

Phone Screen

		Center Number:	_ Partici	oant Number:		Participant's Initials	first middle last
Phone Sc	reen						
V in	Give the caller a brief overv Tisit 1. Ask for verbal conse In order to determine eligibi Ill in blanks and check	nt to record personal i lity. If the caller is elig	nformation	on over the pho	ne. Com	plete all phone screen	
Verbal consent	given by respondent:	No	Interviev	ver's initials: _	irst middle last	-	
Last name:		_ First name:			DOB:	/	
Address:					Z	Zip:	
Phone (home):		Phone (work):			E-mail:		
Height: ft	in Weight:	lbs BMI:		Gender:	₁ Male		
Medical H	listory						
	Have you been diagnosed r ever experienced the follo					Describe (being treated, symptoms/type of/family	•
Heart attack, he	eart-related chest pain, or ot	her heart condition	O No	1 Yes →			
Abnormal hear	t rhythm		O No	\square_1 Yes \rightarrow			
Cancer			O No	\square_1 Yes \rightarrow			
Shortness of br	eath or other breathing pro	oblem	□ ₀ No	\square_1 Yes \rightarrow			
Diabetes (meds))		O No	1 Yes →			
High blood pre	essure (> 140/90)		O No	1 Yes →			
Anemia or othe	er blood condition		O No	1 Yes →			
Thyroid or other	r metabolic disorder such as	phenylketonuria	O No	□ ₁ Yes →			
Stomach or dig	estive disorders		□ ₀ No	1 Yes →			
Immunologic di	isorder or AIDS		O No	1 Yes →			
Depression or o	any other psychiatric or ne	ırologic disease	O No	1 Yes →			
Active liver dise	ease and/or gallstones		O No	1 Yes →			
Kidney or urolo	ogic disorders		□ ₀ No	1 Yes →			
Major abdomin	nal or chest surgery		□ ₀ No	1 Yes →			
Weight loss or	gain of > 3 kg over the pas	t 6 months	□ ₀ No	\square_1 Yes \rightarrow			
Known metallic	objects or implants in you	r body	□ ₀ No	□ ₁ Yes →			
Anaphylaxis, se	evere allergies, or asthma		O No	1 Yes →			



Phone Screen

	Center Number:	Participant Number:	Participant's Initials:
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	If Yes: Specify medications:
2	Have you received more than one episode of medication for depression or any other psychiatric disease ever?	□ ₀ No □ ₁ Yes →	If Yes: Specify medications:
3	Have you been treated with steroids in the last six months?	□₀ No □₁ Yes	
4	Have you been treated with steroids for more than a month in the past five years?	□₀ No □₁ Yes	
5	Do you currently use regular medications other than birth control pills?	\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.)	\square_0 No \square_1 Yes \rightarrow	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	
6	Are you currently practicing a vegan dietary lifestyle?	\square_0 No \square_1 Yes	
7	Do you anticipate difficulties adhering to special diets and clinical visits over a two year period?	□ ₀ No □ ₁ Yes	
E	igibility Information To be completed by the intervie	ewer	
	eview above items marked "Yes" against Exclusion criteri		the appropriate response below:
Eliç	gible: □ ₀ No → If No: Reason for not being eligible:		
		? \square_0 No \square_1 Yes	
	On hold → If on hold: For what reason?		
	Contact to resume screening aft	ter being on hold:	/
Or	ientation (screening visit 1) scheduled:	,	,
Co	mments:		



Screening Visit 1 Checklist

	Center Number:	Participant Number:	Participant's Initials:
Screening Visit 1 Checklis	st		
1 Date of initial clinic visit for Screening	g Visit 1:/	/	
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		
18 Is the participant expected to return	_		
\square_0 No \rightarrow If No: Provide reason (che			
Failed an eligibilit			
Lost interest in the Will take too muc	•		
<u> </u>	icts with work or school		
Doesn't like the st			
	pe involved in a research stu	ndv	
Unwilling to be ro			
	y/transportation problems		
Needs help with a	• •		
Refused with no e	explanation		
Other (specify): _			
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:
Clinic Weight			
Weight date and time:/	/	_ : 0 to 23:59	Staff initials:
OR Not done → Specify reason (a			tirst middle last
Clinic weight (if the first two measure	ements are more than 0.1 kg ap	art, measure weight a third tim	ne):
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Height			
Height (if the first two measurements	are more than 0.1 cm apart, m	easure height a third time):	
1 First height:	cm		
2 Second height:	cm		
3 Third height:	cm		
N.B. C. I.B. 12 a.			All of the second
Not Done Codelist: 1 Participant re	stused 2 Clinician unable to a	obtain 3 Insufficient time	4 Instrument failure 5 Not required



	Center Number:	Participant Numbe	er:	Participant's Initials:	first middle last
Date:/	Maintain completed fo		file at site.		
	Please	print.			
Demographic Questionno	aire				
Name:	mic	Hdle initial	last na	ıme	
Street address:					
City:	St	tate:	Zip:		
Telephone (Home): ()					
	Do you mind being ca Best time to call, and v				
	best time to call, and v	wnere:			
E-mail address:		Cell phone: (_)		
Do you use e-mail regularly? □ ₀ No		w often?			
Date of birth:/	Age:				
Social Security number:					
Occupation:					
Emergency Contact:					
Name:	·		last name		
Telephone: ()	F	Relationship:			
Primary Care Physician					
Name:	,		last name		
Street address:					
City:	St	tate:	Zip:		
Telephone: ()	F	ax: ()		· —— ——	



		Center Number:	Participant Number:	Participant's Initials:
				iirsi iliidale idsi
D	emographics			
1 2	Date of birth:/	year		
3	Ethnicity (check only one): 1 Hispanic of 2 Not Hispanic			
4	Race (check only one): \square_1 American Ind \square_2 Asian	ian or Alaska Native iian or other Pacific Isla an American	nder	
5	Marital status (check only one): 1 Mar 1 Marital status (check only one): 2 Diva 2 Diva 3 Sing	orced	Widowed Separated Not married, but living with partner	
6	Living situation: Where do you live (a	\square_2 Apo \square_3 She \square_4 Dor	artment Iter	
7	Education: What is the highest level (Note: If you have any questions as to which co 1 Elementary school (0-8 th grade) 2 9-11 th grade 3 12 th grade or GED 4 Some college/Associates degree 5 College (includes multiple degrees) 6 Non-doctoral graduate degree 7 Doctoral degree (M.D., J.D., Ph.D., etc.)	tegory you fall in, please co	•	a) ?
8	Family income: What is the total ann	ual income of your ho	$ \begin{array}{c} $)-\$39,999)-\$59,999 -\$79,999

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		Center Number:	Participant Number:	Participant's Initials:
Date comp	leted:/ _{month} /	/		
Stanfo	rd Brief Physica	l Activity Survey		
Section I	On-The-Job Activity activity you usually per but perform work arou	Please check the box next formed while on this job th	is last year. If you are not ga ate that activity in this section	st describes the kinds of physical infully employed outside the home .
□ _B l s _l tele	pent most of the day sittir ephone, assembling smal	g or standing. When I was I parts, or operating a mac	at work, I did such things as	writing, typing, talking on the tion or strength. If I drove a car or aday.
wo mo	ork, I did such things as d achines, house painting, c	elivering mail, patrolling or	guard duty, mechanical wor requires some moderate act	moderate exertion. When I was at rk on automobiles or other large ivity work of me. If I drove a truck or
wo	ork, I did such things as st	acking cargo or inventory,		v in some other way. When I was at or I did work like that of a carpenter
hed	avy tools, or carrying hed	avy loads (bricks, for exam		hings as digging or chopping with are to be used. If I drove a truck or day with only short breaks.
Section II		y Please check the box neary most of the last year.	xt to the one statement that	best describes the way you spent
or ga	playing cards. If I did an	ything else, it was likely to l Only occasionally, no mo	pe light chores around the ho	hings like watching television, reading ouse or yard, or some easy-going h, did I do anything more vigorous,
lig				I was able to get outdoors for some doing some active chores around the
sw dif	imming or riding a bike—	for 15-20 minutes or more	. Or I spent 45 minutes to ar	as brisk walking or slow jogging, n hour or more doing moderately g—or playing games such as double
hed fasi suc	avy physical activity at least on a bicycle for 30 min	ast three times per week. Ex utes or more; heavy garder	camples of heavy physical ac ning or other chores for an ho	cal fitness involving some kind of ctivity are: jogging, running or riding our or more; active games or sports thenics and jogging or the equivalent
		ed in a regular program of e or more times per week.	physical fitness along the lin	es described in the last paragraph (I)



	Center Number: Participant Number:	Participant's I	nitials:
Date o	completed:day /month/ OR Not done → Specify reason (use codelist below	ow):	
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.	, True	o 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.		o False
6	I deliberately take small helpings as a means of controlling my weight.		o False
7	Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	, 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.	, True	□ _o False
9	When I feel anxious, I find myself eating.		o False
10	Life is too short to worry about dieting.		o False
11	Since my weight goes up and down, I have gone on reducing diets more than once.	e □, True	□₀ False
12	I often feel so hungry that I just have to eat something.	1 True	o False
13	When I am with 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	□₀ False
15	Sometimes when I start eating, I just can't seem to stop.		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	□₀ False
18	While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	or True	o False



	Center Number:	Participant Number:	Participant's In	first middle last
Eat	ting 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 comy weight.	llories or watching		o False
22	When I see a real delicacy, I often get so hungry right away.	that I have to eat		o False
23	I often stop eating when I am not really full as a limiting the amount I eat.	conscious means of		o False
24	I get so hungry that my stomach often seems like	e a bottomless pit.		o False
25	My weight has hardly changed at all in the last t	en years.		o False
26	I am always hungry so it is hard for me to stop of food on my plate.	eating before I finish the	, True	o False
27	When I feel lonely, I console myself by eating.		☐₁ True	o False
28	I consciously hold back at meals in order not to	gain weight.	□₁ True	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.		☐₁ True	o False
31	Without even thinking about it, I take a long time	e to eat.	☐₁ True	o False
32	I count calories as a conscious means of controll	ing my weight.	☐₁ True	o False
33	I do not eat some foods because they make me	fat.	☐₁ True	o 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	o False
36	While on a diet, if I eat a food that is not allowed other high calorie foods.	d, I often splurge and eat		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 □₂ Moderately difficult □₃ Very difficult
42	How conscious are you of what you are eating?	□₀ Not at all□₁ Slightly□₂ Moderately□₃ Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	□₀ Almost never □₁ Seldom □₂ Usually □₃ Almost always
44	How likely are you to shop for low calorie foods?	☐₀ Unlikely ☐₁ Slightly likely ☐₂ Moderately likely ☐₃ Very likely
45	Do you eat sensibly in front of others and splurge alone?	□₀ Never □₁ Rarely □₂ Often □₃ Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐₀ Unlikely ☐₁ Slightly likely ☐₂ Moderately likely ☐₃ Very likely
47	How frequently do you skip dessert because you are no longer hungry?	□₀ Almost never □₁ Seldom □₂ At least once a week □₃ Almost every day
48	How likely are you to consciously eat less than you want?	☐₀ Unlikely ☐₁ Slightly likely ☐₃ Woderately likely ☐₃ Very likely
49	Do you go on eating binges though you are not hungry?	□₀ Never □₁ Rarely □₂ Sometimes □₃ At least once a week
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	 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
Date completed:/	year								
Multiaxial Assessment of	Eating Disorder	Symp	otom:	S (MAE	DS)				
Instructions: Using the scale shown, plea	ase 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	e weight.				\square_3	4	5		
2 My sleep isn't as good as it	used to be.				\square_3	4	5		7
3 I avoid eating for as long as	I can.				3	4	5		7
4 Certain foods are "forbidden	n" for me to eat.				\square_3	4	5		7
5 I can't keep certain foods in m binge on them.	y house because I will				3	4			
6 I can easily make myself von	nit.				\square_3	4	5		7
7 I can feel that being fat is ter	rible.				\square_3	4	5		
8 I avoid greasy foods.					\square_3	4	5		7
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	4	5		
11 I think I am a good person.					3	4	5	6	
12 My eating is normal.					3	4	5	6	
13 I can't seem to concentrate l	ately.				\square_3	4	5	6	
14 I try to diet by fasting.					3	4	5	6	7
15 I vomit to control my weight.					3	4	5	6	
16 Lately nothing seems enjoya	ble anymore.				\square_3	4	5	□ ₆	
17 Laxatives help keep you slim					\square_3	4	5		
18 I don't eat red meat.						4	5		7
19 I eat so rapidly I can't even t	aste my food.				3	4	5	6	



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Center Number:	Participant N	umber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of Eating Disorder	Sympto	oms (MAEDS)	(continue	ed)		
	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	6	
22 I overeat too frequently.				4			
23 It's okay to be overweight.			\square_3	4	5		
24 Recently I have felt that I am a worthless person.			\square_3	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	6	
28 Being fat would be terrible.			\square_3	4	5	6	
29 I have thought seriously about suicide lately.				4	5	6	7
30 I don't have any energy anymore.			\square_3	4	5	6	
31 I eat small portions to control my weight.				4	5	6	
32 I eat 3 meals a day.			\square_3	4	5		
33 Lately I have been easily irritated.			3	4	5		
34 Some foods should be totally avoided.			\square_3	4	5		
35 I use laxatives to control my weight.				4	5		7
36 I am terrified by the thought of being overweight	• 🔲 1		\square_3	4	5	6	
37 Purging is a good way to lose weight.			\square_3	4	5		
38 I avoid fatty foods.							

