming	overweight.			\square_3	4	5		
41 I don't eat fried foods.				\square_3		5	6	
42 I skip meals.				\square_3	4	5	6	7
43 Fat people are unhappy.				\square_3		5	6	
44 People are too concerned wit	h the way I eat.			\square_3	4	5	6	7
45 I feel good when I skip meals	•			\square_3		5		
46 I avoid foods with sugar.				\square_3		5	6	
47 I hate it when I feel fat.				\square_3		5	6	
48 I am too fat.				\square_3		5	6	
49 I eat until I am completely stu	ffed.			\square_3			6	
50 I hate to eat.				3	4	5	6	7
51 I feel guilty about a lot of thir	gs these days.			\square_3		5	6	
52 I'm very careful of what I eat				\square_3		5	6	
53 I can "hold off" and not eat e	even if I am hungry.			\square_3	4	5	6	
54 I eat even when I am not hun	gry.			\square_3	4	5	6	
55 Fat people are disgusting.				3	4	5		
56 I wouldn't mind gaining a fev	v pounds.							



Month 18 Submission CR Visit 4

	Center Number:	Participant Number:	Particip	ant's Initials:
Inpatient Admission and	Discharge			
1 Inpatient admission date and time:	/	year 00:00 to 23	:59	
2 Inpatient discharge date and time:	/	year 00:00 to 23:	 59	
Clinic Weight				
Weight date and time:/ _{month}	_/	:	Staff init	ials:
OR Not done → Specify reason (use coo		70 10 23.37		first middle last
Clinic weight (if the two measurements are	more than 0.1 kg apart,	measure weight a third t	time):	
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			
Metabolic Rate				
Sample	Date of	Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 5	/			first middle last
Cart ID	Tufts-003 (623-00		·	016 (623-005) 017 (623-001)
	:			

2 Clinician unable to obtain

3 Insufficient time

4 Instrument failure

Not Done Codelist: 1 Participant refused

5 Not required

Month 18 Submission CR Visit 4

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Todo	Today's date:	////	Day	Day (check only one):		Mon] Thurs	Fri	at Sur	OR No	done 1	Speafy re	eason (use	codelist bel	ow):
_	Were yo	oyed in the last sev	ın days?		°Z °	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	sstion 3	Tes				Interv	Interviewer initials:		first middle last
7	If Yes: M	If Yes: Which days (check all that apply)?	۲.		Mon	Tues Wed		Thurs	i.E.	Sat	Sun				
m	Which d	Which days do you consider your weekend, or non-work, days?	veekend, or n	on-work, days?	Mon	Tues		Thurs	Fi	Sat] Sun				
Day	Day of		Sleek	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	nutes)	Аffer	Afternoon (in minutes)	ninutes)	Ever	Evening (in minutes)	nutes)
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7															
yester- day)		day / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
			10:00 10:00	00:00 10 23:39											
9		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			00:00 to 23:59	00:00 to 23:59											
Ŋ		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			00:00 to 23:59	00:00 to 23:59											
4		day month year			00:00 to 23:59	00:00 to 23:59									
			2000												
c		/	00:00 to 23:59	00:00 to 23:59											
,		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
7		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
			00:00 to 23:59	00:00 to 23:59											
-															
1 week	_	day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
ago)			00:00 to 23:59	00:00 to 23:59											
1															

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

3 Insufficient time



Month 18 Submission CR Visit 4

		Center Number:	Participant Number:	Participant's Initials:	ddle last
S	even-Day Physical Activi	ty Recall (PAR) (continued)		
4	Compared to your physical activity or about the same (check only one)?	ver the past three mon	ths, was last week's physical a	ctivity more, less,	
In	terviewer: Please answer questions b	elow and note any co	mments on interview.		
5	Were there any problems with the Se	even-Day PAR interview	v?		
6	Do you think this was a valid Seven-Do No	Day PAR interview?			
7	Were there any activities reported by \square_0 No \square_1 Yes	the participant that yo	ou don't know how to classify?		



Month 24 Submission Month 23 Visit

	Center Number:	Participant Number:	Participant's	Initials:				
Clinic Weight								
Weight date and time:/ _{month}	/	: 00 to 23:59	Staff initials:	first middle last				
OR Not done → Specify reason (use code	list below):							
Clinic weight (if the two measurements are n	nore than 0.1 kg apart	, measure weight a third time):						
Weight 1:	_ kg							
Weight 2:	_ kg							
Weight 3:	_ kg							
Weight of gown:	_ kg							
Pregnancy Test								
☐ ₀ No ☐ ₁ Yes → If Yes: Date urine pregnan Results: ☐ ₁ Negati ☐ ₂ Positive Outcomes Labs	Complete only for females. Does participant have reproductive potential? □₀ No □₁ Yes → If Yes: Date urine pregnancy test performed: —day / —month / —year Results: □₁ Negative □₂ Positive							
Date and time sample collection started:	/	year 00:00 to 23:59						
Sample If a sample is not obtained, indicate with a N	Sam lot Done.		t Done, Reason codelist below)	Staff Initials				
Blood	□ ₀ No □ ₁ Yes			first middle last				
Vaccine Adn NOTE: Before any vaccine is administe and protocol for pa	red, review the vaccine		t Done, Reason codelist below)	Staff Initials				
Vaccine(s) given:	П Нера	titis A		first middle last				

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



		Center Number:	Participant Number:	Participant's Initials: middle last
C	linic Weight			
W	eight date and time:/	/	:	Staff initials:
	R Not done → Specify reason (use Code	-		first middle last
Cli	nic weight (if the first two measurements a	re more than 0.1	kg apart, measure weight a third	time):
W	eight 1:	_ kg		
W	eight 2:	_ kg		
W	eight 3:	_ kg		
W	eight of gown:	_ kg		
V	ital Signs			
As	sessment date and time:/ _{mon}	th year	:: 00:00 to 23:59	
	If waist measurement not done → Sp	ecify reason (use	e codelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, mea	sure natural waist circumference a th	Staff initials: $\frac{1}{\text{first middle}} = \frac{1}{\text{last}}$
	Natural waist measurement 1:		cm	
	Natural waist measurement 2:		cm	
	Natural waist measurement 3:		cm	
2	Umbilical point waist measurement (if t umbilical point waist circumference a third tir		ements are more than 1.0 cm apart,	measure
	Umbilical point waist measurement 1	:	cm	
	Umbilical point waist measurement 2	:	cm	
	Umbilical point waist measurement 3	:	cm	
3	Pulse: bpm OR Not dor	ne → Specify red	ason (use codelist below):	Staff initials:
4	Temperature:°C C	DR Not done →	Specify reason (use codelist below):	Staff initials: First middle lost
5	Respirations: per minute OR	Not done → S _I	pecify reason (use codelist below):	
6	Blood pressure (check only one):1	eft arm \square_2 Ri	ght arm	Staff initials: First middle last
	6a Blood pressure 1:/	mm Hg liastolic	Time::_O0:00 to 23:59 OR No	t done → ecify reason (use codelist below):
	6b Blood pressure 2:/	mm Hg liastolic	Time::	
	6c Blood pressure 3:/	mm Hg	Time::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unab	ole to obtain 3 Insufficient time	4 Instrument failure 5 Not required



Center	Number: Participant I	Number: Pa	rrticipant's Initials: middle last				
12-Lead ECG							
Date and Time		Findings	Staff Initials				
		l					
Safety Labs Date and time of last meal:/	/						
Date and time of sample collection:/							
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials				
Blood	□₀ No □₁ Yes		first middle last				
Urine	□₀ No □₁ Yes		first middle last				
Pregnancy Test							
Complete only for females.							
Does participant have reproductive potential? □ ₀ No □ ₁ Yes → If Yes: Date urine pregnancy test performed:/							
Positive							
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuff	ficient time 4 Instrument fail	lure 5 Not required				



		Center Number:	Participant I	Number:	Participa	nt's Initials:
D	oubly Labeled V	Vater (DLW)				
1	Date and time of DLW d	losing:/ _{month} /	: year 00:00 to	23:59	Staff initia	first middle last
	OR Not done → Specify	reason (use codelist below): _				
2	DLW dose mixture ID ar	nd bottle number:		CA	4	
3	Exact weight of DLW mix	xture: g	rams			
4	Urine samples:					
	Collection	Sample		Date and	Time Collected	
	Pre dosing (PD)	PDa	/ /	//	year 00:00	: to 23:59
		PDb	/ day	/ / /	year 00:00	: to 23:59
	Day 0 (Visit 1)	D0a	/ day	///	year 00:00	: to 23:59
		DOP	/ day	///	year 00:00	: do 23:59
	Day 7 (Visit 2)	D7a	/ /	///	year 00:00	: to 23:59
		D7b	/ day	///	year 00:00	: do 23:59
	Day 14 (Visit 4)	D14a	/ /	///	year 00:00	: to 23:59
		D14b	/ /	///	year 00:00	: o 23:59
_	Aff: CDE	p		, ,.		
5	ATTIX CKF page label(s)	corresponding to this urine sa	. Af	fix	Affix Retest Sample	
			1	Here	Label Here	
			<u> </u>	i i.	;	

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

3 Insufficient time 4 Instrument failure

5 Not required



	Center Nu	mber:	Participant Nu	mber: Participant's Initials:middle last					
Physical Examination									
Date of examination:/Staff initials:									
OR Not done → Specify reason (use codelist below):									
Assessments Body System If Abnormal or Not Done: Explain									
Body System	Normal	Normal Abnormal N		ii Abiioriiidi or Noi Dolle: Expidiii					
General appearance:		□₀→	₉₇ →						
2 Head, Ears, Eyes, Nose, Throat:		□₀→	□ ₉₇ →						
3 Neck:		□₀→	□ ₉₇ →						
4 Heart:		□₀→	₉₇ →						
5 Lungs:		\square_{o} \rightarrow	□ ₉₇ →						
6 Abdomen:		$\square_{o} \rightarrow$	□ ₉₇ →						
7 Lymph nodes:		o→	□ ₉₇ →						
8 Extremities/Skin:		o→	□ ₉₇ →						
9 Neurological:		□₀→	□ ₉₇ →						
10 Musculoskeletal:		□₀→	□ ₉₇ →						
	Normal	Abnormal	Not Done*						
11 Genitourinary:		□₀→	□ ₉₇ →						
12 Breast:		\square_{o} \rightarrow	□ ₉₇ →						
Physician's Signature									
Investigator:	Investigator: Date:/								
	signatu	ire							