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	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Assessment of	Eating Disorde	r Sympto	oms (MAEDS)	(continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blu	Je.				4	5		
40 I am obsessed with becoming	g overweight.			\square_3		5	6	
41 I don't eat fried foods.				\square_3	4	5	6	
42 I skip meals.				\square_3	4	5		
43 Fat people are unhappy.				\square_3	4	5	6	
44 People are too concerned wi	th the way I eat.			\square_3	4	5	6	
45 I feel good when I skip meal	s.			\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	6	
48 I am too fat.				\square_3		5		
49 I eat until I am completely stu	uffed.			\square_3	4	5	6	
50 I hate to eat.				\square_3	4	5	6	
51 I feel guilty about a lot of this	ngs these days.			\square_3	4	5	6	
52 I'm very careful of what I ea	.			\square_3	4	5	6	
53 I can "hold off" and not eat of	even if I am hungry.			\square_3	4	5	6	
54 I eat even when I am not hur	ngry.				4	5	6	
55 Fat people are disgusting.						5	6	
56 I wouldn't mind gaining a few	w pounds.						6	

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?	O No	1 Yes
4	Do you often worry about being criticized or rejected in social situations?	O No	1 Yes
5	Are you usually quiet when you meet new people?	o No	1 Yes
6	Do you believe that you're not as good, as smart, or as attractive as most other people?	O No	1 Yes
7	Are you afraid to try new things?	O No	1 Yes
8	Do you need a lot of advice or reassurance from other before you can make everyday decisions—like what to wear or what to order in a restaurant?	o 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?	O No	1 Yes
10	Do you find it hard to disagree with people even when you think they are wrong?	O No	1 Yes
11	Do you find it hard to start or work on tasks when there is no one to help you?	o No	Yes
12	Have you often volunteered to do things that are unpleasant?	O No	1 Yes
13	Do you usually feel uncomfortable when you are by yourself?	O No	
14	When a close relationship ends, do you feel you immediately have to find someone else to take care of you?	O No	1 Yes
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



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	Center Number: Participant Number:	icipant'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?	□ ₀ No	
30	Do you often think that it's not fair that other people have more than you do?	O 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	? No	Yes
33	Do you usually feel unhappy or that life is no fun?	□ ₀ No	1 Yes
34	Do you believe that you are basically an inadequate person and often don't feel good about yourself?	□ ₀ No	
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	
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?	□ ₀ 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?	O 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?	O 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	1 Yes
48	Have you often suspected that your spouse or partner has been unfaithful?	O No	



	Center Number: Participant Number:	Participant's Initials:	first middle last
Str	ructured Clinical Interview for DSM-IV (SCID-II) (continued)		
49	When you are out in public and see people talking, do you often feel that they are talking about you?	□ ₀ No	1 Yes
50	Do you often get the feeling that things that have no special meaning to most people are really meant to give you a message?	□ ₀ No	1 Yes
51	When you are around people, do you often get the feeling that you are being watched or stared at?	□ _o No	1 Yes
52	Have you ever felt that you could make things happen just by making a wish or thinking about them?	□ _o No	1 Yes
53	Have you had personal experiences with the supernatural?	□ _o No	1 Yes
54	Do you believe that you have a "sixth sense" that allows you to know and predict things that others can't?	o No	1 Yes
55	Does it often seem that objects or shadows are really people or animals or that noises are actually people's voices?	□ _o No	1 Yes
56	Have you had the sense that some person or force is around you, even though you cannot see anyone?	□ _o No	1 Yes
57	Do you often see auras or energy fields around people?	□ _o No	1 Yes
58	Are there very few people that you're really close to outside of your immediate family?	□ _o No	1 Yes
59	Do you often feel nervous when you are with other people?	□ _o No	1 Yes
60	Is it NOT important to you whether you have any close relationships?	□ ₀ No	1 Yes
61	Would you almost always rather do things alone than with other people?	O No	1 Yes
62	Could you be content without ever being sexually involved with anyone?	O No	1 Yes
63	Are there really very few things that give you pleasure?	□ _o No	1 Yes
64	Does it NOT matter to you what people think of you?	□ _o No	Yes
65	Do you find that nothing makes you very happy or very sad?	□ _o No	1 Yes
66	Do you like to be the center of attention?	□ _o No	Yes
67	Do you flirt a lot?	O No	1 Yes
68	Do you often find yourself "coming on" to people?	□ _o No	1 Yes
69	Do you try to draw attention to yourself by the way you dress or look?	O No	Yes
70	Do you often make a point of being dramatic and colorful?	□ ₀ No	1 Yes
71	Do you often change your mind about things depending on the people you're with or what you have just read or seen on TV?	□ ₀ No	1 Yes
72	Do you have lots of friends that you are very close to?	□ _o No	1 Yes

Participant's Initials: first middle last



	Center Number: Participant Number: Parti	cipant'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	Yes
75	Do you think a lot about the power, fame, or recognition that will be yours someday?	O No	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	1 Yes
78	Do you feel it is important to spend time with people who are special or influential?	□ ₀ No	Yes
79	Is it very important to you that people pay attention to you or admire you in some way?	□ ₀ 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	
82	Do you often find it necessary to step on a few toes to get what you want?	O ₀ No	Yes
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	1 Yes
90	Have you often become frantic when you thought that someone you really cared about was going to leave you?	S ONO	
91	Do your relationships with people you really care about have lots of extreme ups and down	ns? No	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	1 Yes
94	Are you different with different people or in different situations, so that you sometimes don't know who you really are?	□ ₀ No	
95	Have there been lots of sudden changes in your goals, career plans, religious beliefs, and so on	1? No	
96	Have you often done things impulsively?	□ ₀ No	Yes
97	Have you tried to hurt or kill yourself or threatened to do so?	o No	
98	Have you ever cut, burned, or scratched yourself on purpose?	o No	Yes

Participant's Initials: first middle last



	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	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, bri	ck, one No	Yes
108	Before you were 15, did you deliberate and suffering?	ely torture some	one or cause someone physica	Il pain No	1 Yes
109	Before you were 15, did you torture or	hurt animals on	purpose?	o No	
110	Before you were 15, did you rob, mug threatening him or her?	or forcibly take	something from someone by	□ ₀ No	Yes
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 in	n front No	Yes
112	Before you were 15, did you set fires?			□ ₀ 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 int	o houses, other k	ouildings, or cars?	□ ₀ No	1 Yes
115	Before you were 15, did you lie a lot o	r "con" other pe	ople?	o No	
116	Before you were 15, did you sometime someone's signature?	s steal or shoplit	ft things or forge	□ ₀ No	1 Yes
117	Before you were 15, did you run away	from home and	stay away overnight?	o No	1 Yes
118	Before you were 13, did you often stay supposed to be home?	out very late, la	ong after the time you were	□ ₀ No	1 Yes
119	Before you were 13, did you often skip	school?		o No	Yes



		Center Number: _	Participant Number:	Participant's Initials: initials: last
Do	ite completed:/_	/		
В	DI-II			
In	and then p during the	ick out the one statement in e past two weeks, including too	of statements. Please read eac ach group that best describes t day. Check the box beside the s ent for each group, including ite	statement you have picked.
1	Sadness:	 □₀ I do not feel sad □₁ I feel sad much of the time □₂ I am sad all of the time □₃ I am so sad or unhappy the 	ıt I can't stand it	
2	Pessimism:	☐ I am not discouraged abou ☐ I feel more discouraged ab ☐ I do not expect things to wo ☐ I feel my future is hopeless of	out my future than I used to be ork out for me	
3	Past failure:	 □₀ I do not feel like a failure □₁ I have failed more than I sh □₂ As I look back, I see a lot o □₃ I feel I am a total failure as 	f failures	
4	Loss of pleasure:	☐ I get as much pleasure as I ☐ I don't enjoy things as much ☐ I get very little pleasure from ☐ I can't get any pleasure from	n as I used to n the things I used to enjoy	
5	Guilty feelings:	o I don't feel particularly guilt I feel guilty over many thing I feel quite guilty most of the	s I have done or should have don	е
6	Punishment feelings:	o I don't feel I am being punis I feel I may be punished I expect to be punished I feel I am being punished	shed	
7	Self-dislike:	☐ I feel the same about mysel☐ I have lost confidence in my☐ I am disappointed in myself☐ I dislike myself	vself	



		Center Number:	Participant Number:	Participant's Initials:	first middle last
В	DI-II (continued)				
8	Self-criticalness:	o I don't criticize or blam in I am more critical of my in I criticize myself for all of myself for all of myself for every	self than I used to be of my faults		
9	Suicidal thoughts or wishes:		g myself but I would not carry them of	out	
10	Crying:	\square_0 I don't cry any more that \square_1 I cry more than I used t \square_2 I cry over every little thit \square_3 I feel like crying, but I contains	o ng		
11	l Agitation:			oing something	
12	2 Loss of interest:		ther people or things than before nterest in other people or things		
13	3 Indecisiveness:	\square_0 I make decisions about \square_1 I find it more difficult to \square_2 I have much greater dif \square_3 I have trouble making n	make decisions than usual ficulty in making decisions than I use	d to	
14	■ Worthlessness:	o I do not feel I am worth I I don't consider myself o I I feel more worthless as I feel utterly worthless	as worthwhile and useful as I used to		
15	5 Loss of energy:	☐ I have as much energy ☐ I have less energy than ☐ I don't have enough en ☐ I don't have enough en	I used to have ergy to do very much		



	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	☐₁ I sleep somewhat more th ☐₂ I sleep somewhat less that ☐₃ I sleep a lot more than usu ☐₄ I sleep a lot less than usu ☐₅ I sleep most of the day	nan usual an usual sual		
17 Irritability:	\square_0 I am no more irritable than u \square_1 I am more irritable than u \square_2 I am much more irritable t \square_3 I am irritable all of the time	sual than usual		
18 Changes in appetite:	o I have not experienced and have not experienced and have appetite is somewhat have appetite is somewhat have appetite is much less and have appetite is much great have no appetite at all have food all of the time.	less than usual greater than usual than before ter than usual		
19 Concentration difficulty:	\square_0 I can concentrate as well \square_1 I can't concentrate as well \square_2 It's hard to keep my mind \square_3 I find I can't concentrate of	l as usual on anything for very long		
20 Tiredness or fatigue:		-		
21 Loss of interest in sex:	o I have not noticed any red In I am less interested in sex In I am much less interested In I have lost interest in sex of	in sex now		



Screening Visit 2 Checklist

		Center Number:	Participant Number:	Participant's Initials:
S	creening Visit 2 Checklis	st		
1		Visit 2? 5 and provide reason.	!:/ _{month} /	
Cŀ	neck completed items:			
2	Fasting blood sample			
3	Urine sample			
4	☐ Vitals (temperature, pulse, blood pr	ressure)		
5	ECG			
6	Medical and medication history			
7	Concomitant medications log			
8	Physical examination			
9	Barriers interview			
10	0 ☐ Body morph assessment			
11	Additional interviews (SCID-II and	d/or IDED-IV)		
12	2 Meeting with dietitian to review	dietary screening questic	onnaire	
13	3 🗌 14-day food record procedure re	eviewed		
14	4 Meeting with study coordinator/	['] manager		
15	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 Unable to contact	eck all that apply): ity criterion e study ch time icts with work or school tudy's procedures be involved in a research stu andomized sy/transportation problems child care explanation		
	Yes → If Yes: Date of scheduled		//	

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



Baseline Submission 1 Screening

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



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		unter 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	day month year	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.

Retain at site at secure location. Submit with Concomitant Medication Log for Baseline Submission 1.



Physical Examination						
Date of examination:/						
	Assessments					
Body System	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain		
General appearance:		□₀→	₉₇ →			
2 Head, Ears, Eyes, Nose, Throat:		□₀→	₉₇ →			
3 Neck:	\Box_1	□₀→	₉₇ →			
4 Heart:		□₀→	₉₇ →			
5 Lungs:	\Box_1	□₀→	₉₇ →			
6 Abdomen:		□₀→	₉₇ →			
7 Lymph nodes:	\Box_1	□₀→	₉₇ →			
8 Extremities/Skin:		□₀→	₉₇ →			
9 Neurological:		□₀→	₉₇ →			
10 Musculoskeletal:	\Box_1	□₀→	₉₇ →			
	Normal	Abnormal	Not Done*			
11 Genitourinary:		□₀→	□ ₉₇ →			
12 Breast:		□₀→				
Physician's Signature						
Signature:						
* Not done at this examination OR Referred	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						

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



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 □ No, no additional visits → If No a	dditional visits: Provide	, , ,	,	
Yes → If Yes: Additional visit sch		Serooning Visit At	/	
		ocreening Visit 4:/	,	
	Date of scheduled Base	eline Visit:/	year	

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Screening Visit 4 Checklist

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



	Cer	nter Number:	Participant Number:	_ Participant's Initials:	first middle last
Ir	formed Consent				
١,	Did participant present for baseline visit?				
	\square_0 No \rightarrow If No: Specify reason (check on	y one): Failed a	n eligibility criterion (participant no l	onger meets criteria)	
		Lost inter	rest in the study		
			e too much time		
		Scheduli	ng conflicts with work or school		
			ike the study's procedures		
		6 Doesn't	want to be involved in a research stu	ıdy	
			g to be randomized		
			far away/transportation problems		
		, Needs h	elp with child care (unanticipated ch	nild care needs)	
		₁₀ Refused	with no explanation		
		₁₁ Unable	to contact		
	_	98 Other (specify):		
	Yes				
2	Date and time study baseline informed co	nsent signed:	//	: 0:00 to 23:59	



		Center Number:	Participant Number:	Participant's Initials:				
In	Informed Consent Detail							
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	\Box_1	\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: list middle last
C	inic Weight
We	ight date and time:/: day: 00:00 to 23:59 Staff initials:
	Not done → 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	i ght 2: kg
We	ight 3: kg
We	ight of gown: kg
V	tal Signs
As	sessment date and time:/
	If waist measurement not done → Specify reason (use codelist below):
1	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time): Staff initials: First middle last last
	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): Left arm Right arm Staff initials:
	6a Blood pressure 1: / mm Hg
	6b Blood pressure 2:/ mm Hg Time::
	6c Blood pressure 3:/ mm Hg Time::
No	t Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



		Number: Parii	first middle las
12-Lead ECG			
Date and Time		Findings	Staff Initials
		lly significant (specify):	first middle last
Safety Labs			,
Date and time of last meal:/		23:59	
Date and time of sample collection:/	: th year 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
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuf	ficient time 4 Instrument failur	e 5 Not required



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



	Center Nu	mber:	Participant Nu	omber: Participant's Initials:					
Physical Examination									
Date of examination:/									
	Date of examination:/								
Dody Systom		Assessments	3	If Abnormal or Not Dones Evaluin					
Body System	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain					
General appearance:		□₀→	₉₇ →						
2 Head, Ears, Eyes, Nose, Throat:	\Box_1	□₀→	□ ₉₇ →						
3 Neck:		□₀→	□ ₉₇ →						
4 Heart:	\Box_1	□₀→	□ ₉₇ →						
5 Lungs:	\Box_1	□₀→	□ ₉₇ →						
6 Abdomen:		□₀→	□ ₉₇ →						
7 Lymph nodes:		□₀→	□ ₉₇ →						
8 Extremities/Skin:	\Box_1	\square_{o} \rightarrow	□ ₉₇ →						
9 Neurological:		□₀→	₉₇ →						
10 Musculoskeletal:		□₀→	₉₇ →						
	Normal	Abnormal	Not Done*						
11 Genitourinary:		□₀→	□ ₉₇ →						
12 Breast:	\square_1	□ _o →	□ ₉₇ →						
Physician's Signature									
Investigator:	signatu	re		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: first middle last
Clinic Weight			
Weight date and time:/ _{month}	_/	23:59	Staff initials:
OR Not done → Specify reason (use coo			nrst middle idst
Clinic weight (if the two measurements are	more than 0.1 kg apart, me	asure weight a third time):	
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			
☐ Yes → If Yes: Date urine pregna	ncy test performed:	/ _{month} /year	
Results: 🔲 Nega			
	е		
Not Done Codelist: 1 Participant refused	2 Clinician unable to obt	ain 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	ure: gro	ams	
4	Urine samples:			
	Collection	Sample	Date and Time	Collected
	Pre dosing (PD)	PDa	/	: 00:00 to 23:59
		PDb	///year	::::
	Day 0 (Visit 2)	DOα	/	::::::::
		DOb	/	:::
	Day 7 (Visit 3)	D7a	/	: :::
		D7b	/	: : 00:00 to 23:59
	Day 14 (Visit 4)	D14a	/	: : : : : : : : : : : : : : : : : : :
		D14b	/	: : : : : : : : : : : : : : : : : : :
5	Affix CRF page label(s) co	orresponding to this urine san	nple set: Affix Label Here	

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:				
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 Resca	n OR □ ₉₆ NA				
Date of scan:/	ar	Date of rescan:/	onth				
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Scanned Il that apply				
Whole body		☐ Whole b	ody				
Forearm		Forearm					
Spine		Spine					
<u></u> Нір		☐ Hip					
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 Insufficient time 4 Instru	ment failure 5 Not required				



	Center N	Number: Participant Numb	er:	Participant's In	itials: middle last
Da	te completed:/	OR Not done → Specify reason	use codelist below	·):	
R	AND SF-36				
Ins	structions: This survey asks for your views abo to do your usual activities. Please a unsure about how to answer a que	nswer every question by placing	a check "X" in th		
1	In general, would you say your health is:		good □₃ Go	od □₄ Fair	Poor
2	Compared to one year ago, how would you rate your health in general now?	☐₁ Much better now than ☐₂ Somewhat better now ☐₃ About the same ☐₄ Somewhat worse now ☐₅ Much worse now than	than 1 year ag		
ty	e following items are about activities pical day. Does your health now limit so, how much?		Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
3	Vigorous activities, such as running participating in strenuous sports	ng, lifting heavy objects,			
4	Moderate activities , such as movi vacuum cleaner, bowling, or playing		\square_1	\square_{2}	
5	Lifting or carrying groceries				
6	Climbing several flights of stairs				
7	Climbing one flight of stairs				
8	Bending, kneeling or stooping			\square_{2}	\square_3
9	Walking more than a mile				3
10	Walking several blocks				\square_3
11	Walking one block				\square_3
12	Bathing or dressing yourself				
No	ot Done Codelist: 1 Participant refused 2 Clinici	an unable to obtain 3 Insufficient	t time 4 Instrumer	nt failure 5 No	ot required



	Center Number:	Participant Number:	Participant's Initials	first middle last
Rand SF-36 (continued)				
During the past 4 weeks, have y with your work or other regular	•	-		
physical health?	,		Yes	No
13 Cut down on the amount of	time you spent on	work or other activities		
14 Accomplished less than yo	u would like			
15 Were limited in the kind of w	ork or other activiti	es		
16 Had difficulty performing the (for example, it took extra effort)		ivities		
During the past 4 weeks, have y your work or other regular dails	-	-		
problems (such as feeling depresse	ed or anxious)		Yes	No
17 Cut down on the amount of ti	ime you spent on w	ork or other activities		
18 Accomplished less than you	would like			
19 Didn't do work or other activ	ities as carefully as	usual		
20 During the past 4 weeks, to very problems interfered with you neighbors or groups?	-		□, Not at a □, Slightly □, Modera □, Quite a □, Extreme	ately bit
21 How much bodily pain have	you had during the	past 4 weeks?	None Very mi Mild Modero Severe Very se	ate
22 During the past 4 weeks, how interfere with your normal we and housework)?		ork outside the home	Not at a A little b Modera Quite a	oit ately bit



Center Number: Participant Number:	Participant's Initials:	first middle last
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RAND SF-36 (continued)

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

been teeling.						
How much of the time during the past 4 weeks	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	
23 Did you feel full of pep?			\square_3	4	5	6
24 Have you been a very nervous person?			\square_3	4	5	6
25 Have you felt so down in the dumps that nothing could cheer you up?			\square_3	4		
26 Have you felt calm and peaceful?			\square_3	4	5	
27 Did you have a lot of energy?			\square_3	4	5	
28 Have you felt downhearted and blue?			\square_3	4	5	6
29 Did you feel worn out?			\square_3	4	5	6
30 Have you been a happy person?			\square_3	4	5	6
31. Did you feel tired?			\square_3	4	5	6
32 During the past 4 weeks, how much of the tim your physical health or emotional problems interfered with your social activities (like visiting to relatives, etc.)?		All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
How true or false is each of the following statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easier than other pe	eople.			\square_3	4	5
34 I am healthy as anybody I know.			\square_{2}	\square_3		5
35 I expect my health to get worse.				\square_3	4	5
36 My health is excellent.			\square_{2}	\square_3		5



		Center Number:	Participant Number:	Participa	nt's Initials: first middle last
Da	te:/	OR Not done → Spec	cify reason (use codelist below	v):	
В	OI-II				
Ins	pick out the one weeks, including	ire consists of 21 groups of sta e statement in each group that g today. Check the box beside ach group, including item 16 a	best describes the way you the statement you have pic	have been feeling du	ring the past two
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the \square_2 I am sad all of the time \square_3 I am so sad or unhapped.	е		
2	Pessimism:	 □₀ I am not discouraged □₁ I feel more discouraged □₂ I do not expect things □₃ I feel my future is hope 	l about my future than I us to work out for me		
3	Past failure:	 □₀ I do not feel like a fail □₁ I have failed more tha □₂ As I look back, I see c □₃ I feel I am a total failu 	n I should have 1 lot of failures		
4	Loss of pleasure:	 □₀ I get as much pleasure □₁ I don't enjoy things as □₂ I get very little pleasur □₃ I can't get any pleasur 	much as I used to e from the things I used	to enjoy	
5	Guilty feelings:	\square_0 I don't feel particularly \square_1 I feel guilty over many \square_2 I feel quite guilty most \square_3 I feel guilty all of the ti	things I have done or so of the time	hould have done	
6	Punishment feelings:	☐ I don't feel I am being ☐ I feel I may be punishe ☐ I expect to be punishe ☐ I feel I am being punishe	ed d		
7	Self-dislike:	 □₀ I feel the same about □₁ I have lost confidence □₂ I am disappointed in r □₃ I dislike myself 	in myself nyself		
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to	o obtain 3 Insufficient time	4 Instrument failure	5 Not required



		Center Number: Participant Number: Participant's Initials: list middle last
В	DI-II (continued)	
8	Self-criticalness:	 □₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9	Suicidal thoughts or wishes:	 □₀ I don't have any thoughts of killing myself □₁ I have thoughts of killing myself but I would not carry them out □₂ I would like to kill myself □₃ I would kill myself if I had the chance
10	Crying:	□₀ I don't cry any more than I used to □₁ I cry more than I used to □₂ I cry over every little thing □₃ I feel like crying, but I can't
11	Agitation:	 □₀ I am no more wound up or restless than usual □₁ I feel more restless or wound up than usual □₂ I am so restless or agitated that it's hard to stay still □₃ I am so restless or agitated that I have to keep moving or doing something
12	Loss of interest:	 □₀ I have not lost interest in other people or activities □₁ I am less interested in other people or things than before □₂ I have lost most of my interest in other people or things □₃ It's hard to get interested in anything
13	Indecisiveness:	 □₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14	Worthlessness:	□₀ I do not feel I am worthless □₁ I don't consider myself as worthwhile and useful as I used to □₂ I feel more worthless as compared to other people □₃ I feel utterly worthless
15	Loss of energy:	 □₀ I have as much energy as ever □₁ I have less energy than I used to have □₂ I don't have enough energy to do very much □₃ I don't have enough energy to do anything



	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	☐ I sleep somewhat m ☐ I sleep somewhat le ☐ I sleep a lot more the ☐ I sleep a lot less that ☐ I sleep most of the co	ore than usual ess than usual an usual n usual		
17 Irritability:	\square_0 I am no more irritable t \square_1 I am more irritable t \square_2 I am much more irrit \square_3 I am irritable all of t	han usual table than usual		
18 Changes in appetite:	, My appetite is some	ewhat greater than usual n less than before n greater than usual at all	ite	
19 Concentration difficulty:	☐ l can concentrate as ☐ l can't concentrate as ☐ lt's hard to keep my ☐ l find I can't concen	as well as usual mind on anything for very lo	ng	
20 Tiredness or fatigue:	\square_2 I am too tired or fati	or fatigued than usual atigued more easily than usua igued to do a lot of the things igued to do most of the things	s I used to do	
21 Loss of interest in sex:			est in sex	



	Center Number:	Participant N	Number:	Participant's Ir	first middle last				
Date completed:/	Date completed:/OR Not done → Specify reason (use codelist below):								
Profile of Mood States	Profile of Mood States								
Instructions: Please describe how you	y 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 Friendly					4				
2 Tense	\square_{o}		\square_{2}	\square_3	4				
3 Angry				\square_3	4				
4 Worn out	\square_{o}		\square_{2}	\square_3	4				
5 Unhappy				\square_3	4				
6 Clear-headed	\square_{o}			\square_3	4				
7 Lively				\square_3	4				
8 Confused	\square_{o}		\square_{2}	\square_3	4				
9 Sorry for things done					4				
10 Shaky			\square_{2}		4				
11 Listless				\square_3	4				
12 Peeved	\square_{o}		\square_{2}	\square_3	4				
13 Considerate					4				
14 Sad			\square_{2}	\square_3	4				
15 Active				\square_3					
16 On edge	\square_{o}		\square_{2}	\square_3	4				
17 Grouchy	\square_{o}			\square_3	4				
18 Blue	\square_{o}			\square_3	4				
19 Energetic									
20 Panicky	\square_{o}		\square_{2}	\square_3	_4				
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Not Done Codelist: 1 Participant refused	2 Clinician unable to a	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N Participant's I	ot required nitials:				



	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					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

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	Center Number:	Participant Number:		Participant's Initials:		
Profile of Mood States	continued)					
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely	
44 Gloomy	\square_{o}			\square_3	4	
45 Desperate				\square_3	4	
46 Sluggish	\square_{o}		\square_2	\square_3	4	
47 Rebellious					4	
48 Helpless				\square_3	4	
49 Weary				\square_3	4	
50 Bewildered				\square_3		
51 Alert				\square_3	4	
52 Deceived				\square_3		
53 Furious					4	
54 Efficient				\square_3		
55 Trusting						
56 Full of pep				\square_3		
57 Bad-tempered						
58 Worthless				\square_3		
59 Forgetful				\square_3	4	
60 Carefree					4	
61 Terrified					4	
62 Guilty				\square_3		
63 Vigorous						
64 Uncertain about things				\square_3	4	
65 Bushed						

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Center Number:	Participant Number:		Participant's	s Initials:	irst middle last		
Date completed:/ OR Not done → Specify reason (use codelist below):							
Perceived Stress Scale (PSS)							
Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.							
	Never	Almost Never	Some- times	Fairly Often	Very Often		
In the last month, how often have you felt that you unable to control the important things in your life?	were				4		
2 In the last month, how often have you felt confider your ability to handle your personal problems?	nt about		\square_{2}	\square_3	4		
3 In the last month, how often have you felt that thin going your way?	gs were			\square_3	4		
4 In the last month, how often have you felt difficulti piling up so high that you could not overcome ther				\square_3			
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficient time 4	Instrument f	ailure 5	Not requir	red		



	Center Number: Participan	t Number:	Partic	cipant's Initials	first middle last			
Da	Date completed:/OR Not done → Specify reason (use codelist 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: Participar	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_{o}			



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	OR Not done → Specify	reason (use codelist below):	_	
Derogatis Interview for Se	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	o				4	5			8		
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)	o			3	4	5					
1.3 Erotic or romantic situations				3	4	5	6		8		
1.4 Caressing, touching, undressing, or foreplay					_4	5			8		
1.5 Sexual intercourse, oral sex, touching to orgasm					4	5			8		
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Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required											



	Center Number:	Pa	ırticipant N	umber: _		Par	rticipant's	Initials:	st middle last
Derogatis Interview for Se	xual Functi	on (DIS	F-SR) (F)	Female \	/ersion (d	ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the lotime you filled out this inventory, how did you have the following experience	often all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while a	lone				4	5	6		8
2.2 Actively seek sexual satisfaction	on				4	5	6	7	8
2.3 Feel sexually aroused with a partner					4	5	6		8
	Never	Rarely	Sometimes	Usually	Always				
2.4 Have normal lubrication with masturbation					4				
2.5 Have normal lubrication throughout sexual relations									

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Center N	umber:	Po	articipant N	lumber: _		Po	ırticipant's	Initials:	rst middle last
Derogatis Interview for Sexual	Functi	on (DIS	SF-SR) (F)	Female \	/ersion (d	ontinue	d)		
Section 3—Sexual Behavior/Experience									
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			□ ₈
3.3 Casual kissing and petting				3	4	5	6		8
3.4 Sexual foreplay					4	5	6		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					4				
4.2 The intensity of your orgasm					4				
4.3 The ability to have multiple orgasms (if typical for you)					4				
4.4 Feelings of closeness and togetherness with your partner					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					

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Cen	ter Number:		Participant	Number:		P	articipant's	s Initials:	first middle last		
Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)											
Section 5—Drive and Relationship											
	Not at all	Less than 1 per	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		

	all	than 1 per month	per month	week	per week	per week	day	per day	more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?				3	4	5		7	8
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?				3	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?				3	4	5	6		8

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Baseline Submission 1

Calente			Visit 2
	Center Number:	Participant Number:	Participant's Initials: First middle last
Date completed:doy /	- OR Not done → Specif	y reason (use codelist below):	_
Derogatis Interview for S	exual Function	(DISF-SR) (M) Male Version	
Instruction: Below you will find a brief sections that ask about different aspects while another inquires about the kinds o sexual arousal and the quality of your relationship.	of your sexual experiences to	es. One section asks about sexual hat you have. You are also asked a	fantasies or daydreams, bout the nature of your
On some questions you are asked to activities asked about in that section. Sor frequency scales range from "0 = never" of a satisfaction scale. This type of scale Some satisfaction scales range from "0 = "0 = not at all satisfied," to "4 = extreme	me frequency scales go fr " to "4 = always." In the content tells how much you enjoy = could not be worse" to "	om "O = not at all" to "8 = four or case of other questions, you will be ed, or were satisfied by the sexual	more times a day." Other asked to respond in terms activity being asked about.
In every section of the inventory the follow. Although it is brief, take your time describes your personal experience	e with the inventory. For		
If you have any questions, please ask the	e person who gave you t	he inventory for help.	
Continuit Committee /Far			