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

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



	Center Number:	Participant Number:	Participant's Initials:					
DXA Scan								
 Has the participant taken a calcium supplement today? □ No □ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? 								
□ ₀ No □ ₁ Yes								
DXA Scan		DXA Rescan O	R \square_{96} NA					
Date of scan:/		Date of rescan:/ _{month}	_/					
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Sca Check all the						
☐ Whole body		☐ Whole body						
Forearm		Forearm						
Spine		Spine						
☐ Hip		□ Нір						
Not Done Codelist: 1 Participant refused 2	Clinician unable to obtai	n 3 Insufficient time 4 Instrument	failure 5 Not required					



		Center Number:	Participant N	Number:	Participant's Ir	first middle last
Date c	ompleted:/ _{month} /	OR Not dor	e → Specify re	ason (use codelist be	low):	
Prof	ile of Mood States					
Instru	ctions: Please describe how you	feel right now by cl	necking one bo	x for each of the wo	ords listed below.	
	Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Fri	iendly					4
2 Te	nse	\square_{o}		\square_2	\square_3	4
3 Ar	ngry				\square_3	4
4 W	orn out				\square_3	4
5 U	nhappy				\square_3	4
6 Cl	ear-headed	\square_{o}		\square_2	\square_3	4
7 Liv	vely			\square_2	\square_3	4
8 Co	onfused	\square_{o}		\square_{2}	\square_3	4
9 Sc	orry for things done				\square_3	4
10 Sh	aky				\square_3	4
11 Lis	itless				\square_3	4
12 Pe	eeved	\square_{o}		\square_2	\square_3	4
13 Co	onsiderate				\square_3	4
14 Sc	ıd	\square_{o}		\square_{2}	\square_3	4
15 A	tive				\square_3	4
16 O	n edge	\square_{o}		\square_{2}	\square_3	4
17 G	rouchy				\square_3	4
18 Bl	ue	\square_{o}		\square_2	\square_3	4
19 En	ergetic				\square_3	4
20 Pc	ınicky	\Box_{o}			\square_3	4
	2003, 2005 Maurice Lorr, Ph.D., Douglas M. Mc Tonawanda, NY 14120-0950. In Canada, 3770 V			license to Multi-Health System	ns Inc. All rights reserved.	In the U.S.A., P.O. Box
Not D	one Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N	ot required



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States	continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed					
23 Unworthy					4
24 Spiteful				\square_3	4
25 Sympathetic					4
26 Uneasy	\Box_{o}			\square_3	4
27 Restless				\square_3	4
28 Unable to concentrate	\square_{o}			\square_3	4
29 Fatigued				\square_3	4
30 Helpful	\square_{o}			\square_3	4
31 Annoyed				\square_3	4
32 Discouraged	\square_{o}			\square_3	4
33 Resentful					4
34 Nervous	\square_{o}			3	4
35 Lonely				\square_3	4
36 Miserable	\square_{0}			\square_3	4
37 Muddled				\square_3	4
38 Cheerful					4
39 Bitter					4
40 Exhausted	\square_{0}			\square_3	4
41 Anxious					4
42 Ready to fight				\square_3	4
43 Good-natured				\square_3	4

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 Ave., Toronto, ON M2H 3M6.



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States (d	continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy				\square_3	4
45 Desperate					4
46 Sluggish	\square_{o}		\square_{2}	\square_3	4
47 Rebellious	o				4
48 Helpless				\square_3	4
49 Weary					4
50 Bewildered				\square_3	4
51 Alert					4
52 Deceived				\square_3	4
53 Furious					4
54 Efficient				\square_3	4
55 Trusting					4
56 Full of pep				\square_3	4
57 Bad-tempered					4
58 Worthless				\square_3	4
59 Forgetful				\square_3	4
60 Carefree					4
61 Terrified					4
62 Guilty	\square_{o}		\square_{2}	\square_3	4
63 Vigorous				\square_3	4
64 Uncertain about things				\square_3	4
65 Bushed				\square_3	4

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 Ave., Toronto, ON M2H 3M6.



Ce	nter Number:	Participant Number	er:		Participant'	s Initials:	irst middle last
Date completed:/	OR Not done —	Specify reason	(use codel	list below):			
Perceived Stress Scale (PSS)							
Instructions: The questions in this scale ask indicate how often you felt or	•	•	-				lease
			Never	Almost Never	Some- times	Fairly Often	Very Often
In the last month, how often have unable to control the important to							
2 In the last month, how often have your ability to handle your person	-	ent about			\square_{2}	\square_3	4
3 In the last month, how often have going your way?	e you felt that thi	ngs were	o			\square_3	4
4 In the last month, how often have piling up so high that you could t	-					\square_3	
Not Done Codelist: 1 Participant refused 2 C	Clinician unable to obta	in 3 Insufficient	time 4	Instrument f	ailure 5	Not requir	red



	Center Number: Participal	nt Number:	Partici	pant's Initials	first middle last					
Da	Date completed: / OR Not done → Specify reason (use codelist below):									
Pi	ttsburgh Sleep Quality Index (PSQI)									
Ins	tructions: The following questions relate to your usual sleep habits dur the most accurate reply for the majority of days and nights i									
Du	ring the past month									
1	When have you usually gone to bed?:									
2	How long (in minutes) has it taken you to fall asleep each	h night?	minutes							
3	When have you usually gotten up in the morning?	: to 23:59								
4	How many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) hours									
5	During the past month, how often have you had trouble sleeping because you (check only one answer per question)	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week					
	a Cannot get to sleep within 30 minutes	o			\square_3					
	b Wake up in the middle of the night or early morning	\Box_{o}			\square_3					
	c Have to get up to use the bathroom				\square_3					
	d Cannot breathe comfortably				\square_3					
	e Cough or snore loudly				\square_3					
	f Feel too cold				\square_3					
	g Feel too hot				\square_3					
	h Have bad dreams				\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):	o								
6	During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				\square_3					
198	39,with permission from Elsevier Science.									
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Ins	ufficient time 4	nstrument failure	5 Not re	quired					



	Center Number: Participar	nt Number:	Parti	icipant's Initials	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (continued)				
		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?				
		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?	o			\square_3
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?	\square_{o}			



Month 24 Submission

Jaiono								Vi	sit 1
Center Numbe	r:	Partici	pant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed:/OR Not done	e → Spec	ify reaso	on (use co	delist bei	low):				
Derogatis Interview for Sexual Fu	nction	(DISF-S	R) (F) Fe	male Ve	rsion				
Instruction: Below you will find a brief set of questions sections that ask about different aspects of your sexual while another inquires about the kinds of sexual expessexual arousal and the quality of your orgasm . The relationship.	experien eriences	ces. One that you	section have. Y	asks abo ou are a	out sexu Iso aske	al fant d about t	asies or the natu	daydre re of you	ams, Jr
On some questions you are asked to respond in ter activities asked about in that section. Some frequency so frequency scales range from "0 = never" to "4 = alway of a satisfaction scale. This type of scale tells how much Some satisfaction scales range from "0 = could not be v"0 = not at all satisfied," to "4 = extremely satisfied."	cales go f s." In the you enjo	from "O case of yed, or	= not at other qu were sati	all" to " estions, sfied by	8 = four you will the sexu	or more be askec val activit	times a I to resp y being	day." Of ond in to asked a	ther erms bout.
In every section of the inventory the scales required follow. Although it is brief, take your time with the inverdescribes your personal experience.									
If you have any questions, please ask the person who g	gave you	the inve	ntory for	help.					
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4				8
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)							□ ₆		8

Copyright © 1987 by Leonard R. Derogatis, PhD.

1.3 Erotic or romantic situations

1.4 Caressing, touching, undressing, or

1.5 Sexual intercourse, oral sex, touching

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

foreplay

to orgasm



Ce	nter Number:	Pa	rticipant N	umber:		Par	ticipant's I	nitials:	st middle last
Derogatis Interview for Sex	ual Functio	on (DIS	F-SR) (F)	Female V	/ersion (c	ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how of did you have the following experiences:	ften 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 alo	ne				4		6	7	8
2.2 Actively seek sexual satisfaction					4		6		8
2.3 Feel sexually aroused with a partner					4	5	6	7	8
	Never	Rarely	Sometimes	Usually	Always				

Copyright © 1987 by Leonard R. Derogatis, PhD.

throughout sexual relations

2.5 Have normal lubrication

2.4 Have normal lubrication with

masturbation



Center Nu	mber:	Po	articipant N	umber:		Po	ırticipant'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	,								
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	O				4	5	<u> </u>		8
3.2 Masturbation	По			3	□ ₄	□ ₅			
3.3 Casual kissing and petting	По			3	4	5			
3.4 Sexual foreplay	По			\square_3	4	5			
3.5 Sexual intercourse, oral sex, etc.	o				4	5	<u></u> 6		8
Section 4—Orgasm									
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	О				4				
4.2 The intensity of your orgasm	По			\square_3	4				
4.3 The ability to have multiple orgasms (if typical for you)				\square_3	4				
4.4 Feelings of closeness and togetherness with your partner	О			\square_3	4				
4.5 Your sense of control (timing) of your orgasm	По				4				
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_{3}					

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Derogatis Interview for Se	exual Function (DISF-SR) (F) Female Version (contin	ued)	

Section 5—Drive and Relationship Not at 1 or 2 2 or 3 4 to 6 1 per 2 or 3 Less 1 per 4 or per all than 1 week day per per per more month day per week week per month day 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse? Not at Slightly Moderately Highly Extremely all 5.2 During this period, how interested have you been in sex?