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		8		
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	\Box_{o}			\square_3	4	\square_5			8		
1.3 Erotic or romantic situations					4	5			8		
1.4 Caressing, touching, undressing, or foreplay	По					5			8		
1.5 Sexual intercourse, oral sex, touching to orgasm	По				4	5			8		
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Not Dono Codolist: 1 Participant refused 2 Clinician un	able to ob	tain 3	Incufficion	at time	1 Instrum	ont failur	5 N.	ot roquire	, <u>d</u>		



	Center Numb	oer:	Part	ricipant Nu	mber:		Part	icipant's lı	nitials:	st middle last
Derogatis Interview for Se	exual Fu	unctio	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 oft you have the following experiences?	en did	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 awakeni	ing	o				4	5	6	7	8
2.2 A full erection during a sexual fantasy or daydream	al	o			\square_3		5	6		
2.3 A full erection while looking a sexually arousing person, mapicture		□ _o				4	5	6	7	8
2.4 A full erection during mastur	bation	□ _o					5	6		8
2.5 A full erection throughout the of a normal sexual response that is from undressing and full through intercourse and organization.	cycle, oreplay	o				4	5	6	7	8

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Participant's Initials: first middle last

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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		6		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									

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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	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?				\square_3	\square_4	5	□ ₆	_ ₇	□ ₈
	Not at	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					
	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			8

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		Center Number:	Participant Nun	nber:		Participar	nt's Initials:	first middle last					
Da	te completed:/ _{month} /	OR Not done →	Specify reaso	on (use code	elist below)	:	-						
Fo	Food Cravings Questionnaire—Trait												
Ple	Please indicate the extent to which you agree with each statement below, in general, by checking the appropriate box.												
			Never OR NA	Rarely	Some- times	Often	Usually	Always					
1	Being with someone who is me hungry.	eating often makes				4	5						
2	When I crave something, I k stop eating once I start.	know I won't be able to	P			4	5						
3	If I eat what I am craving, I eat too much.	often lose control and				4	5						
4	I hate it when I give in to cre	avings.			\square_3	4	5	6					
5	Food cravings invariably me get what I want to eat.	ake me think of ways t	0										
6	I feel like I have food on my	mind all the time.			\square_3	4	5	6					
7	I often feel guilty for craving	g certain foods.			\square_3		5						
8	I find myself preoccupied w	ith food.			\square_3	4	5	6					
9	I eat to feel better.				\square_3	4	5						
10	Sometimes, eating makes th	ings seem just perfect.			\square_3	4	5						
11	Thinking about my favorite mouth water.	foods makes my											
12	I crave foods when my ston	nach is empty.			\square_3	4	5	6					
13	I feel as if my body asks for	certain foods.				4	5						
14	I get so hungry that my stor bottomless pit.	mach seems like a					5	6					
15	Eating what I crave makes i	me feel better.				4							
16	When I satisfy a craving, I f	eel less depressed.			\square_3		5						
17	When I eat what I am cravi about myself.	ng, I feel guilty			\square_3								
18	Whenever I have cravings, plans to eat.	I find myself making					5						
19	Eating calms me down.				\square_3	4	5	6					
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obtain	a 3 Insufficie	ent time 4	Instrument	failure	5 Not requ	ired					



	Center Number:	Participant N	Numb	er:		Participan	t's Initials:	first middle last
Food Cravings Question	naire—Trait (continu	ed)						
		Nev OR I		Rarely	Some- times	Often	Usually	Always
20 I crave foods when I am bor	red, angry, or sad.],		\square_3	4	5	
21 I feel less anxious after I eat	l.],			4	5	
22 If I get what I am craving, I eating it.	cannot stop myself fro	om _],			4	5	
23 When I crave certain foods, I soon as I can.	usually try to eat them	as],		\square_3	4		
24 When I eat what I crave, I fe	eel great.],		\square_3	4		6
25 I have no will power to resis	st my food crave.]1		\square_3	4	5	6
26 Once I start eating, I have tr	ouble stopping.],		\square_3		5	6
27 I can't stop thinking about e hard I try.	ating, no matter how],		\square_3	4		
28 I spend a lot of time thinking will eat next.	g about whatever it is	I],		\square_3	4		6
29 If I give in to a food craving,	, all control is lost.],		\square_3	4		
30 When I'm stressed out, I cra	ve food.],		\square_3	4		
31 I daydream about food.],		\square_3	4		
32 Whenever I have a food cra about eating until I actually		ng],		\square_3	4	5	6
33 If I am craving something, the consume me.	noughts of eating it],		\square_3	4		
34 My emotions often make me	e want to eat.],		\square_3	4		
35 Whenever I go to a buffet, I than what I needed.	end up eating more],		\square_3	4		
36 It is hard for me to resist the appetizing foods that are in],		\square_3	4	5	6
37 When I am with someone who usually overeat too.	no is overeating, I],		\square_3	4		6
38 When I eat food, I feel comf	orted.],		\square_3	4	5	
39 I crave foods when I'm upse	et.],		\square_3			



		С	enter Number:		Participant Number:	Participant's Initials:	first middle last
Date completed: _	/_	 /	OR Not do	ne –	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].				4	
2	I'm craving [one or more specific foods].			\square_3		5
3	I have an urge for [one or more specific foods]			\square_3		
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3		
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3		5
6	Eating [one or more specific foods] would feel wonderful.		\square_{2}	\square_3	\square_{4}	
7	If I ate something, I wouldn't feel so sluggish and lethargic.			\square_3		
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.				4	
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		5
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			\square_3		
13	I am hungry.			\square_3		
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		5



Center Numb	er: Pa	rticipant Number:		Participant's	Initials:
Date completed:/OR					tirst middle idst
Food Craving Inventory (FCI-II)					
For each of the foods listed below, please check the ap	propriate box.				
Note: A craving is defined as an intense desire to cons	-	ır food or food 1	ype that is diff	icult to resist.	
Over the past month, how often	Never	Rarely	Sometimes	Often	Always/Almost
have you experienced a craving for		(once or twice)		——————————————————————————————————————	Every Day
1 Cake	L ₁			4	5
2 Pizza			\square_3	4	5
3 Fried chicken			\square_3	4	
4 Gravy			\square_3	4	
5 Sandwich bread				4	
6 Sausage					
7 French fries				4	
8 Cinnamon rolls					
9 Rice				4	
10 Hot dog			\square_3		
11 Hamburger			\square_3	4	
12 Biscuits			\square_3		
13 Ice cream			\square_3	4	
14 Pasta					
15 Fried fish				4	
16 Cookies					
17 Chocolate				4	
18 Pancakes or waffles					
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		
26 Bacon					
27 Steak				4	
28 Baked potato					
Not Done Codelist: 1 Participant refused 2 Clinician un	nable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	Not required



		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	t 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.	, True	o False
6	I deliberately take small he	elpings as a means (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	₁ 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.		, True	o False
11	Since my weight goes up o more than once.	nd down, I have go	ne 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.	, True	o False
14	I have a pretty good idea	of the number of ca	lories in common food.		☐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	se I have gotten used	₁ 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	in 3 Insufficient time 4 Instrumen	t failure 5 N	ot required



Baseline Submission 1

	Cen	rer Number: Participant Number:	Participant's Ir	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 oft right away.	en 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	n 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.	, True	o False
29	I sometimes get very hungry lat	re in the evening or at night.	☐₁ True	□₀ False
30	I eat anything I want, any time	I want.	₁ True	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 r	neans of controlling my weight.	☐₁ True	o False
33	I do not eat some foods becaus	e 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 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?	\square_1 Rarely \square_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	☐₂ Slightly likely ☐₄ 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."	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of ☐₄ Describes me perfectly	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 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, v □₁ Usually eat whatever you □₂ Often eat whatever you w □₃ Often limit food intake, b □₄ Usually limit food intake, □₅ Constantly limiting food in	want, whenever you want it vant, whenever you want it ut often "give in" rarely "give in"



		Center Nu	umber:	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.

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	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			8			
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				8			
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			
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.				\square_3			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	required	<u> </u>		

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					Very confident that you can resist the desire to eat					
	0	1	2	3	4	5	6	7	8	9	
10 I can resist eating when I am reading.				\square_3			6		8		
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.				\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	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.							6		8	9	
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	9	
20 I can resist eating when I am happy.											



		Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last			
Da	Date completed:/OR Not done → Specify reason (use codelist below):												
M	Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)												
Ins	Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.												
				Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always			
1	Fasting is a good way to lose	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.	y 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.				\square_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		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.					4	5	6				
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			



Center Nun	nber: Pari	ticipant N	umber: _		Pai	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of Eating	Disorder Sy	mpto	ms (/	MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being ov	erweight.			\square_3	4	5	6	
21 When I feel bloated, I must do something of that feeling.	to rid myself			\square_3	4	5		
22 I overeat too frequently.				\square_3			6	
23 It's okay to be overweight.				\square_3	4	5	6	
24 Recently I have felt that I am a worthle	ess person.			$\square_{_3}$	4			
25 I would be very upset if I gained 2 pou	unds.			\square_3	4	5	6	7
26 I crave sweets and carbohydrates.				\square_3	4	5		
27 I lose control when I eat.					4	5	6	7
28 Being fat would be terrible.				\square_{3}	4			
29 I have thought seriously about suicide	lately.			\square_3	4			7
30 I don't have any energy anymore.				\square_{3}	4	5	6	
31 I eat small portions to control my weig	ht.				4	5	6	7
32 I eat 3 meals a day.					4	5		
33 Lately I have been easily irritated.				\square_3	4	5	6	7
34 Some foods should be totally avoided.				\square_{3}	4	5		
35 I use laxatives to control my weight.					4	5		7
36 I am terrified by the thought of being o	overweight.			\square_{3}	4			
37 Purging is a good way to lose weight.					4			7
38 I avoid fatty foods.				\square_3	4	5	6	7



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	6	
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	6	
48 I am too fat.					5		
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			4	5	6	
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:	Participant N	Number: _		Par	ticipant's I	nitials:	t middle last
Da	te completed:/ _{month} /	OR Not done =	→ Specify re	ason (use	codelist b	elow):			
В	ody Shape Questionnai	re (BSQ)							
	would like to know how you have b ase read each question and check th		•	_					
Ov	er the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you	brood about your sl	hape?			\square_3	4	5	
2	Have you been so worried a have been feeling that you o		t you			\square_3	\square_{4}	5	
3	Have you thought that your too large for the rest of you?		m are			\square_3	4	5	6
4	Have you been afraid that you fatter)?	ou might become fat	(or			\square_3	\square_{4}	5	6
5	Have you worried about you enough?	ur flesh not being firn	n			\square_{3}	4	5	
6	Has feeling full (e.g., after eating fat?	a large meal) made you	feel			$\square_{_3}$		5	6
7	Have you felt so bad about y cried?	your shape that you	have			\square_3	4	5	6
8	Have you avoided running b wobble?	ecause your flesh mi	ght			\square_3	4	5	6
9	Has being with thin women/ self-conscious about your sho					\square_3	4	5	6
	Have you worried about you sitting down?					\square_3	4	5	
11	Has eating even a small amo fat?	ount of food made yo	ou feel			\square_{3}	4	5	6
	Have you noticed the shape felt that your own shape con	npared unfavorably?)				4	5	6
13	Has thinking about your sha ability to concentrate (e.g., whil to conversations)?					3	4	5	
14	Has being naked, such as wl feel fat?	hen taking a bath, m	ade you			\square_3	\square_{4}	5	6
15	Have you avoided wearing a particularly aware of the sho		/OU			\square_3	4	5	6
16	Have you imagined cutting a body?	off fleshy areas of yo	ur			\square_3	4	5	6
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insuff	icient time	4 Instru	ıment failu	re 5 N	lot require	ed



	Center Number:	Participant N	umber: _		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?	es or other high calorie fo	od made			\square_3	4		
18 Have you not gone out because you have felt b		arties)			\square_3	\square_4	5	6
19 Have you felt excessive	ly large and rounded?				\square_3	4	5	
20 Have you felt ashamed	of your body?				3	4	5	6
21 Has worry about your s	shape made you diet?				\square_3	4	5	6
22 Have you felt happiest stomach has been empt		our .			\square_3	4	5	
23 Have you thought that y because you lack self-co		e			\square_3	4	5	
24 Have you worried about flesh around your waist		ls of			\square_3	\square_4	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 or	der to feel thinner?				\square_3	4	5	6
27 When in company, have much room (e.g., sitting on a		ng up too			\square_3	4	5	
28 Have you worried abou	ut your flesh being dimply	·?			\square_3	\square_4	5	
29 Has seeing your reflecti you feel bad about you		ow) made			\square_3	4	5	6
30 Have you pinched area fat is there?	s of your body to see hov	v much			\square_3	\square_{4}	5	
31 Have you avoided situate 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	?				4	5	
33 Have you been particul shape when in the com		your					5	6
34 Has worry about your sto exercise?	shape made you feel you	ought				4	5	6



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

Baseline Submission 1 Visit 3

niddle last
_

3 Insufficient time

4 Instrument failure

5 Not required

Participant's Initials:

Participant Number:

Center Number:

calerie Phase 2

Se	ven-L	Seven-Day Physical Activity Recall (PAR)	Activ	rity Reca	(PAR)											
Tod	Today's date:	ie:/		Day	Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Speafy reason (use codelist below):	Mon Tue	ss Med	Thurs	Fri	at Sur	OR Not	done →	Specify re	ason (use	sodelist bela	
_	Were yo	oyed	last seve	ın days?		°Z °	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	stion 3	Tes				Interv	Interviewer initials:		first middle last
7	If Yes: W	If Yes: Which days (check all that apply)?	hat apply)".	٥.		Mon	Mon Tues Wed Thurs Fri	Med	Thurs	Ш	Sat	Sun				
8	Which d	Which days do you consider your weekend, or non-work, days?	r your v	veekend, or no	on-work, days?	Mon	Tues [Wed Thurs		Fri	Sat	Sun				
Day	Jo vod			Sleep	Sleep Time	Work Time	Time	Mor	Morning (in minutes)	utes)	After	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
#	Week	Date		ln Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
(yester-day)		/	year		00:00 to 23:59 00:00 to 23:59 00:00 to 23:59											
9			year				00:00 to 23:59									
5		/	year		00:00 to 23:59 00:00 to 23:59 											
4		/	year			00:00 to 23:59	00:00 to 23:59									
3		/	уеаг		:		00:00 to 23:59									
4			year	00:00 to 23:59	: : : : : : : : : : : : : : : : : : :											
1 (1 week ago)		/	year	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: Farticipant'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)? More
In	erviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? No Yes
6	Do you think this was a valid Seven-Day PAR interview? No Yes
7	Were there any activities reported by the participant that you don't know how to classify?



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



4 Instrument failure

5 Not required

	Center Number:	Participant Number: F	Participant's Initials:
Clinic Weight			
Weight date and time	:/	3:59 Sto	aff initials: First middle last
OR Not done → Spec	ify reason (use codelist below):		iis iiiede ies
Clinic weight (if the two	o measurements are more than 0.1 kg apart, med	asure 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

Participant's Initials: first middle last

Participant Number:

Center Number:

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

5 Not required

4 Instrument failure

7705 CRF, page 75



		Center Number:	Participant Number:	Participant's Initials: _	irst middle last
S	even-Day Physical Activi	ty Recall (PAR) (continued)		
4	Compared to your physical activity or or about the same (check only one)?	ver the past three mont	hs, was last week's physico	l activity more, less,	
Int	erviewer: Please answer questions b	pelow and note any cor	mments on interview.		
5	Were there any problems with the Se	ven-Day PAR interview	?		
6	Do you think this was a valid Seven-E	Day PAR interview?			
7	Were there any activities reported by □ ₀ No □ ₁ Yes	the participant that yo	u don't know how to classi	fy?	



		Center Number	: Participant Num	ber: Part	icipant's Initials:	
Hai	Handgrip Strength					
	Date and time of assessment:/					
1 D	ynometer handle position	n:				
2 D	ominant hand (check only	one): 🔲 1 Left 🔠 2 Right				
3 H	andgrip 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	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required					



			Center Number:	Participant Number: _	Particip	pant's Initials:
Is	sometric/Isokine	tic Kne	e Extension and	l Flexion		
Do	ate and time of assessment	:/_	month year	00:00 to 23:59	Staff ini	first middle last
O	R Not done → Specify rea	son (use cod	delist below):			
1	Recent injury or pain—rig	ht knee?	O No 1 Yes			
2	Recent injury or pain—lef	t knee?				
3	Specify machine used (PE	BRC only): [
	All values corrected	for gravit	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	
No	ot Done Codelist: 1 Particip	ant refused	2 Clinician unable to ob	tain 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	osing:/ _{month} /	year 00:00 to 23:59	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 C	Collected
	Day 0 (Visit 4)	DOα	/	00:00 to 23:59
		DOP	/	: 00:00 to 23:59
	Day 7 (Visit 5)	D7a	/	00:00 to 23:59
		D7b	/	: 00:00 to 23:59
	Day 14 (Visit 7)	D14a	/	
		D14b	/	: 00:00 to 23:59
5	Affix CRF page label(s) co	orresponding 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: ${day} / {month} / {year} = {00:00 \text{ to } 23:59}$ OR Not done \rightarrow Specify reason (see Codelist below):	Staff initials: First 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 Instrume	ent failure 5 Not required



5 Not required

		Center Number:	Participant Num	ber:	Participant's Initials: First middle last
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	Rest ECG: Rhythm (check only one): Ventricular conduction (che	\Box_1 Sireck only one): \Box_1 No		orillation	
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 Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress in Orthopedic/extremity complaints (particular (specify):	mage study, complete	ischemic ECG chan	ges occurred:	bpm or ₉₆ NA bpm or ₉₆ NA
6	Did frequent ventricular ectopy occur No Yes → If Yes: When did it occur (c	_			y
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:	_		between the firm b RER ≥ 1.1	eau in VO₂ (change ≤ 150 mL) nal two stages om of age-predicted maximum
9	Exercise time: : : seconds				
10	Blood pressure at VO ₂ peak/VO ₂ ma	x:/	mm Hg ic		
11	Borg RPE score at VO ₂ peak/VO ₂ ma	x: (6-2	0)		
12	Peak RER:				
13	B 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

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

Pole	Too	Todav's date:	į.	_	_	Todav's date: / Day (check only	(check only one):	Mon	Med Se	Thurs	Fi	Sun	OR Not	done 1	specify re	dson (use	codelist bela	:(wc
Which days (seed of that copy)?	_	Were yo	ov empl	oyed in t	the last seve			o Z	Skip to que	estion 3	, Yes]			Interv	iewer ini	ials:	middle last
Which days do you consider your weekend, or non-work, days? I won find the days do you consider your weekend, or non-work, days? I won find the day and in the days. I won find the days.<		If Yes: V	Which do	ays (check	call that apply)	٥.		Mon	Tues			Ē		unç				
Day of week Date Step Time Work Time Modinaria (in montred) Attention (in montred) Evening (in montred) Evening (in montred) Week In Bed Upp Start Stort Stort Stort Stort Stort Modinary Modi	က	Which 6	days do	you con	sider your	weekend, or n	on-work, days?			Wed	Thurs			nno				
March Mode Line Bold Up Start Stop Mode Hard Mode Hard Mode Hard Mode Hard Mode Hard Hard Mode Hard Hard Hard Hard Mode Hard Ha	Dav	_				Sleek	. Time	Work	Time	Woru	iing (in mir	iutes)	Afteri	ioon (in mi	nutes)	Ever	ing (in min	utes)
day / month / year 00000 is 23.59 00000 is 23.59 00:00 is 23.59 0	#			Date	σ.	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
day //month //monthh	(yester-day)		-/ day				00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
day /	•		-/		/ year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
day month i day i	Ŋ		-/		/ year		00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
day	4		-/		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									
day //month //month : 00:00 to 23:59 : : 00:00 to 23:59 : : : 00:00 to 23:59 : : : 00:00 to 23:59 : <t< th=""><th>က</th><th></th><th>-/</th><th></th><th>/ year</th><th>00:00 to 23:59</th><th>00:00 to 23:59 00:00 to 23:59</th><th>00:00 to 23:59</th><th>00:00 to 23:59</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></t<>	က		-/		/ 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									
day / month / year 00:00 to 23:59 00:00 to 23:59 : : : : : : : : : : : : : : : : : :	4		-/		/ year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
	(7 week		-/ day	month	/ year	00:00 to 23:59	00:00 to 23:59	. :	00:00 to 23:59									

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

5 Not required

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused



	Center Number: Participant Number: Farticipant'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)? More Less About the same
Int	terviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? No Yes
6	Do you think this was a valid Seven-Day PAR interview? No Yes
7	Were there any activities reported by the participant that you don't know how to classify?



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	finitials:
				Replacement Va	lues
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	8	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
3	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
5	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12	/ _{month} / year	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
6	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	13	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
		·			·

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



		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): First middle	last					
4	Arm injected: 1 Right	2 Left					
	Note: For each reaction, med 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	e shape of a circ dicular to it. Do r than 5 mm.	le. If the indur	ation is an oval sh ythema. Reaction	ape, first measur	e the long
	Antigen			- In			
	 Normal saline Tetanus toxoid (∏) 	A (diameter) mm	B (diameter)	Read By:	A (diameter)	B (diameter) mm	Read By:
	2 Tetanus toxoid (∏) 3 Candida	mm	mm	first middle last	mm	mm	first middle last
	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



		Center Number:	Participant Number:	Participant's Initials: initials: last
C	linic Weight			
	eight date and time:/ _{month} R Not done → Specify reason (use Coo			Staff initials: First middle last
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	eight 2:	kg		
We	eight 3:	kg		
We	eight of gown:	kg		
	ital Signs			
As	sessment date and time:/	onth year	:	
1	If waist measurement not done → S Natural waist measurement (if the first two measurements are more than Natural waist measurement 1:		natural waist circumference a third time)	Staff initials:
	Natural waist measurement 2:	·_	cm	
	Natural waist measurement 3:	·_	cm	
2	Umbilical point waist measurement (in umbilical point waist circumference a third		nts are more than 1.0 cm apart, measure	3
	Umbilical point waist measurement	1:	cm	
	Umbilical point waist measurement	2:	cm	
	Umbilical point waist measurement	3:	cm	
3	Pulse: bpm OR Not do	one → Specify reaso	n (use codelist below):	Staff initials: First middle last
4	Temperature: °C	OR Not done → Spe	ecify reason (use codelist below):	Staff initials: first middle last
5	Respirations: per minute OR	Not done → Spec	ify reason (use codelist below):	
6	Blood pressure (check only one):	Left arm \square_2 Right	arm	Staff initials:
	6a Blood pressure 1:/_	mm Hg Ti	me:: OR Not done Specify red	→ ason (use codelist below):
	6b Blood pressure 2:/_	mm Hg Ti	me:::	
	6c Blood pressure 3:/_	mm Hg Tir	me:::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable t	o obtain 3 Insufficient time 4 Ins	trument failure 5 Not required



		Center Number: Po	articipant Number:	Particip	pant's Initials:
Pregnancy	Test				
Complete only	for females.				
No	Yes: Date urine pregna Results: 1 Nega 2 Positiv	ncy test performed:/_	/year		
Core Temp	erature				
Staff Initials		ride Date of llection/Procedure		of Sample n/Procedure	If Not Done, Reason (Use codelist below)
		itart Date:		rt Time _ : 0 to 23:59	
first middle last		itop Date:/		p Time _ : 0 to 23:59	
Inpatient A	Admission and	Discharge			
		/			
Not Done Codelis	st: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient time	4 Instrument failure	5 Not required

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Tod	Today's date:	ie		^/	Today's date:/	one):	Mon Tues Wed Thurs Fri Sat Sun OR Not done → Speafy reason (use codelist below):	ss Wed	Thurs	Fri S	at Sur	OR Not	done 1	Specify re	esn) uospa	codelist bel	ow):
_	Were yo	on emp	y loyed in	e last sev	en days?		°Z °	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	estion 3	Types Yes				Interv	Interviewer initials:	ials: first	first middle last
7	If Yes: V	Vhich d	l ays (check	If Yes: Which days (check all that apply)?	ر) خ		Mon	Tues Wed		Thurs	Œ E	Sat	Sun				
m	Which o	lays dc	you con	ısider your	weekend, or no	Which days do you consider your weekend, or non-work, days?	Mon	Tues Wed	Ш	Thurs	Fri	Sat	Sun				
200	Day of				Sleek	Sleep Time	Work Time	Time	Morr	Morning (in minutes)	nutes)	Affen	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	nutes)
#	Week		Date	Φ	ln Bed	dη	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
7					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									
•		day	/ — — / month	/	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
rO.		day	, — — month	/ year		00:00 to 23:59	00:00 to 23:59										
4		day	, — — — — — — — — — — — — — — — — — — —	/year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
n		day		/year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
7		/	/	/year				00:00 to 23:59									
T week ago)		day		year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									

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5 Not required

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused



	Center Number: Participant Number: Farticipant'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)?
In	erviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview? No Yes
6	Do you think this was a valid Seven-Day PAR interview? No Yes
7	Were there any activities reported by the participant that you don't know how to classify?



		Center Number:	_ Participant Number: _	Partici	pant's Initials:				
Outcomes Labs									
Date and time of last med				5 9 -					
	Sample		Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials				
Cat	techolamines		o No		first middle last				
	Blood	_	□ ₀ No □ ₁ Yes		first middle last				
Oral glucos	e tolerance test	1()(¬1 1 1)	o No		first middle last				
If a sample is not obtained,	indicate with a N	Not Done.							
Biopsy Labs									
Sample		Date of (collection	If Not Done, Reason (Use codelist below)	Staff Initials				
Muscle biops	Бу	/	/		first middle last				
Fat biopsy		/	/		first middle last				
24-hour Urine Collection									
Total Volume Collected		Date of le Collection	Time of Sample Collectio	If Not Dor Reason (Use codelist b	Staff Initials				
	Si	rart Date:	Start Time:						
mL	/ day m	onth year	00:00 to 23:59		first middle last				
	Si	top Date:	Stop Time:						
	/	onth year	00:00 to 23:59						
Not Done Codelist: 1 Par	ticipant refused	2 Clinician unable to o	btain 3 Insufficient time	4 Instrument failure	5 Not required				
	pain released	_ = ===================================	- Instruction line	- I monomoni randre	2 1 (5) 1540H64				



	Center Number:	Participant Number:		Participant's Initia	first middle las
Sex Hormone					
If Not Done → Specify reason (use codelist	below):				
Contraception method (females only):	None OR C	heck all that apply: Oral contraceptive - Other → Specify (e	Record on Co	ncomitant Medico	itions page
Day 1	ı	Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Day 1 of menses (females only)					
Date and time of last meal (males only)	/	/	00:00 to 23:59		
Hormone level blood draw 1 (males only		/	00:00 to 23:59		first middle last
Hormone level blood draw 2 (females on Progesterone level	 y 				
Day 2	ı	ate	Time	If Not Done, Reason (use codelist)	Staff Initials
Date and time of last meal					
Hormone level blood draw 3 (females on Progesterone level	l y)				
DXA Scan					
 Has the participant taken a calcium su □ No □ Yes → If Yes: Proceed w Were any studies involving barium or □ No □ Yes 	ith scan and document				,
DXA Scan			OXA Rescan O	RNA	
Date of scan:/		Date of rescan:	/ _{month}	_ /	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Area Scar Check all the		
☐ Whole body			Whole body		
Not Done Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient tim	e 4 Instrument	failure 5 Not re	eauired

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	Center Number: Participant Number	Particip	ant's Initials: first middle last
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☐ Tufts-006 (623-006)☐ WASH U-002	·	016 (623-005) 017 (623-001)
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 8			first middle last
Cart ID	☐ Tufts-003 (623-002) ☐ WASH U-001 ☐ Tufts-006 (623-006) ☐ WASH U-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 partic	i pant assigned (check o	only one):		
Intervention				
Did participant start intervention? □₀ No → Complete the Study comp □₁ Yes → If Yes: Date intervention s				
Staff Signature NOTE: Signature	re of staff that randon	nized participant		
Signature:		Date:	:/	_