5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate		Above average	Good	Very good	Could not be better
5.4 In general, what would represent									

Copyright © 1987 by Leonard R. Derogatis, PhD.

of your sexual functioning?

the best description of the quality

calerie Phase 2

Month 24 Submission Visit 1

										_
	Center Number	:	Partici	pant Numl	ber:		_ Partic	cipant's In	itials:	t middle last
Date completed: —_day /— month /— year —	OR Not done	→ Spec	cify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Se	exual Fur	nction	(DISF-S	R) (M) <i>N</i>	lale Vers	sion				
Instruction: Below you will find a brief so sections that ask about different aspects o while another inquires about the kinds of sexual arousal and the quality of your relationship.	f your sexual expe	experien riences	ces. One	section of have. You	asks abo ou are a	out sexu Iso aske	a l fanto d about t	isies or he natu	daydre re of you	ams, Jr
On some questions you are asked to a activities asked about in that section. Some frequency scales range from "0 = never" to a satisfaction scale. This type of scale to some satisfaction scales range from "0 = 6"0 = not at all satisfied," to "4 = extremely line every section of the inventory the set follow. Although it is brief, take your time describes your personal experience. If you have any questions, please ask the	e frequency so to "4 = always ells how much could not be w y satisfied." cales required with the inven	ales go f s." In the you enjo vorse" to for that tory. Fo	from "O case of yed, or "8 = co section a reach i	= not at a other qua were satisuld not be are printe	all" to "6 estions, y sfied by e better. d just ab	8 = four you will the sexu " Other oove the	or more be asked al activit satisfaction question	times a of to resp y being on scale s so it w	day." Of ond in to asked a s go froi ill be ea	ther erms bout. m
Section 1—Sexual Cognition/Fan	tasy									
During the past 30 days or since the you filled out this inventory, how ofto you had thoughts, dreams, or fantasi	en have	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person						4	5	□ ₆		8
1.2 Erotic parts of a woman's bo- face, genitals, legs)	dy (e.g.,	\square_{o}			\square_3	4	□ ₅	□ ₆		8
1.3 Erotic or romantic situations		\square_{o}			\square_3	4	5	6		8
1.4 Caressing, touching, undressi foreplay	ng, or				\square_3	4	₅	□ ₆		8
1.5 Sexual intercourse, oral sex, to orgasm	touching				\square_3	4	5	6		8

Participant's Initials: first middle last

5 Not required

4 Instrument failure

2 Clinician unable to obtain

Copyright © 1987 by Leonard R. Derogatis, PhD. Not Done Codelist: 1 Participant refused

3 Insufficient time



ber:	Pari	ricipant Nu	mber:		Part	icipant's l	nitials:	st middle last
unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
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	4	5			8
			\square_3	4				
				4	5			8
			3	4	5			8
	Not at all	Not at all Less than 1 per month	Not at all less than 1 per month less month less less than 1 per month less less less less less less less les	Not at all Less than 1 per month less month less less all less of the less month less less month less less less less less less less les	Not at all than 1 per month per month logo logo logo logo logo logo logo log	Not at all less than 1 per month less week les	Not at all than 1 per month per month month logo logo logo logo logo logo logo log	Not at all than 1 per month per month logon logo

Copyright © 1987 by Leonard R. Derogatis, PhD.

2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm



Center Num	ber:	Par	ticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DIS	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 3—Sexual Behavior/Experiences									
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	По				4	5			
3.2 Masturbation	o			\square_3	4	5	6	7	8
3.3 Casual kissing and petting					4	5			8
3.4 Sexual foreplay				\square_3	4	5			8
3.5 Sexual intercourse, oral sex, etc.					4	5		7	8
Section 4—Orgasm									
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					4				
4.2 The intensity of your orgasm	o			\square_3	4				
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				
4.5 Your sense of control (timing) of your orgasm	О				4				
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3					

Copyright © 1987 by Leonard R. Derogatis, PhD.



Center Number: Participant Number: Participant's Initials:									
Derogatis Interview for Sexua	l Fund	tion (DISF-SR) (M) Male \	/ersion (d	continue	d)		
Section 5—Drive and Relationship									
	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?					4	5	□ ₆		□ ₈
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?									
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?							□ ₆		8

Copyright © 1987 by Leonard R. Derogatis, PhD.



Facility is a continuous				
Date completed:/	OR Not done →	Specify reason (use codelist below):		
	Center Number:	Participant Number:	Participant's Initials:	first middle last

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.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I have an intense desire to eat [one or more specific foods].			\square_3	4	5
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	5
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3	4	
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3	4	
6	Eating [one or more specific foods] would feel wonderful.			\square_3	4	5
7	If I ate something, I wouldn't feel so sluggish and lethargic.			\square_3	4	
8	Satisfying my craving would make me feel less grouchy and irritable.			\square_3		
9	I would feel more alert if I could satisfy my craving.			\square_3		5
10	If I had [one or more specific foods], I could not stop eating it.			\square_3	4	5
11	My desire to eat [one or more specific foods] seems overpowering.			\square_3		
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			\square_3	\square_{4}	5
13	I am hungry.					5
14	If I ate right now, my stomach wouldn't feel as empty.			\square_3		5
15	I feel weak because of not eating.			\square_3	4	5
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time	4 Instrume	ent failure	5 Not req	uired



Center Num	ber: Po	rticipant Number:		Participant's I	nitials: middle last					
Date completed:/OF	R Not done → S _l	pecify reason (us	se codelist below	·):						
Food Craving Inventory (FCI-II)										
For each of the foods listed below, please check the appropriate box.										
Note: A craving is defined as an intense desire to consume a particular food or food type that is difficult to resist. Over the past month, how often Rarely Always/Almost										
Over the past month, how often have you experienced a craving for	Never	Rarely (once or twice)	Sometimes	Often	Every Day					
1 Cake				4						
2 Pizza										
3 Fried chicken				4						
4 Gravy										
5 Sandwich bread										
6 Sausage			\square_3		5					
7 French fries										
8 Cinnamon rolls				4						
9 Rice			\square_3							
10 Hot dog			\square_3	4						
11 Hamburger			\square_3	4						
12 Biscuits			\square_3							
13 lce cream										
14 Pasta										
15 Fried fish			\square_3							
16 Cookies			\square_3	4	5					
17 Chocolate			\square_3							
18 Pancakes or waffles			\square_3	4						
19 Corn bread			\square_3	4						
20 Chips			\square_3	4						
21 Rolls			\square_3	4						
22 Cereal			\square_3	4						
23 Donuts			\square_3	4						
24 Candy			\square_3	4	5					
25 Brownies			\square_3	4						
26 Bacon			\square_3	4						
27 Steak			\square_3	4						
28 Baked potato			\square_3							
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										

calerie Phase 2

Month 24 Submission Visit 1

		Center Number:	Participant Number:		Participant's I	nitials: middle last		
Date c	ompleted:/ _{month} /	OR Not done	Specify reason (use co	delist below):				
Eati	ng Inventory							
1	When I smell a sizzling ste difficult to keep from eating			t very	, True	□₀ False		
2	I usually eat too much at se	ocial occasions, like	parties and picnic	s.		o False		
3	I am usually so hungry tha	t I eat more than th	ree times a day.		, True	o False		
4	When I have eaten my quo not eating anymore.	ota of calories, I am	usually good abo	ut		o False		
5	Dieting is so hard for me b	ecause I just get too	hungry.		1 True	o False		
6	I deliberately take small he	elpings as a means	of controlling my w	veight.	, True	o False		
7	Sometimes things just taste I am no longer hungry.	so good that I keep	o on eating even w	hen	, True	o False		
8	Since I am often hungry, I expert would tell me that I something more to eat.			, an	, True	o False		
9	When I feel anxious, I find	myself eating.			1 True	o False		
10	Life is too short to worry a	bout dieting.			, True	o False		
11	Since my weight goes up a more than once.	nd down, I have go	ne on reducing die	ets	₁ True	□₀ False		
12	I often feel so hungry that	I just have to eat so	mething.			o False		
13	When I am with someone	who is overeating, I	usually overeat to	0.	1 True	o False		
14	I have a pretty good idea	of the number of ca	lories in common f	ood.		o False		
15	Sometimes when I start ea	ting, I just can't seei	m to stop.		, True	o False		
16	It is not difficult for me to le	eave something on	my plate.			o False		
17	At certain times of the day, to eating then.	I get hungry becau	use I have gotten u	sed	, True	o False		
18	While on a diet, if I eat foo for a period of time to mak		d, I consciously ea	t less		o False		
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required								



	Center Number: Participant Number:	Participant's Initials: first middle last
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.	
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.	, True False
27	When I feel lonely, I console myself by eating.	
28	I consciously hold back at meals in order not to gain weight.	, True False
29	I sometimes get very hungry late in the evening or at night.	
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.	, True False
32	I count calories as a conscious means of controlling my weight.	
33	I do not eat some foods because they make me fat.	
34	I am always hungry enough to eat at any time.	
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 Phase 2

Month 24 Submission Visit 1

	Center Number:	Participant Number:	Participant's Initials: middle last
Eat	ing Inventory (continued)		
Plea	se check one answer that is most appropriate t	o you for each question below.	
37	How often are you dieting in a conscious effort to control your weight?	Rarely Sometimes	□₃ Usually □₄ Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\square_1 Rarely \square_2 Sometimes	□₃ Usually □₄ Always
39	How often do you feel hungry?	☐₁ Rarely ☐₂ Sometimes	□₃ Usually □₄ Always
40	Do your feelings of guilt about overeating help you to control your food intake?	g □ ₁ Rarely □ ₂ Sometimes	□₃ Usually □₄ Always
41	How difficult would it be for you to stop eating halfway through dinner and not e for the next four hours?		_₂ Slightly difficult _₄ Very difficult
42	How conscious are you of what you are eating?	•	₂ Slightly ₄ Extremely
43	How frequently do you avoid "stocking uon tempting foods?		Seldom 4 Almost always
44	How likely are you to shop for low calorie foods?		₂ Slightly likely ₄ Very likely
45	Do you eat sensibly in front of others and splurge alone?	d 🔲 1 Never 🔲 2 Rarely 🔲	₃ Often □ ₄ Always
46	How likely are you to consciously eat slow in order to cut down on how much you expense.		₂ Slightly likely ₄ Very likely
47	How frequently do you skip dessert beca you are no longer hungry?	ause \square_1 Almost never \square_3 At least once a week	_₂ Seldom _₄ Almost every day
48	How likely are you to consciously eat less than you want?		₂ Slightly likely ₄ Very likely
49	Do you go on eating binges though you on not hungry?	are, Never	
50	To what extent does this statement descriyour 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 was promising myself to start dieting again tomorrow."	he, Not like me	of me
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 mean total restraint (constantly limiting food intake and never "giving in"), what numb would you give yourself?	Often eat whatever you Grant of the seat whatever you Grant	u want, whenever you want it want, whenever you want it but often "give in" e, rarely "give in"