Month 1 Submission

		Center Number:	Participant Number:	Participant's Initials: itst middle last
C	linic Weight			
W	eight date and time:/		:	Staff initials:
	R Not done → Specify reason (us		TO 23:39	first middle last
Cli	nic weight (if the first two measuren	nents are more than 0.1 kg ap	art, measure weight a third time):	
W	eight 1:	_ . kg		
W	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 mor		st below): atural waist circumference a third time):	Staff initials: first middle last
	Natural waist measurement 1:	·		
	Natural waist measurement 2:	·_	cm	
	Natural waist measurement 3:	·	cm	
2	Umbilical point waist measurement umbilical point waist circumference a		are more than 1.0 cm apart, measure	
	Umbilical point waist measuren	nent 1:	cm	
	Umbilical point waist measuren	nent 2:	cm	
	Umbilical point waist measuren	nent 3:	cm	
3	Pulse: bpm OR N	ot done → Specify reason (use codelist below):	Staff initials: First middle last
4	Temperature:	°C OR Not done → Specif	y 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):			Staff initials: First middle last
	6a Blood pressure 1:systolic	/ mm Hg Time	OR Not done Specify red	ason (use codelist below):
	6b Blood pressure 2:	/ mm Hg Time	00:00 to 23:59	
	6c Blood pressure 3:	/ mm Hg Time	::	
No	ot Done Codelist: 1 Participant refu	used 2 Clinician unable to a	obtain 3 Insufficient time 4 Inst	rument failure 5 Not required



Center	Number: Participant	Number: I	Participant's Initials:				
12-Lead ECG							
Date and Time		Findings	Staff Initials				
		l					
Safety Labs							
Date and time of last meal:							
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials				
Blood	□ ₀ No □ ₁ Yes		first middle last				
Urine	□₀ No □₁ Yes		first middle last				
Contraception							
If Not Done → Specify reason (use codelist below)	:						
Contraception method (females only): □ None OR Check all that apply: □ Oral contraceptive → Specify: □ Record on Concomitant Medications page □ Other → Specify (e.g., barrier, IUD): □ Oral contraceptive → Specify (e.g., barrier, IUD):							
Not Done Codelist: 1 Participant refused 2 Clinic	cian unable to obtain 3 Insuf	ficient time 4 Instrument fo	ailure 5 Not required				

Month 1 Submission

		Center Number:	Participant Number:	Participo	ant's Initials:
Do	ate completed:/ _{mon}	/ OR Not done			
В	DI-II				
ln	pick out the one weeks, includin	ire consists of 21 groups of staten e statement in each group that be g today. Check the box beside the ach group, including item 16 and	st describes the way you statement you have pic	have been feeling d	uring the past two
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the time \square_2 I am sad all of the time \square_3 I am so sad or unhappy			
2	Pessimism:	 □₀ I am not discouraged ab □₁ I feel more discouraged a □₂ I do not expect things to □₃ I feel my future is hopele 	oout my future than I u work out for me		
3	Past failure:	 □₀ I do not feel like a failure □₁ I have failed more than I □₂ As I look back, I see a lo □₃ I feel I am a total failure 	should have of failures		
4	Loss of pleasure:	 □₀ I get as much pleasure a □₁ I don't enjoy things as m □₂ I get very little pleasure f □₃ I can't get any pleasure 	uch as I used to rom the things I used	to enjoy	
5	Guilty feelings:	\square_0 I don't feel particularly g \square_1 I feel guilty over many th \square_2 I feel quite guilty most of \square_3 I feel guilty all of the time	ings I have done or s the time	hould have done	
6	Punishment feelings:	☐ I don't feel I am being pool of I feel I may be punished ☐ I expect to be punished ☐ I feel I am being punished ☐ I feel I am being punished			
7	Self-dislike:	 □₀ I feel the same about my □₁ I have lost confidence in □₂ I am disappointed in mys □₃ I dislike myself 	myself		
N	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to ob	otain 3 Insufficient time	4 Instrument failure	5 Not required

Participant's Initials: first middle last

Month 1 Submission

		Center Number:	Participant Number:	Participant's Initials:
BDI-II (contin	nued)			
8 Self-critica	lness:	\Box_1 I am more critical \Box_2 I criticize myself for	blame myself more than usual of myself than I used to be or all of my faults everything bad that happens	
9 Suicidal the	oughts or wishes:		•	carry them out
10 Crying:		☐₀ I don't cry any mo ☐₁ I cry more than I u ☐₂ I cry over every lit ☐₃ I feel like crying, b	used to tle thing	
11 Agitation:		\square_1 I feel more restless \square_2 I am so restless or	und up or restless than usual s or wound up than usual agitated that it's hard to stay s agitated that I have to keep m	
12 Loss of int	erest:	, I am less interested	erest in other people or activitied in other people or things that f my interest in other people or erested in anything	n before
13 Indecisive	ness:	•	cult to make decisions than usua ter difficulty in making decision:	
14 Worthless	ness:		yself as worthwhile and useful ess as compared to other peop	
15 Loss of en	ergy:			

Participant's Initials: first middle last

Month 1 Submission

	Center Number:	Participant Number:	Participant's Initials:	middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	\square_1 I sleep somewhat more \square_2 I sleep somewhat less that \square_3 I sleep a lot more than \square_4 I sleep a lot less than upon \square_5 I sleep most of the day	e than usual than usual usual sual		
17 Irritability:	\square_0 I am no more irritable to \square_1 I am more irritable that \square_2 I am much more irritable \square_3 I am irritable all of the	n usual le than usual		
18 Changes in appetite:	☐ I have not experienced ☐ My appetite is somewh ☐ My appetite is somewh ☐ My appetite is much le ☐ My appetite is much go ☐ I have no appetite at a ☐ I crave food all of the te	nat greater than usual ss than before reater than usual II		
19 Concentration difficulty:	\square_1 I can't concentrate as v	well as usual nd on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatigue	atigued than usual gued more easily than usual ed to do a lot of the things I us ed to do most of the things I us		
21 Loss of interest in sex:	\square_0 I have not noticed any \square_1 I am less interested in s \square_2 I am much less interest \square_3 I have lost interest in se	ed in sex now	ı sex	



		Center Number:	Participant Number:	Participant's Initials:
C	inic Weight			
	eight date and time:/			Staff initials:
Cli	nic weight (if the first two measurements	are more than 0.1 k	ka apart, measure weight a third time):	
	eight 1:		g apar, modello molgim a milia milojo	
We	eight 2:			
We	eight 3:	kg		
We	eight of gown:	kg		
V	ital Signs			
	sessment date and time:/	/	:: : 00:00 to 23:59	
1	If waist measurement not done → S Natural waist measurement (if the first two measurements are more than Natural waist measurement 1:	-	sure 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		ements 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	3:	cm	
3	Pulse: bpm OR Not do	ne → Specify red	ison (use codelist below):	Staff initials:
4	Temperature:°C	OR Not done → S	Specify reason (use codelist below):	Staff initials: First middle last
5	Respirations: per minute OR	Not done → Sp	pecify reason (use codelist below):	Staff initials: first middle last
6	Blood pressure (check only one):1	Left arm	ght arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time:: OR Not done = Specify rea:	
	6b Blood pressure 2:/_	mm Hg	Time: : : : : : : : : : : : : : : : : : :	
	6c Blood pressure 3:/	mm Hg	Time: : : : : : : : : : : : : : : : : : :	
No	at Done Codelist: 1 Participant refused	2 Clinician unab	le to obtain 3 Insufficient time 4 Instru	ument failure 5 Not required



C	enter Number:	Participant	Number: _	Partici	pant's Initials:	
12-Lead ECG						
Date and Time			Findin	gs	Staff Initials	
/		Is ECG (check only one):			first middle last	
Safety Labs						
	/					
Date and time of sample collection:/	/	ear 00:00 to	23:59			
Sample	Sample	e 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:	/	/	::	 59		
Date and time sample collection started: _	day month	/	00:00 to 23:	<u>-</u>		
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 I	Done.					
Contraception						
If Not Done → Specify reason (use codelist b	elow):					
Contraception method (females only):	☐ None C	R Check all that				
		Oral contra	ceptive →		ant Medications page	
		Other → S	pecify (e.g	g., barrier, IUD):		
N.B. G. H. I.S. S. C. C. C.	Cl		76	41	F M	
Not Done Codelist: 1 Participant refused 2	Clinician unable to	obtain 3 Insut	ficient time	4 Instrument failure	5 Not required	

Month 3 Submission

		Center Number:	Participant Number:	Participant's Initials:
Da	te completed:/	/OR Not done	e → Specify reason (use codel	ist below):
В	DI-II			
Ins	pick out the one weeks, including	statement in each group that be	est describes the way you have statement you have picked.	up of statements carefully and then we been feeling during the past two . Be sure that you check only one
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the time \square_2 I am sad all of the time \square_3 I am so sad or unhappy		
2	Pessimism:	 □₀ I am not discouraged at □₁ I feel more discouraged of □₂ I do not expect things to □₃ I feel my future is hopele 	about my future than I used work out for me	
3	Past failure:	 □₀ I do not feel like a failur □₁ I have failed more than □₂ As I look back, I see a look □₃ I feel I am a total failure 	I should have ot of failures	
4	Loss of pleasure:	 □₀ I get as much pleasure of the pleasure of the	nuch as I used to from the things I used to e	enjoy
5	Guilty feelings:	 □₀ I don't feel particularly g □₁ I feel guilty over many th □₂ I feel quite guilty most o □₃ I feel guilty all of the time 	nings I have done or shou f the time	ld have done
6	Punishment feelings:	☐ I don't feel I am being p ☐ I feel I may be punished ☐ I expect to be punished ☐ I feel I am being punished		
7	Self-dislike:	 □₀ I feel the same about my □₁ I have lost confidence in □₂ I am disappointed in my □₃ I dislike myself 	myself	
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to o	btain 3 Insufficient time 4 I	Instrument failure 5 Not required

Month 3 Submission

		Center Number: Participant Number: Participant's Initials: itst middle last
В	DI-II (continued)	
8	Self-criticalness:	 □₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9	Suicidal thoughts or wishes:	 □₀ I don't have any thoughts of killing myself □₁ I have thoughts of killing myself but I would not carry them out □₂ I would like to kill myself □₃ I would kill myself if I had the chance
10	Crying:	 □₀ I don't cry any more than I used to □₁ I cry more than I used to □₂ I cry over every little thing □₃ I feel like crying, but I can't
11	Agitation:	\square_0 I am no more wound up or restless than usual \square_1 I feel more restless or wound up than usual \square_2 I am so restless or agitated that it's hard to stay still \square_3 I am so restless or agitated that I have to keep moving or doing something
12	Loss of interest:	\square_0 I have not lost interest in other people or activities \square_1 I am less interested in other people or things than before \square_2 I have lost most of my interest in other people or things \square_3 It's hard to get interested in anything
13	Indecisiveness:	 □₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14	Worthlessness:	 □₀ I do not feel I am worthless □₁ I don't consider myself as worthwhile and useful as I used to □₂ I feel more worthless as compared to other people □₃ I feel utterly worthless
15	Loss of energy:	 □₀ I have as much energy as ever □₁ I have less energy than I used to have □₂ I don't have enough energy to do very much □₃ I don't have enough energy to do anything

Month 3 Submission

	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	\square_1 I sleep somewhat more \square_2 I sleep somewhat less t \square_3 I sleep a lot more than \square_4 I sleep a lot less than us \square_5 I sleep most of the day	e than usual rhan usual usual sual		
17 Irritability:	\square_0 I am no more irritable to \square_1 I am more irritable than \square_2 I am much more irritable \square_3 I am irritable all of the	n usual le than usual		
18 Changes in appetite:	☐₀ I have not experienced ☐₁ My appetite is somewh ☐₂ My appetite is somewh ☐₃ My appetite is much le ☐₄ My appetite is much gr ☐₅ I have no appetite at a ☐₀ I crave food all of the te	nat greater than usual ss than before reater than usual II		
19 Concentration difficulty:	\square_1 I can't concentrate as v	well as usual nd on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatigue	atigued than usual gued more easily than usual ed to do a lot of the things I us ed to do most of the things I us		
21 Loss of interest in sex:	\square_0 I have not noticed any \square_1 I am less interested in s \square_2 I am much less interested \square_3 I have lost interest in se	ed in sex now	n sex	



	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.					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		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.				4		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.				3				
23 It's okay to be overweight.				\square_3	4	5	6	
24 Recently I have felt that I am	a worthless person.			\square_3		5	6	
25 I would be very upset if I gain	ned 2 pounds.			\square_3		5	6	
26 I crave sweets and carbohydr	rates.			\square_3	4	5		
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 abou	ıt suicide lately.			\square_3	4	5	6	7
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		
32 I eat 3 meals a day.				\square_{3}	4	5		
33 Lately I have been easily irrite	ated.			3	4	5	6	
34 Some foods should be totally	avoided.			\square_3		5		
35 I use laxatives to control my v	weight.			3	4	5	6	7
36 I am terrified by the thought of	of being overweight.			\square_3	4	5		
37 Purging is a good way to lose	e weight.				4	5		7
38 I avoid fatty foods.				\square_3				



	Center Number:	Participant No	umber: _		Pai	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)								
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty 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.				\square_3	\square_4	5		
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			\square_3	\square_4	5		
45 I feel good when I skip meals	i.			\square_3	4	5		
46 I avoid foods with sugar.				\square_3	\square_{4}	5		
47 I hate it when I feel fat.				\square_3	4	5		
48 I am too fat.				\square_3	4	5		
49 I eat until I am completely stu	iffed.			\square_3	4	5		
50 I hate to eat.				\square_3	\square_4	5		
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.				3	4	5		
56 I wouldn't mind gaining a fev	v pounds.				4	5		

Participant's Initials: first middle last



Month 6 Submission CR Visit 1/Control Visit 2

		Center Number:	Participant Nu	mber: Par	ticipant's Initials: first middle last
C	linic Weight				
W	eight date and time:/	_/	:-	Staff	initials:
	R Not done → Specify reason (use Cod	•			first middle last
Cli	nic weight (if the first two measurements	are more than 0.1	kg apart, measure weigh	t 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:/	onth year	00:00 to 23:59		
	If waist measurement not done → S	pecify reason (us	e codelist below):		
1	Natural waist measurement (if the first two measurements are more than	n 1.0 cm apart, med	asure natural waist circumfei	Staff initioning staff initions at third time):	itials:
	Natural waist measurement 1:		cm		
	Natural waist measurement 2:		cm		
	Natural waist measurement 3:		cm		
2	Umbilical point waist measurement (if umbilical point waist circumference a third t		rements are more than 1.0 c	m apart, measure	
	Umbilical point waist measurement	1:	cm		
	Umbilical point waist measurement 2	2:	cm		
	Umbilical point waist measurement	3:	cm		
3	Pulse: bpm OR Not do	one → Specify re	eason (use codelist below):	Staff ini	tials: first middle last
4	Temperature: °C	OR Not done →	Specify reason (use codelis	t below): Staff ini	tials:
5	Respirations: per minute OR	Not done → S	pecify reason (use codelis	t below): Staff ini	first middle last
6	Blood pressure (check only one):1	Left arm \square_2 R	ight arm	Staff ini	first middle last
	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 refused	2 Clinician unal	ble to obtain 3 Insuffici	ent time 4 Instrument failu	ure 5 Not required