Participant's Initials: first middle last



				Center N	Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:	/_	 month	/		OR Not done →	Specify reason (use codelist below):		

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

Ια	ım confident that:	Not confident at all that you can resist the desire to eat						Very confident that you can resist the desire to eat				
		0	1	2	3	4	5	6	7	8	9	
1	I can resist eating when I am anxious (nervous).					4	5			8		
2	I can control my eating on the weekends.				\square_3	4	5	6		8	9	
3	I can resist eating even when I have to say "no" to others.					4	5			8		
4	I can resist eating when I feel physically run down.	\Box_{o}			\square_3	4		6		8	9	
5	I can resist eating when I am watching TV.					4	5			8		
6	I can resist eating when I am depressed (or down).				\square_3	4	5			8	9	
7	I can resist eating when there are many different kinds of food available.	o				4	5			8	9	
8	I can resist eating even when I feel it is impolite to refuse a second helping.	o				4	5			8	9	
9	I can resist eating even when I have a headache.				\square_3	4				8		
N	ot Done Codelist: 1 Participant refused 2 Clinician unable	to obta	in 3	nsufficie	ent time	4 Ins	trument	failure	5 Not	required	1	



Center Number:				mber: _			Particip	oant's Ini	first	middle last
Weight Efficacy Lifestyle Questionna	ire (v	VEL) (co	ontinue	d)						
I am confident that:			ent at a st the d	all that esire to	yo			onfide i e desire		
	0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am reading.				\square_{3}		5	6		8	9
11 can resist eating when I am angry (or irritable).							6			9
12 I can resist eating even when I am at a party.				$\square_{_3}$	4		6		8	9
13 I can resist eating even when others are pressuring me to eat.				\square_3	4		6		8	9
14 I can resist eating when I am in pain.				\square_3	4					9
15 I can resist eating just before going to bed.					4				8	9
16 I can resist eating when I have experienced failure.				\square_3					8	9
17 I can resist eating when high-calorie foods are available.									8	9
18 I can resist eating even when I think others will be upset if I don't eat.							6		8	9
19 I can resist eating when I feel uncomfortable.									8	
20 I can resist eating when I am happy.							6		8	9



	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	middle last
Date completed:/	OR Not done →	Specify	reason	(use code	elist belov	v):			
Multiaxial Assessment of	Eating Disorder	Sym	ptom	S (MAE	DS)				
Instructions: Using the scale shown, pleas	e rate the following items o	on a sca	le from 1	to 7. Ple	ase ansv	ver as tru	uthfully	as possi	ble.
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	weight.				\square_3	4	5		
2 My sleep isn't as good as it us	sed to be.				\square_3	\square_4	5	6	
3 I avoid eating for as long as I	can.				\square_3	4	5	6	
4 Certain foods are "forbidden"	' for me to eat.					4	5	6	
5 I can't keep certain foods in my binge on them.	house because I will					4	5		
6 I can easily make myself vom	it.				\square_3	\square_4	5	6	
7 I can feel that being fat is terr	ible.				3	4	5	6	
8 I avoid greasy foods.					\square_3	4	5	6	
9 It's okay to binge and purge	once in a while.				\square_3	4	5	6	
10 I don't eat certain foods.					\square_{3}	4	5	6	
11 I think I am a good person.					\square_3	4	5	6	
12 My eating is normal.					\square_3	\square_4	5	6	
13 I can't seem to concentrate la	tely.				3	4	5	6	
14 I try to diet by fasting.					\square_3		5	6	
15 I vomit to control my weight.					\square_3	4	5	6	
16 Lately nothing seems enjoyab	le anymore.				\square_3	4	5		
17 Laxatives help keep you slim.					\square_3	4	5	6	
18 I don't eat red meat.					\square_3	4		6	
19 I eat so rapidly I can't even to	iste my food.						5	6	
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	d



	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.					5	6	
21 When I feel bloated, I must do so of that feeling.	something to rid mysel	If			4	5		
22 I overeat too frequently.				\square_3				
23 It's okay to be overweight.				\square_3	4	5	6	
24 Recently I have felt that I am	a worthless person.							
25 I would be very upset if I gain	ned 2 pounds.			\square_3	4	5	6	
26 I crave sweets and carbohyde	rates.			\square_3		5		
27 I lose control when I eat.				\square_3	4	5	6	
28 Being fat would be terrible.				\square_3		5		
29 I have thought seriously abou	ut suicide lately.			\square_3	4	5	6	
30 I don't have any energy anymo	ore.			\square_3		5		
31 I eat small portions to control	my weight.			\square_3	4	5	6	7
32 I eat 3 meals a day.				\square_3		5		
33 Lately I have been easily irrite	ated.			\square_3	4	5	6	
34 Some foods should be totally	avoided.			\square_3		5		
35 I use laxatives to control my	weight.			\square_3	4	5	6	
36 I am terrified by the thought	of being overweight.				4	5		
37 Purging is a good way to lose	e weight.			\square_3		5	6	
38 I avoid fatty foods.								



	Center Number:	Participant N	umber: _		Pai	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of	Eating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blu	e.			\square_3	4	5	6	
40 I am obsessed with becoming	overweight.			\square_3	4	5		
41 I don't eat fried foods.				\square_3	4	5		
42 I skip meals.				\square_3	\square_4	5		
43 Fat people are unhappy.				\square_3	4	5	6	
44 People are too concerned wit	h the way I eat.			\square_3	\square_4	5	6	
45 I feel good when I skip meals	j.			3	4	5		
46 I avoid foods with sugar.				\square_3	4	5		
47 I hate it when I feel fat.				3	4			
48 I am too fat.				\square_3	4	5	6	
49 I eat until I am completely stu	ffed.			\square_3	4	5		
50 I hate to eat.				\square_3	4	5		
51 I feel guilty about a lot of thir	ngs these days.			\square_3	4	5	6	
52 I'm very careful of what I eat	•			\square_3	4	5		
53 I can "hold off" and not eat e	even if I am hungry.			\square_3	4	5		
54 I eat even when I am not hun	gry.			\square_3	4	5	6	
55 Fat people are disgusting.					4	5	6	
56 I wouldn't mind gaining a fev	v pounds.				4	5	6	

Participant's Initials: first middle last



		Center Number:	_ Participant I	Number: _		Par	ticipant's I	nitials:	t middle last
Da	te completed:day / _{month} /	OR Not done	e → Specify re	ason (use	codelist be	elow):			
В	ody Shape Questionnai	r e (BSQ)							
	e would like to know how you have be ase read each question and check the								
Ov	er the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you	brood about your	shape?			\square_3		5	
2	Have you been so worried all have been feeling that you or		nat you			\square_3	4		6
3	Have you thought that your t too large for the rest of you?	highs, hips, or bot	tom are			\square_3		5	
4	Have you been afraid that you fatter)?	ou might become f	at (or			\square_3		5	
5	Have you worried about you enough?	r flesh not being fi	rm			\square_3	4	5	6
6	Has feeling full (e.g., after eating of fat?	a large meal) made yo	ou feel			\square_3	4	5	
7	Have you felt so bad about y cried?	our shape that yo	u have			\square_3	4	5	6
8	Have you avoided running be wobble?	ecause your flesh	might			\square_3	4	5	
9	Has being with thin women/r self-conscious about your sha		I			\square_3	4		6
10	Have you worried about you sitting down?	r thighs spreading	out when				4	5	6
11	Has eating even a small amo fat?	unt of food made	you feel			\square_3	4	5	6
12	Have you noticed the shape of felt that your own shape com	of other women/m pared unfavorabl	ien and y?			\square_3	4	5	6
13	Has thinking about your shap ability to concentrate (e.g., while to conversations)?					\square_3	4	5	6
14	Has being naked, such as whe feel fat?	en taking a bath,	made you			\square_3	4	5	
15	Have you avoided wearing c particularly aware of the sha		e you			\square_3	4		6
16	Have you imagined cutting of body?	ff fleshy areas of y	our					5	

Participant's Initials: first middle last

5 Not required

4 Instrument failure

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused

3 Insufficient time



	Center Number:	Participant N	lumber: _		Par	ticipant's	Initials:	rst middle last
Body Shape Question	nnaire (BSQ) (continued)							
Over the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cake you feel fat?	s or other high calorie fo	od made				4	5	
18 Have you not gone out because you have felt b		arties)			\square_3		5	
19 Have you felt excessivel	y large and rounded?				\square_3		5	
20 Have you felt ashamed	of your body?				3	4	5	6
21 Has worry about your s	hape made you diet?				\square_3	4	5	6
22 Have you felt happiest of stomach has been empt		our					5	
23 Have you thought that y because you lack self-co		•			\square_3	4	5	6
24 Have you worried about flesh around your waist		s of			\square_3		5	
25 Have you felt that it is not thinner than you?	ot fair that other women/	men are			\square_3	4	5	
26 Have you vomited in ord	der to feel thinner?				\square_3	\square_{4}	5	6
27 When in company, have much room (e.g., sitting on a	· ·	g up too			\square_3	4	5	
28 Have you worried abou	t your flesh being dimply	?			\square_3	\square_4	5	6
29 Has seeing your reflection you feel bad about you		w) made			\square_3	4	5	
30 Have you pinched areas fat is there?	s of your body to see how	v much			\square_3		5	
31 Have you avoided situa your body (e.g., communal c	tions where people could hanging rooms or swimming pools)					4	5	6
32 Have you taken laxative	es in order to feel thinner?	?			\square_3	4	5	
33 Have you been particularly shape when in the comp	arly self-conscious about young of other people?	our/					5	6
34 Has worry about your s to exercise?	hape made you feel you	ought					5	



		Center Number	: Participant Num	ber: Part	icipant's Initials: first middle last						
Hai	ndgrip Strength										
	Date and time of assessment:										
1 D	2 Dominant hand (check only one): Left Right Ambidextrous										
	Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand						
	Test 1—peak force		kg		kg						
	Test 2—peak force	\square_{0}	kg	\square_{0}	kg						
	Test 3—peak force □₀ kg kg										
Not D	Pone Codelist: 1 Participar	nt refused 2 Clinician una	ble to obtain 3 Insufficie	nt time 4 Instrument failu	re 5 Not required						



			Center Number:	Participant Number: _	Particip	pant's Initials:						
Is	ometric/Isokineti	ic Kne	e Extension and	d Flexion								
	Date and time of assessment://											
_												
1	Recent injury or pain—righ	nt knee?										
2	Recent injury or pain—left	knee?										
3	Specify machine used (PBF	RC only):										
	All values corrected f	or gravi	ty effect torque	Right Leg	Left Leg	If Not Done, Specify Reason (Use codelist below)						
3	60°/sec knee extension		peak torque	N.m	N.m							
			total work	N.m	N.m							
			average power	watts	watts							
4	60°/sec knee flexion		peak torque	N.m	N.m							
			total work	N.m	N.m							
			average power	watts	watts							
5	180°/sec knee extension		peak torque	N.m	N.m							
			total work	N.m	N.m							
			average power	watts	watts							
			work fatigue index	%	%							
6	180°/sec knee flexion		peak torque	N.m	N.m							
			total work	N.m	N.m							
			average power	watts	watts							
			work fatigue index	%	%							
7	Isometric knee extension:	trial 1	peak torque	N.m	N.m							
		trial 2	peak torque	N.m	N.m							
		trial 3	peak torque	N.m	N.m							
8	Isometric knee flexion:	trial 1	peak torque	N.m	N.m							
		trial 2	peak torque	N.m	N.m							
		trial 3	peak torque	N.m	N.m							
N	ot Done Codelist: 1 Participa	ınt refused	2 Clinician unable to ob	otain 3 Insufficient time	4 Instrument failure	5 Not required						

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



5 Not required

	tirst middle last
Clinic Weight	
	Staff initials: First middle last
OR Not done → Specify reason (use codelist below):	
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):	
Weight 1: kg	
Weight 2: kg	
Weight 3: kg	
Weight of gown: kg	

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

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

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

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Į Š	Today's date:			Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Tue	wed	Thurs	Fi S	at Sur	OR No	done	Specify re	eason (use	codelist bel	ow):
_	Were yo	day month year Were you employed in the last seven days?	ın days?		°Z °	$\square_{\rm o}$ ${ m No}$ $ ightarrow$ Skip to question 3	stion 3	Types				Interv	Interviewer initials:	ials:	first middle last
7	If Yes: M	If Yes: Which days (check all that apply)?	۵.		Mon	Tues	pew] Thurs	Œ	Sat	Sun				
m	Which d	Which days do you consider your weekend, or non-work, days?	veekend, or n	on-work, days?	Mon	Tues	Med	Thurs	Ë	Sat	Sun				
700	Day of		Sleek	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	ninutes)	Even	Evening (in minutes)	nutes)
#	Week	Date	In Bed	dη	Start	Stop	.boM	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
yester-		day month year	00:00 to 23:59	00:00 to 23:59											
day)			00:00 to 23:59	00:00 to 23:59											
v			00:00 to 23:59	00:00 to 23:59											
•		day month year			00:00 to 23:59	00:00 to 23:59									
			00:00 to 23:59	00:00 to 23:59											
		`	:												
Ŋ		day month year	\$5:53 pt 00:00		00:00 to 23:59										
			00:00 to 23:59	00:00 to 23:59											
		,	00:00 to 23:59	00:00 % 23:59											
4		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
e		/	00:00 to 23:59	00:00 to 23:59											
			00:00 to 23:59	00:00 to 23:59	00:00 to 23:39	00:00 TO 23:39									
•		,	00:00 to 23:59	00:00 to 23:59											
4		day month year	00:00 to 23:59	00:00 % 23:59	00:00 to 23:59	00:00 to 23:59									
-															
] week		//	00:00 to 23:59	00:00 to 23:59	:	:									
ago)			00:00 to 23:59	00:00 to 23:59	60:00	VC:52 50 00:00									

Not Done Codelist: 1 Participant refused

2 Clinician unable to obtain

3 Insufficient time

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



		Center Number:	Participant Number:	Participant's Initials:	first middle last
S	even-Day Physical Activ	ity Recall (PAR) (c	ontinued)		
4	Compared to your physical activity of about the same (check only one)?	ver the past three month	ns, was last week's physical	activity more, less,	
In	terviewer: Please answer questions l	pelow and note any com	ments on interview.		
5	Were there any problems with the So \square_0 No \square_1 Yes	even-Day PAR interviews	?		
6	Do you think this was a valid Seven-logon No	Day PAR interview?			
7	Were there any activities reported by Oo No	the participant that you	u don't know how to classify	?	



		Center Number:	Partic	ipant Number: Particip	pant's Initials:
6-D	ay Food Record				
Comp	olete below OR Not done → Speci	fy reason (use Codelist b	pelow): _	Staff init	rials: first middle last
				Replacement Value	s
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	/	Reliable D 2 Unreliable D 3 Missing	8	/	1 Reliable 2 Unreliable 3 Missing
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	1 Reliable 2 Unreliable 3 Missing
3	/	Reliable D2 Unreliable D3 Missing	10	/	1 Reliable 2 Unreliable 3 Missing
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	1 Reliable 2 Unreliable 3 Missing
5	/	Reliable	12	/	Reliable Unreliable Missing
6	/	Reliable	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 Not required

4 Instrument failure

		Center Number:	Participant Number:	Participant's Initials:
V	O ₂ Max			
1	Date and time of test:/	/	: 00:00 to 23:59	Staff initials: first middle last
	OR Not done → Specify reason (use	codelist below):		
2	At what time was the participant's la	st meal/snack eaten?	: 00:00 to 23:59	
3		\square_1 Sin	us Atrial fibrillation	o
4	Heart rate (HR) data: Resting heart r Age-predicted Heart rate (max	heart rate:	bpm	
5	Reason(s) for termination of testing (a Symptom limited (dyspnea, fatigue) Angina/ischemia → Complete all the	nat apply: HR when t	_	red: bpm or NA
	Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress in Orthopedic/extremity complaints (pa	image study, complete v ins/cramps)	ventricular episode report)	curred: bpm or □ ₉₆ NA
6	Did frequent ventricular ectopy occur No Yes → If Yes: When did it occur (a	-		
7	Peak VO ₂ : mL/kg/min	L/min		
8	Did the participant meet at least 2 of ☐ ₀ No ☐ ₁ Yes → If Yes: VO ₂ max:	_	b.	chieve a plateau in VO₂ (change ≤ 150 mL) etween the final two stages ER ≥ 1.1 R max ± 5 bpm of age-predicted maximum
9	Exercise time: : : seconds			
10	Blood pressure at VO ₂ peak/VO ₂ ma	X:/diastoli	mm Hg	
11	Borg RPE score at VO ₂ peak/VO ₂ ma	x: (6-20	0)	
12	Peak RER:			
13	VE at VO ₂ peak/VO ₂ max:	L/min		
14	VE/VO ₂ at VO ₂ peak/VO ₂ max	L/min		

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



Outcomes L	ple collection started:/_	month year	00:00 to 23:59		
If a sample is not ob	Sample tained, indicate with a Not Done.	Sample Comple		Done, Reason odelist below)	Staff Initials
	Blood	□ ₀ No □ ₁ Yes	-		first middle last
Core Tempe	rature				
Staff Initials	Provide Date Sample Collection/P		Time of S Collection/P	- 1	If Not Done, Reason (Use codelist below)
	Start Date:	year	Start Time		
first middle last	Stop Date:	year			
Inpatient Ac	lmission and Discha	rge			
	ssion date and time:/_				
2 Inpatient discha	arge date and time:/	month year	00:00 to 23:59		



5 Not required

		Center N	umber:	Participant Num	ber:	Participant's Init	first middle las	
D	elayed-type Hypei	rsensitivity	(DTH)					
1	Was the DTH worksheet con \square_0 No \square_1 Yes \rightarrow If Yes: Were any				test udminister test.			
2	Date of injection:/	/	OR Not done	→ Specify reas	on (use codelist below)	:		
3	Injection by (initials): First middle	last						
4	Arm injected: 1 Right	2 Left						
	DTH results: Note: For each reaction, medical because the induration diameter and then the average diameter is e A = Largest diameter B = Second diameter	n may not be in the diameter perpendiqual to or greater perpendicular to A	e shape of a circ dicular to it. Do n than 5 mm.	le. If the indur	ation is an oval sho ythema. Reaction	ape, first measur is considered po	e the long	
	Antigen	24	Hour (@ Visit 4)		48 Hour (@ Visit 5)			
	Ailigen	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:	
	1 Normal saline	mm	mm		mm	mm		
	2 Tetanus toxoid (TT)	mm	mm	first middle last	mm	mm	first middle last	
	3 Candida	mm	mm	(initials)	mm _	mm	(initials)	
	4 Trichophyton	mm	mm		mm _	mm		

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



Clinic Weight					
Weight date and time: _ OR Not done → Specify	day month year 00: reason (use codelist below):	: 00 to 23:59	Staff init	first middle last	
Clinic weight (if the two m	easurements are more than 0.1 kg apart,	. measure weight a third tim	re):		
Weight 1:	kg				
Weight 2:	kg				
Weight 3:	kg				
Weight of gown:	kg				
Outcomes Labs					
Date and time of last me	day month	year			
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials	
Са	techolamines	□₀ No □₁ Yes		first middle last	
	Blood	□ ₀ No □ ₁ Yes		first middle last	
Oral glucos	e tolerance test (OGTT)	□₀ No □₁ Yes		first middle last	
If a sample is not obtained,	indicate with a Not Done.				
24-hour Urine (Collection				
Total Volume Collected	Date of Sample Collection	Time of Sample Collectio	If Not Don Reason (Use codelist be	Staff Initials	
	Start Date:	Start Time:			
	/	00:00 to 23:59			
mL	Stop Date:	Stop Time:		first middle last	