Cen	ter Number:	Participant I	Number:	Participant's Init	ials:
12-Lead ECG					
Date and Time			Findings		Staff Initials
		Is ECG (check only one):			first middle last
Safety Labs					
Date and time of last meal: /_ Date and time of sample collection:/_ day	month year				
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
Contraception					
If Not Done → Specify reason (use codelist belo	ow):				
Contraception method (females only):	☐ None OR		apply: ceptive → Specify: Record on Con pecify (e.g., barrier, IUD):	comitant Medic	cations page
Not Done Codelist: 1 Participant refused 2 Cl	inician unable to c	btain 3 Insuf	ficient time 4 Instrument f	failure 5 Not	required



Month 6 Submission CR Visit 2

Ce	enter Number:	Participant Number:	Participant's Initials: first middle last
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	I		
Pregnancy Test			
Complete only for females.			
□ ₀ No □ ₁ Yes → If Yes: Date urine pregnancy t Results: □ ₁ Negative □ ₂ Positive	est performed:	//	
DXA Scan			
 Has the participant taken a calcium supp □ No □ Yes → If Yes: Proceed with Were any studies involving barium or ranged No □ Yes 	scan and document in	n the Subject Scan Log to inform to the scho	
DXA Scan		DXA Rescan	ORNA
Date of scan:/	_	Date of rescan:/	/
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area So Check all t	
☐ Whole body		☐ Whole body	/
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: midd
oubly Labeled W	/ater (DLW)		
Date and time of DLW do	osing:/ _{month} /	year 00:00 to 23:59	Staff initials:
OR Not done → Specify	reason (use codelist below): _	_	
DLW dose mixture ID and	d bottle number:	CA	
Exact weight of DLW mix	ture:g	rams	
Urine samples:			
Collection	Sample	Date and Tin	ne Collected
Pre dosing (PD)	PDα	/	ar:
	PDb	/	ar 00:00 to 23:59
Day 0 (Visit 2)	D0a	/	ar 00:00 to 23:59
	DOP	/	gar 00:00 to 23:59
Day 7 (Visit 3)	D7a	/	ar 00:00 to 23:59
	D7b	/ _{month} /	::::
Day 14 (Visit 5)	D14a	/	ar 00:00 to 23:59
	D14b	/	ar 00:00 to 23:59
Affix CRF page label(s) c	orresponding to this urine sa	Affix	Affix etest Sample Label Here

3 Insufficient time

4 Instrument failure

5 Not required

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



		Center Number: Particip	oant Number:		Participant's Init	ials: middle last
Da	ite completed:/ _{month} / _{ye}	OR Not done → Speci	fy reason (use co	delist below):		
R	AND SF-36					
Ins		ews about your health. This inf Please answer every question b or a question, give the best answ	y placing a chec			
1	In general, would you say your health is:		₂ Very good	☐₃ Goo	d □₄ Fair	□₅ Poor
2	Compared to one year ago, how would you rate your heal general now?	In Much better not be the in	tter now than 1 ne rse now than	year ago l year ago		
ty	ne following items are about act pical day. Does your health not so, how much?		vities?	Limited You	_	No, Not Limited At All
3	Vigorous activities, such as participating in strenuous spor		pjects,	1		
4	Moderate activities , such a vacuum cleaner, bowling, or p	s moving a table, pushing laying golf	g a	1		
5	Lifting or carrying groceries					
6	Climbing several flights of sta	iirs		1		
7	Climbing one flight of stairs			1		
8	Bending, kneeling or stooping			1		
9	Walking more than a mile		l	1		\square_3
10	Walking several blocks			1		\square_3
11	Walking one block			1		\square_3
12	Bathing or dressing yourself			1		
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3	Insufficient time	4 Instrument	failure 5 No	required



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Rand SF-36 (continued)				
During the past 4 weeks, have with your work or other regula		-		
physical health?	,		Yes	No
13 Cut down on the amount o	If time you spent on	work or other activities		
14 Accomplished less than y	ou would like			
15 Were limited in the kind of	work or other activiti	es		
16 Had difficulty performing (for example, it took extra effor		ivities		
During the past 4 weeks, have your work or other regular da				
problems (such as feeling depres	-		Yes	No
17 Cut down on the amount of	time you spent on w	ork or other activities		
18 Accomplished less than you	would like			
19 Didn't do work or other acti	ivities as carefully as	usual		
20 During the past 4 weeks, to problems interfered with yo neighbors or groups?	-	. ,	☐ ₁ Not at a II ☐ ₂ Slightly ☐ ₃ Modera ☐ ₄ Quite a ☐ ₅ Extreme	tely bit
21 How much bodily pain have	e you had during the	past 4 weeks?	□₁ None □₂ Very mil □₃ Mild □₄ Modera □₅ Severe □₅ Very sev	tely
22 During the past 4 weeks, he interfere with your normal vand housework)?	-	ork outside the home	☐ ₁ Not at a ☐ ₂ A little b ☐ ₃ Modera ☐ ₄ Quite a ☐ ₅ Extreme	it Itely bit



	Center Number: Participant			pant Number: Participant's Initials:			first middle last
RAND SF-36 (continued)							
These questions are about ho weeks. For each question, ple been feeling.	-	•		_		-	
How much of the time during the	oast 4 weeks	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	
23 Did you feel full of pep?				\square_3	4	5	6
24 Have you been a very nerv	ous person?			\square_3	4	5	6
25 Have you felt so down in the nothing could cheer you up	ne dumps that ?			\square_3	4	5	6
26 Have you felt calm and peo	aceful?			\square_3	4	5	6
27 Did you have a lot of energ	jy?			\square_3	4	5	6
28 Have you felt downhearted	d and blue?			\square_3	4	5	6
29 Did you feel worn out?				\square_3	4		6
30 Have you been a happy pe	erson?			\square_3	4	5	6
31. Did you feel tired?				\square_3	4	5	6
32 During the past 4 weeks, how your physical health or emointerfered with your social relatives, etc)?	otional problems		All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
How true or false is each of the fo	llowing statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little ea	sier than other p	eople.			\square_3	4	5
34 I am healthy as anybody I	know.				\square_3	4	5
35 I expect my health to get w	orse.				\square_3	4	5
36 My health is excellent.							5



		Center Number: Participant Number: Participant's Initials: first_middle last
Da	te completed:/	/OR Not done → Specify reason (use codelist below):
		iii yeu
D	DI-II	
Ins	pick out the one weeks, including	ire consists of 21 groups of statements. Please read each group of statements carefully and then e statement in each group that best describes the way you have been feeling during the past two g today. Check the box beside the statement you have picked. Be sure that you check only one ach group, including item 16 and item 18.
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the time \square_2 I am sad all of the time \square_3 I am so sad or unhappy that I can't stand it
2	Pessimism:	\square_0 I am not discouraged about my future \square_1 I feel more discouraged about my future than I used to be \square_2 I do not expect things to work out for me \square_3 I feel my future is hopeless and will only get worse
3	Past failure:	 □₀ I do not feel like a failure □₁ I have failed more than I should have □₂ As I look back, I see a lot of failures □₃ I feel I am a total failure as a person
4	Loss of pleasure:	□₀ I get as much pleasure as I ever did from the things I enjoy □₁ I don't enjoy things as much as I used to □₂ I get very little pleasure from the things I used to enjoy □₃ I can't get any pleasure from the things I used to enjoy
5	Guilty feelings:	\square_0 I don't feel particularly guilty \square_1 I feel guilty over many things I have done or should have done \square_2 I feel quite guilty most of the time \square_3 I feel guilty all of the time
6	Punishment feelings:	☐ I don't feel I am being punished ☐ I feel I may be punished ☐ I expect to be punished ☐ I feel I am being punished ☐ I feel I am being punished
7	Self-dislike:	□₀ I feel the same about myself as ever □₁ I have lost confidence in myself □₂ I am disappointed in myself □₃ I dislike myself
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



		Center Number:	Participant Number:	Participant's Initials:
В	DI-II (continued)			
	Self-criticalness:	\Box_1 I am more critica \Box_2 I criticize myself	r blame myself more than usual of myself than I used to be for all of my faults or everything bad that happen	
9	Suicidal thoughts or wishes:	,	· ·	t carry them out
10	Crying:	 □₀ I don't cry any m □₁ I cry more than I □₂ I cry over every I □₃ I feel like crying, 	used to ittle thing	
11	Agitation:	\square_1 I feel more restle \square_2 I am so restless of	ound up or restless than usual ss or wound up than usual or agitated that it's hard to stay or agitated that I have to keep	
12	Loss of interest:	, I am less intereste	terest in other people or activited in other people or things the of my interest in other people of terested in anything	nan before
13	Indecisiveness:	, I find it more diffi	about as well as ever icult to make decisions than us ater difficulty in making decisions aking my decisions	
14	Worthlessness:		nyself as worthwhile and usef lless as compared to other pe	
15	Loss of energy:	I don't have enou	energy as ever y than I used to have ugh energy to do very much ugh energy to do anything	

Participant's Initials: first middle last



	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	☐ I sleep somewhat mo ☐ I sleep somewhat les ☐ I sleep a lot more tha ☐ I sleep a lot less than ☐ I sleep most of the do	s than usual n usual usual		
17 Irritability:	\square_0 I am no more irritable \square_1 I am more irritable th \square_2 I am much more irritable \square_3 I am irritable all of the	an usual able than usual		
18 Changes in appetite:	☐₀ I have not experience ☐₁ My appetite is somev ☐₂ My appetite is somev ☐₃ My appetite is much ☐₄ My appetite is much ☐₅ I have no appetite at ☐₀ I crave food all of the	what greater than usual less than before greater than usual all		
19 Concentration difficulty:	\square_0 I can concentrate as \square_1 I can't concentrate as \square_2 It's hard to keep my I \square_3 I find I can't concentr	s well as usual mind on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatig	r fatigued than usual tigued more easily than usual gued to do a lot of the things I u gued to do most of the things I u		
21 Loss of interest in sex:	\square_0 I have not noticed an \square_1 I am less interested in \square_2 I am much less intere \square_3 I have lost interest in	sted in sex now	in sex	



	Center Number:	Participant I	Number:	Participant's I	nitials: first middle last
Date completed:/ _{month}	OR Not do	one → Specify re	ason (use codelist be	:low):	
Profile of Mood State	es				
Instructions: Please describe ho	w you feel right now by		x for each of the w	ords listed below.	
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly				3	4
2 Tense					4
3 Angry					
4 Worn out				\square_3	
5 Unhappy				\square_3	4
6 Clear-headed				\square_3	
7 Lively					
8 Confused			\square_{2}	\square_3	
9 Sorry for things done				\square_3	4
10 Shaky					
11 Listless				\square_3	4
12 Peeved			\square_{2}	\square_3	
13 Considerate				\square_3	4
14 Sad	\Box_{o}			\square_3	
15 Active					4
16 On edge					
17 Grouchy					4
18 Blue	\Box_{o}				4
19 Energetic					
20 Panicky					4
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Not Done Codelist: 1 Participant re	fused 2 Clinician unable to	o obtain 3 Insuf	ficient time 4 Instru	ment failure 5 N Participant's I	nitials:
					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	\Box_{o}		\square_{2}	\square_3	4
25 Sympathetic				\square_3	4
26 Uneasy			\square_{2}	\square_3	4
27 Restless					4
28 Unable to concentrate				\square_3	4
29 Fatigued				\square_3	4
30 Helpful				\square_3	4
31 Annoyed				\square_3	4
32 Discouraged				\square_3	4
33 Resentful					4
34 Nervous				\square_3	4
35 Lonely					4
36 Miserable				\square_3	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

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	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				\square_3	4
46 Sluggish	\square_{o}		\square_{2}	\square_3	4
47 Rebellious	o			\square_3	4
48 Helpless				\square_3	4
49 Weary					4
50 Bewildered				\square_3	4
51 Alert					4
52 Deceived					4
53 Furious					4
54 Efficient				\square_3	4
55 Trusting					4
56 Full of pep					4
57 Bad-tempered					4
58 Worthless				\square_3	4
59 Forgetful					4
60 Carefree	\square_{o}			\square_3	4
61 Terrified	\square_{o}			\square_3	4
62 Guilty	\square_{o}			\square_3	
63 Vigorous				\square_3	4
64 Uncertain about things					4
65 Bushed					4

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	Center Number:	Participant Numbe	r:		Participant's	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 indicate how often you felt			-			-	lease
			Never	Almost Never	Some- times	Fairly Often	Very Often
In the last month, how often h unable to control the importar	•	were					
2 In the last month, how often h your ability to handle your pe	2	t about	\square_{o}		\square_{2}	\square_3	4
3 In the last month, how often h going your way?	ave you felt that thin	gs were	□ _o			\square_3	4
4 In the last month, how often h piling up so high that you coul	2						
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient	ime 4	Instrument f	ailure 5	Not requi	red

Participant's Initials: first middle last



		Center Number: F	Participant Number:	Particip	ant's Initials	first middle last
Da	te completed:/ _{month} /	OR Not done → S	Specify reason (use co	odelist below):		
Pi	ttsburgh Sleep Quality I	ndex (PSQI)				
		late to your usual sleep ha r the majority of days and		-		
Du	ring the past month					
1	When have you usually gone	to bed?::				
2	How long (in minutes) has it to	aken you to fall aslee	p each night? _	minutes		
3	When have you usually gotte	n up in the morning?	:: 00:00 to 23:59			
4	How many hours of actual sleep (This may be different than the number of hours	, ,	nours			
5	During the past month, how o sleeping because you (check	•	the pas		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	he night or early mor	ning			\square_3
	• Have to get up to use the b	athroom				\square_3
	d Cannot breathe comfortable	У				\square_3
	e Cough or snore loudly					
	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 des you have had trouble sleep reason(s):	•	often			\square_3
6	During the past month, how o medicine (prescribed or "over the country to be prescribed or "over the country	~	?			
	89, with permission from Elsevier Science. at Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient time	4 Instrument failure	5 Not re	quired



		Center Number:	Participant	Number:	Parti	cipant's Initials:	first middle last
Pi	ttsburgh Sleep Quality I	ndex (PSQI) (continue	ed)				
				Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how often staying awake while driving, east 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 m been for you to keep up enthu	•					3
				Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how w quality overall?	rould you rate your	sleep				\square_3