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



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

					tirst middle last
Sex Hormone					
If Not Done → Specify reason (use code	list below)	:			
Contraception method (females only):			:	ncomitant Med	
Day 1		Date	Time	If Not Done Reason (use codelist	
Day 1 of menses (females only)					
Date and time of last meal (males only	r)	/	: :: : : : :		
Hormone level blood draw 1 (males o	nly)	/	00:00 to 23:59		– first middle last
Hormone level blood draw 2 (females of Progesterone level	o nly)				
Day 2		Date	Time	If Not Done Reason (use codelist	
Date and time of last meal					
Hormone level blood draw 3 (females of Progesterone level	o nly)				
Metabolic Rate					
Sample		Date of Collection	If Not Done, Ro (Use codelist be		aff Initials
Resting Metabolic Rate (RMR)—Visit 4	d	day /			first middle last
Cart ID		-003 (623-002)		PBRC-016 (62 PBRC-017 (62	· ·
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	me 4 Instrument	failure 5 Na	ot required

calerie Phase 2

Month 24 Submission

						Center N	umber:	Po	articipant I	Number: _		Po	articipant's	Initials:	rst middle last
Se	ven-D	Day Physical Activ	rity Reca	II (PAR)											
		e:/	_		Mon Tu	es Wed	Thurs	Fri S	Sat Su	n OR No	t done →	Specify re	eason (use	codelist be	low):
1	Were yo	ou employed in the last seve	en days?		□ ₀ No	→ Skip to qu	estion 3	1 Yes				Interv	viewer ini	tials:	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 v						_	Fri _		Sun		F	·· /: ·	. 1
	Day of	Date		o Time	Work			ning (in mi	Very		rnoon (in n	Very		ning (in mi	Very
#	Week		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	:::::::									
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									
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	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									



		Center Number:	Participant Number:	Participant's Initials:	ddle last
S	even-Day Physical Activ	ity Recall (PAR) (continued)		
4	Compared to your physical activity of or about the same (check only one)? More Less	over the past three mon	ths, was last week's physical c	ictivity more, less,	
In	terviewer: Please answer questions	below and note any co	mments on interview.		
5	Were there any problems with the S No Yes	even-Day PAR interviev	v?		
6	Do you think this was a valid Seven-	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	ou don't know how to classify?	•	



	Center Number: Participant Number: _	Particip	pant's Initials:
Biopsy Labs			
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Muscle biopsy	/		first middle last
Fat biopsy	/		first middle last

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

calerie Phase 2

Signs, Symptoms and Adverse Events Log

Participant's Initials:

Center Number: ___ _ Participant Number: ___ _ _ _

Sia	Signs, Symptoms and Adverse Events						
Updo	Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline: Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24						
AE#	Adverse Event	Serious	Intensity	Causality (check only one)	Action Taken Due to AE (check all that apply)	Outcome	Start/End Date OR Check if Continuing
		□ ₀ No □ ₁ Yes*	☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe	☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely	Intervention temporarily discontinued Medical therapy required Intervention permanently discontinued general Other (specify):	☐ ₁ Still present and unchanged ☐ ₂ Improving ☐ ₃ Resolved ☐ ₄ Resolved with sequelae ☐ ₅ Death	Start Date:
		□ ₀ No □ ₁ Yes*	☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe	☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely	None lackground lackgr	Still present and unchanged 1 Still present and unchanged 2 Improving 3 Resolved 4 Resolved with sequelae 5 Death	Start Date:
		□ ₀ No □ ₁ Yes*	☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe	☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely	None lackground lackgr	Still present and unchanged 1 Still present and unchanged 2 Improving 3 Resolved 4 Resolved with sequelae 5 Death	Start Date:
		□ ₀ No □ ₁ Yes*	☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe	☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely	None Intervention temporarily discontinued Intervention permanently discontinued Intervention permanently discontinued Intervention permanently	Still present and unchanged 1 Improving 1 Resolved 1 Resolved with sequelae 1 Death	Start Date:

2 Life threatening

^{*}If Serious is Yes, submit expedited SAE form. SAE Reporting Criteria: 1 Death

³ Persistent or significant disability/incapacity

⁵ Congenital anomaly or birth defect

⁴ Prolonged or required hospitalization



Concomitant Medications Log

	Center Number:	Participant Number:	Participant's Initials:
Concomitant Medica	tions Log		
	tions. Update form for each visit ch submission starting with base		
Medication	Start Date or ✓ if Pre-study	Stop Date or ☑ if Continuing	Indication
Study vitamin-mineral supplement	day month year	//	
2 Study calcium supplement	day month year	/ / day month year	
3	OR 1 Pre-study	or	
4	OR 1 Pre-study	or	
5	OR 1 Pre-study	or	
6	OR 1 Pre-study	or	
7	OR 1 Pre-study	or	
8	OR 1 Pre-study	or	
9	OR 1 Pre-study	or1 Continuing	
10	OR	or	
11	OR 1 Pre-study	or	
12	OR	day month year OR 1 Continuing	



Concomitant Medications Log

	Center Number:	Participant Number:	Participant's Initials: middle last			
Concomitant Medications Log						
Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline:						
Baseline 1 Baseline 2	Month 1 Month 3 Mont		☐ Month 18 ☐ Month 24			
Medication	Start Date or ☑ if Pre-study	Stop Date or ✓ if Continuing	Indication			
1	OR 1 Pre-study	OR				
2	OR 1 Pre-study	or				
3	OR 1 Pre-study	OR				
4	OR 1 Pre-study	or				
5	OR 1 Pre-study	OR				
6	OR 1 Pre-study	OR				
7	OR 1 Pre-study	OR				
8	OR 1 Pre-study	OR				
9	OR 1 Pre-study	OR				
10	OR 1 Pre-study	or				
11	OR 1 Pre-study	OR				
12	OR 1 Pre-study	or				

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



Date received at DCRI Safety Surveillance	

Serious Adverse Event Form

Report type: Initial Follow-up #: Center Num	ıber:	Participant Number: _	Participant's Initials:	
SAE Details:			Participant's Details:	
SAE Term (Medical Diagnosis):		Date of birth:	Date of birth:/	
SAE Onset Date:/		Gender: Male Female		
SAE Stop Date:/				
Serious Reporting Criteria: (check all that apply)	1	sality & Intensity: heck only one)	Outcome (at time of report): (check only one)	
Death Life-threatening Persistent or significant disability or incapacity Prolonged or required hospitalization Congenital anomaly or birth defect Other significant event requiring medical and/or surgical intervention Causality: 1 N Causality: 1 N 1 N Intensity:		None Doubtful Ossibly Trobably Very likely Aild Moderate	☐ Still present and unchanged ☐ Improving ☐ Resolved ☐ Resolved with sequelae ☐ Death → If Death: Date of death: ☐ Many / Month / Mon	
Action Taken with Study Intervention: (check all that apply) None Intervention temporarily discontinued → Complete and fax the Temporary Discontinuation from CR Intervention form Medical therapy required Intervention permanently discontinued → Complete and fax the Permanent Discontinuation from CR Intervention form Other (specify):				

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



Date received at DCRI Safety Surveillance	

Serious Adverse Event Form

Report type: Initial Follow-up #:	Cont	tor Numbor		Participant Number:	Davi	ticinant's Initials
	Ceni	lei idollibei		rumcipum Number		ticipant's Initials: first middle last
Medical History (relevant to event):						
Concomitant Medication (do not list	medication o	administered t	to treat this	s event):		
Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				//	□ _o No	/
				day month year	1 Yes	day month year
				/	□ _o No	/
				, ,	□ ₁ Yes	, ,
				day month year	Yes	day month year
				/	□ ₀ No	//
				day month year	Yes	day month year
				day month year	U₀ No U₁ Yes	/
				/ /		/ /
				day month year	Yes	day month year
				/	∏₀ No	/
					1 Yes	,
Relevant Lab Tests:				T		
Test		Date		Value/Results	1	Normal Range
	/	/	ear			
	/	/	vear			
	/	/	vear			
	/	/	rear			

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

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



Date received at DCRI Safety Surveillance	

Serious Adverse Event Form

Report type: Initial Follow-up #: Center Number:	Participant Number:	Participant's Initials:	first middle last
Please provide a brief summary of the event:			
Please describe the sequence of events including action taken, treat	tment given, hospital dates, etc.:		
Information Source:	1		
Date Investigator notified of Event:/	Date of this report:/	/	
Person completing form:	Phone number: ()		
PI name:	Fax number: ()		
PI signature:	Date of signature:/	/	

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

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



Excessive Weight Loss Episode Report

		Center Number:	Participant Number:	Participant's Initials:
xce	ssive Weight Loss I	Episode		
en th	=	$< 18.5 \text{ kg/m}^2$, and ends w	s completed for each episode of exce hen the episode either resolves or the e.	
Ide	ntifying information			
1	Date of initial report:/_			
	Name of person making this r			
BMI	l below 18.5 kg/m²			
3	Date of threshold value:	_//		
	Height: cm		at Screening)	
5	Weight: kg			
	Calculated BMI:	kg/m²		
7		ued and a diet plan pres reason why it was not ter	mporarily discontinued: tion from CR Intervention form an	
	low-up BMI Value			
	•		kg/m² or higher after one month of	treatment.
	Date of follow-up value:	/		
9	Weight: kg			
10	Calculated BMI:	kg/m²		
Per	manent Discontinuation			
	<u> </u>		intake, CR intervention is permanent	ly discontinued.
	Was the participant permaner	•		nale
		ned to 18.5 kg/m² or highe	anently discontinued (check only or er	16):
	Yes → If Yes: Complete the immediately.		tion from CR Intervention form an	d fax to Safety Surveillance
any		_	from the CR intervention if a s, complete the Permanent Di	



Excessive Weight Loss Episode Report

		Center Number:	Participant Number: _		Participant's Initials:	first middle last
E	xcessive Weight Loss Epis	sode (continued)				
F	Please provide a description of thi	is episode including a	ctions taken:			
S	tudy Manager's Signatu	re				
Si	gnature:			Date: /	/	
J.,	<u></u>			day	month year	-



Depression Episode Report

		Center Number:	Participant Number:	Participant's Initials: first middle last
D	Depression Episode			
	Pepression is defined as a BDI score \geq 20. TIDI is \geq 20, and ends when the episode eith		·	•
A	Identifying information			
	1 Date of initial report:/	/		
	2 Name of person making this repo			
В	Initial Elevation in BDI Score \geq 20)		
	3 Date of initial elevation:/_	/		
	4 BDI score:			
C	Repeat BDI Score			
	The questionnaire is repeated in one we	∍ek.		
	5 Date of follow-up questionnaire:	////		
	6 BDI score:			
D	Temporary Discontinuation			
	If the repeat score is \geq 20, the CR intervestudy.	ention is temporarily dis	scontinued and a participant is advise	d to seek medical help outside of the
	7 Was the participant temporarily d	discontinued from the	CR intervention?	
		son CR was not temp	orarily discontinued (check only one	e) :
	☐ ₁ BDI score retu	urned to < 20 → If the resol	BDI score returned to < 20, then a ved.	stop here; the episode has
	_	Sign	the form on the last page and sto	re in participant's binder.
	98 Other (speci			
		mporary Discontinua	ition from CR Intervention form an	d fax to Safety Surveillance
E	Follow-up BDI Score			
	The questionnaire is repeated in one mo	onth.		
	8 Date of follow-up questionnaire:	////	 year	
	9 BDI score:	•		



Depression Episode Report

	Center Number:	Participant Number:	Participant's Initials:
Depression Episode (contin	ued)		
F Permanent Discontinuation If BDI score is ≥ 20 after one month of t intervention will be permanently disconti 10 Was the participant permanently □₀ No → If No: Indicate why CF □₁ BDI score ret □₂ Mental healt	treatment, or a qualified minued. It discontinued from the R was not permanently sturned below 20 th professional indicated it cify): Permanent Discontinuation this happens, please	CR intervention? discontinued (check only one): t is safe to resume ion from CR Intervention form m the CR intervention if a B e complete the Permanent D	and fax to Safety Surveillance DI score ≥ 20 occurs at any
Study Manager's Signature:		Date:	/



Eating Disorder Episode Report

		Center Number:	Participant Number: Partic	cipant's Initials:
Eati	ng Disorder Episode			
Accept and/or	tability Morph (BAM) and Interview fo	or the Diagnosis of Eating D	ment of Eating Disorder Symptoms (MAEDS) a Disorders—Fourth Version (IDED-IV). Reporting s the episode either resolves or the participant is	starts when MAEDS
A Ide	entifying information			
1	Date of initial report:/	nth year		
	2 Name of person making this report:			
BAM, B Dis	, or both.	-	the episode was defined in terms of the score of 70 or higher on any subscale of the M	
	MAEDS Domain	t-score	MAEDS Domain	t-score
3	Binge eating		6 Purgative behavior	
4	Restrictive eating		7 Avoidance of forbidden foods	
5	Fear of fatness		8 Depression	
A por () 9 10 11 D Foll Theorem	(c) shows confirming acceptability of the Was an alert issued for the curred Was an alert issued for the ideal Was there confirming acceptabilities. When we with IDED-IV is diagnostic criteria for anorexia nervolits diagnostic criteria. A sub threshold	body size scale?	body size, (b) scores a t-score lower than 30 to in the acceptability phase of the measure is a block of the measure is a	of "3" or more for each
-	mptoms for bulimia nervosa and anore	•	(
12	2 Did the participant meet the follow Anorexia nervosa		check all that apply)?	



Eating Disorder Episode Report

		Center Number:	Participant Number:	Participant's Initials: first middle last
E	ating Disorder Episode 🖟	ontinued)		
E	Permanent Discontinuation If a participant meets one or more of these advised to seek medical help outside of the 13 Was the participant permanently d □₀ No → If No: Indicate why CR v	e diagnostic criteria, the Cl ne study. discontinued from the CR was not permanently dis diagnostic criteria for these	R intervention? scontinued (check only one): eating disorders	
F	Please provide a description of this	s episode including a	ctions taken:	
C	ind Managaria Signatur			
31	Study Manager's Signatur	е		
Siç	ignature:		Date:	



Elevated Potassium Episode Report

		Center Number:	Participant Number:	Participant's Initials: middle last
E	levated Potassium Episoc	le		
rep	yperkalemia is defined as an initial potassium port is completed for each episode of hyperl hen the episode either resolves or the partici	kalemia. Reporting start	ts when the initial potassium level	is greater than 5.5 mEq/L., and ends
A	Identifying information			
	1 Date of initial report:/	/		
	2 Name of person making this repor			
В	Initial Elevation in Potassium Leve			
	3 Date of initial elevation:/	nonth year		
	4 Potassium level: mEq	/L		
C	Follow-up Repeat Potassium Level If the initial potassium level is between 5.5 mEq/L, it is repeated within 48 hours. 5 Date of follow-up test:	5 mEq/L and 6.0 mEq/L	. (inclusive), the test is repeated in	one week; if it is greater than 6.0
	6 Potassium level: mEq	/L		
D	If the follow-up test is > 5.5 mEq/L, the CR to seek medical help outside of the study. 7 Was the participant temporarily di □₀ No → If No: Indicate the reasc □₁ Potassium retur	scontinued from the Con CR was not temporned to 5.5 mEq/L or la	CR intervention? rarily discontinued (check only obwer → If potassium returned to	one): o 5.5 mEq/L or lower, then the Stop here, sign the form on the last
E		nporary Discontinuat ntinue to Section E bel	low.	
	Date of follow-up test: / mon Potassium level: mEq			



Elevated Potassium Episode Report

		Center Number:	Participant Number:	Participant's Initials:
Elev	vated Potassium Epi	isode (continued)		
F Pe	ermanent Discontinuation f potassium level is still elevated about 10 Was the participant permane	ove 5.0 mEq/L after one montently discontinued from the y CR was not permanently m returned to 5.0 mEq/L or losspecify): he Permanent Discontinuation. y. nently discontinued from the CR was restarted. If	CR intervention? discontinued (check only one): ower tion from CR Intervention form the CR intervention if a p	and fax to Safety Surveillance ootassium level of 5.5 mEq/L or e Permanent Discontinuation
- - -				
- - -				
_				
Stu	dy Manager's Signo	ature:		
Signa	ature:		Date:	/



Anemia Episode Report

	Center Number:	Participant Number:	rarticipant's Initials:
nemia Episode	•		
•			
	•	crit level below the lower limit of normal (LLN) for	•
		s when the initial value is observed, and ends w	hen the episode either
solves or the participant is	s permanently discontinued from the	CR intervention.	
Identifying Informa	ntion		
	ort:/		
2 Name of person r	making this report:		
lease complete Section	on B according to whether the	e hemoglobin and/or hematocrit was be	low the lower limit o
Value(s) Below the	Lower Limit of Normal:		
3 Date of lab test:	/		
	Value	Lower Limit of Normal (LLN)	Polow IIN2
4 Hansadahin	Value	Lower Limit of Normal (LLN)	Below LLN?
4 Hemoglobin:			No 1 Yes
5 Hematocrit:			□ No □₁ Yes
6 RBC:			□ □ No □ 1 Yes
7 Iron level:			□ ₀ No □ ₁ Yes
Repeat Test:			
The hematology panel i	is repeated in two weeks. The iron le	vel is also repeated.	
11 Date of repeat lab	o test:/	_	
	Value	Lower Limit of Normal (LLN)	Below LLN?
12 Hemoglobin:		201101 211111 01 1101 11111 (21. 1)	\square_{0} No \square_{1} Yes
13 Hematocrit:			\square_0 No \square_1 Yes
14 RBC:			□ ₀ No □ ₁ Yes
			\square_0 No \square_1 Yes
15 Iron level:			



Anemia Episode Report

		Center Number:	Participant Number:	Participant's Initials:
A	nemia Episode ((continued)		
E	\square_0 No \rightarrow If No: Ind	advised to seek medical help outsid dicate the reason why not:		
			episode h sign the f store in th	acceptable values, then the nas resolved. Stop here, form on the last page, and he participant's binder.
		₉₈ Other (specify):ate on which patient was advised: _		
F	the treatment was initiated	n levels do not return to acceptable valu	ues, the hematology panel and iron levels	s are repeated one month after
		Value	Lower Limit of Normal (LLN)	Below LLN?
	18 Hemoglobin:			□ No □ Yes
	19 Hematocrit:			
	20 RBC:			
	21 Iron level:			\square_0 No \square_1 Yes
G	If anemia is not improving 22 Was the participant □₀ No → If No: Inc	or worsens, the CR intervention is temporarily discontinued from the C dicate the reason why CR was not te	CR intervention? emporarily discontinued (check only on urned to acceptable values → If the her return to episode l the form forward	
	\square_1 Yes \rightarrow If Yes: Co		ion from CR Intervention form and fa	x to Safety Surveillance



Anemia Episode Report

		Center Number:	Participant Number:	Participant's Initials:
Δ	nemia Episode (co	ontinued)		
Н				
	• •	=	ion was temporarily discontinued for one mo	onth, the intervention
	is permanently discontinued.		,	
	23 Date of two month toll	low-up lab test://	year	
Г		w.L.	1 1 1 - 1 N 1 ((A)	D.L. IINO
-	A4 1.1.	Value	Lower Limit of Normal (LLN)	Below LLN?
-	24 Hemoglobin:			□ No □ Yes
-	25 Hematocrit:			□ No □ Yes
-	26 RBC:			□ ₀ No □ ₁ Yes
Ĺ	27 Iron level:			□ ₀ No □ ₁ Yes
I	Permanent Discontinua	ıtion		
	28 Was the participant pe	ermanently discontinued from the	e CR intervention?	
			permanently discontinued (check only one	=):
		Hemoglobin panel and iron levels re		
			ontinuation from CR Intervention form ar	nd fax to Safety
	Surve	eillance immediately.		
J	Please provide a descri	iption of this episode includi	ng actions taken:	
S	tudy Manager's S	Signature:		
		-		
Siç	gnature:		Date:/_	



Ventricular Ischemia Episode Report

	Center Number: Participant Number: Participant's Initials: first middle last
V	entricular Ischemia Episode
wh	is report is completed if an episode of ventricular ischemia occurs during the VO ₂ max measurement (12 or 24 months). Reporting starts hen it is first observed, and ends when the episode either resolves or the participant is permanently discontinued from the R intervention.
A	Identifying information
	1 Date of initial report:/
	2 Name of person making this report:
В	Date when the ventricular ischemia was observed
	3 Date:/
C	Temporary Discontinuation
	The CR intervention is temporarily discontinued and a stress imaging study is recommended within two weeks.
	4 Was CR temporarily discontinued and a stress imaging study ordered?
	No → If No: Indicate the reason CR was not temporarily discontinued:
	Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section D below.
D	Stress Imaging Study
	If a stress imaging study confirms presence of ventricular ischemia, the CR intervention will be permanently discontinued and a participant
	will follow all other study procedures to the study end.
	5 Date of study:/
	6 Did the study confirm the presence of ventricular ischemia?
	□ _o No
E	Permanent Discontinuation
	7 Was the participant permanently discontinued from the CR intervention?
	The study did not confirm the presence of ventricular ischemia.
	immediately.



Ventricular Ischemia Episode Report

	Center Number:	Participant Number:	Participant's Initials:	first middle last
Ventricular Ischei	mia Episode (continued)			
F. Blamas musella datuit				
r Please provide detail	s of ECG findings including acti	ons taken:		
Study Manager's	s Signature:			
-				
Signature:		Date:	/	_



Temporary Discontinuation from CR Intervention

Check one: Initial	Follow-up		
Center Number:	Participant Numbe	r: Participant's Initials:	first middle last

Temporary Discontinuation						
No	te: Compl	ete one fo	rm per r	eason for discontinuati	on.	
Date of temporary discontinua	- tion:	//_				
2 Reason for discontinuation (che			year			
Persistent potassium level > 5.5			at anv point	during study, confirmed by re	peat testina at	1 week
Persistent potassium level ≥ 6.						· · · · · · · · · · · · · · · · · · ·
if second level is above 5.5 n		7 1	0 //	, 1		
🔲 3 Treatment resistant anemia (a	-	ot improved a	ıfter one m	onth of treatment)		
4 Ventricular ischemia observed	with exercis	se (stress imag	ge perform	ed in 2 weeks)		
₆ Moderate depression (BDI ≥						
Personal reasons (specify):						
Other (includes any other disec						ecovery from trauma,
surgery, or severe infections) (s _i	pecity):					
Participant's Details:						
Date of birth://			Hei	ght: cm		
Gender: Male Female			Wei	ght: kg		
			ВМІ	(if applicable):	_	
Relevant Medical History:						
Relevant Concomitant Medication (do not list me	edication adm	ninistered to	o treat this event):		
Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
				day month year	□ _o No	/
				ddy monin yeur	Yes	day monin yeur
				day month year	□₀ No□₁ Yes	day month year
				, ,		/ /
				day month year		day month year
Relevant Lab Tests:						
Test Date Value/Results Normal Range						
/						
	/	/				
	/	/				
	/_	/	year			
	day	month	year			



Temporary Discontinuation from CR Intervention

	Center Number:	Participant Number:	Participant's Initials:
Temporary Disc	ontinuation (continued)		
Please describe any addit	ional action taken (e.g., observation or s	eek medical attention outside study)	:
Intervention Res	sumption		
Was interprentian records	d? If No: Fill out Permanent Discontinu	ation from CD Intervention form	
was intervention resumed	If Yes: Date intervention was resum		
		day month year	
Investigator's S	ignature		
Investigator:		Detai	/ /
investigator	signature	Dale:	/



Permanent Discontinuation from CR Intervention

		Center Number:	Participant Number:	Participant's Initials:
P	ermanent Discontinuatio	on		
		711		
1	Date of permanent discontinuation:	/	7r	
2	□ ₁ Persistent potassium level > 5.0 mEq □ ₂ Persistent potassium level ≥ 5.5 mEq, □ ₃ Persistent anemia (anemia still not in □ ₄ Ventricular ischemia confirmed by st □ ₅ Decrease in BMD at the hip or spine	q/L resistant to one month q/L after CR was temporal improving or worsening of stress image are of 5% or greater from all neck, or total spine) of nervosa, bulimia nervosanth of increase calorie initiatervention restarted are depression) sion (BDI still > 20) after amporary discontinuation cer) talization or bed rest for my for more than one year	carily discontinued and restarted one month after temporary discontinuate baseline at any time during first 12 months asseline at any time during months 12 less than -2.5 at any time during studia or binge eating OR experiencing a subtake OR temporary discontinuation of CCCR intervention restarted OR moderate of CR intervention more than one month or (women only)	onths of CR 2–24 of CR dy ub-threshold eating disorder) CR intervention OR persistent
Рс	articipant's Details:			
Do	ate of birth://		Height: cm	
	ender: Male Female		Weight: kg BMI (if applicable):	
Re	elevant Medical History:			



Permanent Discontinuation from CR Intervention

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

Jation (d	ontinued)				
		ninistered t	o treat this event):		
Dose	Frequency	Route	Start Date	Continued	Stop Date
			/	O No	day month year
				□ ₀ No □ ₁ Yes	
			/	□ ₀ No □ ₁ Yes	/
	Date		Value/Results		Normal Range
/	/	year			
/					
/					
/_	/	year			
on taken (e.	g., observatio	on or seek	medical attention outside stu	dy):	
ure					
			Dat	e• /	,
	signature			day	month year
	Dose & Unit ———————————————————————————————————	Date Date Jre Date Jre	Dose & Unit Frequency Route	Dose & Unit Frequency Route Start Date	Dose & Unit Frequency Route Start Date Continued



2 Study Completion/ Early Discontinuation of Study Evaluation

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

Completion/Early Discontinuation						
1 Date of study completion or early discontinuation of study:						
2 Did the participant complete the study through Month 24?						
\square_0 No \rightarrow If No: Date of last contact: \square_{day} / \square_{month} / \square_{vear}						
Indicate the primary reason for discontinuation (check only one):						
\square_2 Lost to follow-up						
If serious adverse event, complete Serious Adverse Event (SAE) form						
\square_4 Death \rightarrow Date of death: \square_{day} / \square_{month} / \square_{year}						
• Complete Signs, Symptoms and Adverse Events Log						
Complete Serious Adverse Events form						
Report cause of death as a Serious Adverse Event						
98 Other (specify):						
□ ₁ Yes						

Send to DCRI Forms Management •

2400 Pratt St. • Room 0311 Terrace Level • Durham NC 27705

calerie Phase 2

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

			Center Numbe	r: Participant Nun	nber: Part	icipant's Initials: First middle last
Daily Home W	eight Log					
Were you issued a new	scale? O No 1 Yes	s → If Yes: Date first used	month day / year —	Serial no.:		
Please complete this log	g in either blue or black ir	ık.				
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
Date:	Date:	Date:	Date:	Date:	Date:	Date:
		month day year	month day year year			
Time: 1 AM 2 PM	Time: AMPM	Time: □ ₁ AM □ ₂ PM	Time: 1 AM 2 PM	Time: AM PM	Time: □ ₁ AM □ ₂ PM	Time: AM PM
: 00:00 to 11:59	00:00 to 11:59	: 00:00 to 11:59	: 00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	: 00:00 to 11:59
Weight:	Weight:	Weight:	Weight:	Weight:	Weight:	Weight:
lb	lb	lb	lb	lb	lb	lb
						Check scale memory
	I	I				
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week:
Date:	Date:	Date:	Date:	Date:	Date:	Date:
			month day / year			month day / year
Time:1 AM	Time: AM PM	Time: \square_1 AM \square_2 PM	Time: AM PM	Time: AM PM	Time: AM	Time: \square_1 AM \square_2 PM
00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59
Weight:	Weight:	Weight:	Weight:	Weight:	Weight:	Weight:
lb	lb	lb	lb	lb	lb	Check scale memory
						THEER STATE INCIDENT



Protocol Deviation

Ce	enter Number:	Participant Number:	Participant's Initials:			
Protocol Deviation						
Please indicate below any deviations from th	e Calerie Pro	otocol taken for this participant.				
Check all that apply (one participant per form):		•				
Baseline 1 Baseline 2 Month 1	Month 3	Month 6 Month 9 Month 12	Month 18 Month 24			
Date of deviation:day /month /year	,					
☐ Informed Consent		Study/laboratory procedures (spe	ecify):			
Inclusion/Exclusion criteria		Participant non-fasting	,,			
Randomization/treatment assignment		Participant safety (specify):				
Concomitant Medications		Other (specify):				
Brief explanation of deviation:						
Baseline 1 Baseline 2 Month 1	Month 3	Month 6 Month 9 Month 12	☐ Month 18 ☐ Month 24			
Date of deviation:/	ır					
☐ Informed Consent		Study/laboratory procedures (spe	ecify):			
Inclusion/Exclusion criteria		Participant non-fasting				
Randomization/treatment assignment		Participant safety (specify):				
Concomitant Medications		Other (specify):				
Brief explanation of deviation:						
Baseline 1 Baseline 2 Month 1	Month 3	Month 6 Month 9 Month 12	☐ Month 18 ☐ Month 24			
Date of deviation:/	ır					
☐ Informed Consent		Study/laboratory procedures (spe	ecify):			
Inclusion/Exclusion criteria		Participant non-fasting				
Randomization/treatment assignment		Participant safety (specify):				
Concomitant Medications		Other (specify):				
Brief explanation of deviation:						
-						
Submission date:/		day month year day	_//year			