				CK	V 1511	2/0	Omr	OI VI	511 Z
Cente	er Number:	_ Partic	ipant Num	ber:		_ Parti	cipant's In	nitials:	t middle last
Date completed:/OR N	Not done → Spe	cify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Sexu	al Functio	1 (DISF-S	R) (F) Fe	male Ve	rsion				
Instruction: Below you will find a brief set of a sections that ask about different aspects of your while another inquires about the kinds of sexusexual arousal and the quality of your organ relationship.	r sexual experie al experience	nces. One s that you	e section J have. Yo	asks abo ou are a	out sexu Iso aske	al fanto d about t	isies or he natu	daydre	ams, Jr
On some questions you are asked to respond activities asked about in that section. Some frequency scales range from "0 = never" to "4 of a satisfaction scale. This type of scale tells ho Some satisfaction scales range from "0 = could "0 = not at all satisfied," to "4 = extremely satisfied.	uency scales go = always." In th w much you en not be worse" t	from "O e case of oyed, or	= not at other qu were sati	all" to "8 estions, y sfied by	8 = four you will the sexu	or more be asked al activit	times a I to resp y being	day." Ot ond in te asked a	ther erms bout.
In every section of the inventory the scales of follow. Although it is brief, take your time with the describes your personal experience.									
If you have any questions, please ask the perso	on who gave yo	the inve	ntory for	help.					
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last to you filled out this inventory, how often ha you had thoughts, dreams, or fantasies ab	ive 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	7	8
1.2 Erotic parts of a man's body (e.g., f shoulders, legs)	ace,			3	4	5	6		8
1.3 Erotic or romantic situations				\square_3	4	5	6		
1.4 Caressing, touching, undressing, of foreplay	or			\square_3	4	5			8
1.5 Sexual intercourse, oral sex, toucl to orgasm	hing				4	5	6	7	8
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4 Instrument failure

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused

5 Not required

3 Insufficient time



C	enter Number:	Pa	ırticipant N	umber: _		Par	ticipant's	Initials:	st middle last
Derogatis Interview for Sex Section 2—Sexual Arousal	ual Functi	on (DIS	F-SR) (F)	Female \	ersion (d	ontinued)		
During the past 30 days or since the last time you filled out this inventory, how did you have the following experiences	often all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alo	one				4		6	7	8
2.2 Actively seek sexual satisfaction	n				4		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 throughout sexual relations									

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Center Nu	mber:	Po	articipant N	umber:		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				\square_3	4	5	□ ₆		8
3.2 Masturbation	По			3	4	5	□ ₆	\square_{7}	
3.3 Casual kissing and petting				\square_3	4	5			8
3.4 Sexual foreplay	По			\square_3	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	По			\square_3	4				
4.2 The intensity of your orgasm	По			3	4				
4.3 The ability to have multiple orgasms (if typical for you)				3	4				
4.4 Feelings of closeness and togetherness with your partner	По			3	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	4				

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	Center Number:		Participant	Number:		P	articipant's	s Initials:	irst middle last
Derogatis Interview for So	exual Fund	tion (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	l 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 intercount				3	4	5		7	
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in s	sex?			3	4				
5.3 During this period, how satisfy have you been with your personal relationship with you sexual partner?					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 repretent the best description of the quof your sexual functioning?				3	4	5	6		

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Month 6 Submission

				CR	Visit	2/C	ontr	ol Vi	sit 2
Center Numb	oer:	Partic	ipant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed: — day / — month / — year — OR Not do	ne → Spe	cify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Sexual Fu	unction	DISF-S	R) (M) N	Nale Ver	sion				
Instruction: Below you will find a brief set of questio 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.	ıl experier periences	nces. One that you	e section have. Y	asks abo ou are a	out sexu Iso aske	al fant d about t	asies or the natu	daydre	ams, ur
On some questions you are asked to respond in to activities asked about in that section. Some frequency 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 "0 = not at all satisfied," to "4 = extremely satisfied."	scales go ys." In the h you enjo	from "O case of yed, or	= not at other qu were sati	all" to "8 estions, y sfied by	8 = four you will the sexu	or more be askec val activit	times a I to resp y being	day." Ot ond in te asked a	ther erms bout.
In every section of the inventory the scales require follow. Although it is brief, take your time with the inventoribes your personal experience. If you have any questions, please ask the person who	entory. Fo	r each i	tem, ple	ase ch					
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		8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)						5			8
1.3 Erotic or romantic situations					_4	5			□ ₈
1.4 Caressing, touching, undressing, or foreplay					_4	5	□ ₆		
1.5 Sexual intercourse, oral sex, touching to orgasm					4	5	6		

Participant's Initials: first middle last

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

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

5 Not required



Center N	Number:	Par	ticipant Nu	mber:		Part	ticipant's I	nitials:	st middle last
Derogatis Interview for Sexual	Functio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal									
During the past 30 days or since the last tim you filled out this inventory, how often did you have the following experiences?	e 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					4		6		8
2.2 A full erection during a sexual fantasy or daydream									8
2.3 A full erection while looking at a sexually arousing person, movie, or picture					4		6	7	8
2.4 A full erection during masturbation	По						6		8
2.5 A full erection throughout the phase of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm							6	7	8

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Center Num	ber:	Par	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	По				4		6		
3.2 Masturbation	o			\square_3	4	5	6		
3.3 Casual kissing and petting	По				4		6		
3.4 Sexual foreplay				\square_3	4	5	6		
3.5 Sexual intercourse, oral sex, etc.				\square_3	_4	5	6	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	По			\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									
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3	4				_

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	Center Number:		Participant	Number:		P	articipant's	s Initials: _	irst middle last
Derogatis Interview for Se	xual Func	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		

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Participant's Initials: first middle last



		V 1311	-		
Center Number: Participe	ant Number: _		Participa	nt's Initials:	first middle last
Date completed: $\underline{\hspace{1cm}}_{day}$ / $\underline{\hspace{1cm}}_{month}$ / $\underline{\hspace{1cm}}_{year}$ OR Not done \rightarrow Specify	reason (use	codelist belo	w):	_	
Food Cravings Questionnaire—State (FCQ-S)					
Below is a list of comments made by people about their eating habits. Pleas how much you agree with the comment right now, at this very moment while others refer to one or more specific foods. Please respond to each ite	l. Notice that	some ques	tions refer		
	Strongly Disagree	IJICAAFAA	Neutral	Agree	Strongly Agree
1 I have an intense desire to eat [one or more specific foods].				4	
2 I'm craving [one or more specific foods].				4	
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		
5 If I were to eat what I am craving, I am sure my mood would improve.			\square_3	4	5
6 Eating [one or more specific foods] would feel wonderful.			\square_3	4	
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		
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	4	5
11 My desire to eat [one or more specific foods] seems overpowering.				4	5
12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.				4	5
13 I am hungry.					

4 Instrument failure

3 Insufficient time

2 Clinician unable to obtain

15 I feel weak because of not eating.

Not Done Codelist: 1 Participant refused

14 If I ate right now, my stomach wouldn't feel as empty.

5 Not required



	Center Number: P	articipant Number:		Participant's I	nitials: middle last
Date completed:/	OR Not done → S	pecify reason (us	e codelist below	·):	
Food Craving Inventory (FC					
For each of the foods listed below, please	check the appropriate box	•			
Note: A craving is defined as an intense de			ype that is diff	icult to resist.	AL /AL -
Over the past month, how ofto have you experienced a craving		Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake			\square_3	4	
2 Pizza			\square_3		
3 Fried chicken			\square_3		
4 Gravy					
5 Sandwich bread			\square_3		
6 Sausage			\square_3		
7 French fries			\square_3	4	
8 Cinnamon rolls			\square_3		
9 Rice				4	
10 Hot dog			\square_3	4	
11 Hamburger			\square_3	4	
12 Biscuits					
13 Ice cream				4	
14 Pasta			\square_3		
15 Fried fish			\square_3		
16 Cookies			\square_3		
17 Chocolate			\square_3		
18 Pancakes or waffles			\square_3	4	
19 Corn bread			\square_3		
20 Chips			\square_3		
21 Rolls			\square_3		
22 Cereal			$\square_{_{3}}$		
23 Donuts			\square_3		
24 Candy			\square_{3}		
25 Brownies			\square_3		
26 Bacon			\Box_3		
27 Steak			\square_3		
28 Baked potato					
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient tim	e 4 Instrumer	nt failure 5 N	lot required



	Center Number: Participant Number:	Participant's I	nitials: first_middle_last
Date c	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.	, 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.	₁ True	o 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.	ղ 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	nt failure 5 N	lot required
	·		

Participant's Initials: first middle last



	Cer	nter Number: Participant Number:	Participant's In	first middle last
Eat	ing Inventory (continued)			
19	Being with someone who is ear	ting often makes me hungry to eat also.	1 True	o False
20	When I feel blue, I often overed	at.	, True	o False
21	I enjoy eating too much to spoi my weight.	l 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 r limiting the amount I eat.	not really full as a conscious means of	, True	o False
24	I get so hungry that my stomac	ch often seems like a bottomless pit.	, True	o False
25	My weight has hardly changed	l at all in the last ten years.	, True	o False
26	I am always hungry so it is har the food on my plate.	d for me to stop eating before I finish	, True	o False
27	When I feel lonely, I console m	yself by eating.	, True	o False
28	I consciously hold back at mea	ls in order not to gain weight.	, True	o False
29	I sometimes get very hungry la	ite 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.	, True	□₀ False
32	I count calories as a conscious	means of controlling my weight.	☐₁ True	o False
33	I do not eat some foods becaus	se they make me fat.		□₀ False
34	I am always hungry enough to	eat at any time.		□₀ 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 eat other high calorie foods.	that is not allowed, I often splurge and	, True	o False

calerie Phase 2

Month 6 Submission CR Visit 2/Control Visit 2

	Cente	er Number:	Participant Number:	Participant's Initials:
Eat	ing Inventory (continued)			
Plea	se check one answer that is most appı	opriate to you	for each question below.	
37	How often are you dieting in a coeffort to control your weight?	onscious		es □₃ Usually □₄ Always
38	Would a weight fluctuation of 5 paffect the way you live your life?		☐₁ Rarely ☐₂ Sometim	es \square_3 Usually \square_4 Always
39	How often do you feel hungry?		\square_1 Rarely \square_2 Sometime	es 🔲 3 Usually 🔲 4 Always
40	Do your feelings of guilt about or help you to control your food into	vereating ake?	☐₁ Rarely ☐₂ Sometim	es □₃ Usually □₄ Always
41	How difficult would it be for you eating halfway through dinner a for the next four hours?		☐₁ Easy ☐₃ Moderately difficult	□₂ Slightly difficult□₄ Very difficult
42	How conscious are you of what y eating?	you are	□₁ Not at all□₃ Moderately	□₂ Slightly □₄ Extremely
43	How frequently do you avoid "st on tempting foods?	ocking up"	☐₁ Almost never ☐₃ Usually	□₂ Seldom □₄ Almost always
44	How likely are you to shop for localorie foods?	ow .	□₁ Unlikely □₃ Moderately likely	□₂ Slightly likely □₄ Very likely
45	Do you eat sensibly in front of ot splurge alone?	hers and	☐₁ Never ☐₂ Rarely	□₃ Often □₄ Always
46	How likely are you to consciously in order to cut down on how much		☐, Unlikely ☐₃ Moderately likely	□₂ Slightly likely □₄ Very likely
47	How frequently do you skip dess you are no longer hungry?	ert because	☐₁ Almost never ☐₃ At least once a week	□₂ Seldom □₄ Almost every day
48	How likely are you to consciously than you want?	y eat less	☐₁ Unlikely ☐₃ Moderately likely	Slightly likely √ Very likely
49	Do you go on eating binges thou not hungry?	gh you are	Never Sometimes	☐₂ Rarely ☐₄ At least once a week
50	To what extent does this statemed your eating behavior? "I start die morning, but because of any number things that happen during the day evening I have given up and eat want, promising myself to start dagain tomorrow."	eting in the aber of y, by what I	 Not like me Little like me Pretty good description Describes me perfect 	
51	On a scale of 0 to 5, where 0 me restraint in eating (eating whatever want, whenever you want it) and total restraint (constantly limiting intake and never "giving in"), who would you give yourself?	er you 5 means food	Usually eat whatever often eat whatever you often limit food intak usually limit food intak	



	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.

Ια	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.	o			\square_3	4	5	6		8	9		
5	I can resist eating when I am watching TV.					4				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.	O				4	5			8	9		
8	I can resist eating even when I feel it is impolite to refuse a second helping.	o				4				8	9		
9	I can resist eating even when I have a headache.					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	ŀ		

Participant's Initials:



	Center Number:		Particip	ant Nun	nber:			Particip	ant's Initi	ials:	middle last
Weight Efficacy Lifestyle Q	uestionnaiı	re (w	EL) (co	ntinuec	l)						
I am confident that:				e nt at a t the de	ll that esire to	eat	yo		Very co		
		0	1	2	3	4	5	6	7	8	9
10 I can resist eating when I am re	eading.				\square_3	4	5	6		8	9
11 can resist eating when I am a (or irritable).	ingry				\square_3	4				8	9
12 I can resist eating even when I a party.	am at				\square_3	4	5	6		8	9
13 I can resist eating even when o pressuring me to eat.	thers are					4	5			8	9
14 I can resist eating when I am in	pain.				\square_3	\square_{4}	5	6		8	9
15 I can resist eating just before g	oing to				\square_3	4				8	9
16 I can resist eating when I have experienced failure.					\square_3	4	5	6		8	9
17 I can resist eating when high-coare available.	alorie foods				\square_3	4	5			8	9
18 I can resist eating even when I others will be upset if I don't ea	think at.				\square_3	4	5	6		8	9
19 I can resist eating when I feel uncomfortable.						4	5			8	9
20 I can resist eating when I am h	арру.				\square_3	4	5			8	9



	Center Number:	Participa	nt Numbe	r:		Partici	pant's Ini	tials:	middle last
Date completed:/ _{month} /	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, plea	se rate the following items o	on a scal	e from 1	to 7. Ple		ver as tr	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 u	sed to be.				\square_3	\square_4	5	6	
3 I avoid eating for as long as	I can.				3	4	5	6	
4 Certain foods are "forbidden	" for me to eat.				$\square_{_3}$	\square_{4}	5		
5 I can't keep certain foods in my binge on them.	house because I will				\square_3				
6 I can easily make myself vom	iit.				\square_{3}	4	5	6	
7 I can feel that being fat is term	rible.				\square_3	4	5		
8 I avoid greasy foods.							5		
9 It's okay to binge and purge	once in a while.					4	5		
10 I don't eat certain foods.					\square_3	4	5	6	
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 la	itely.				\square_3	4	5		
14 I try to diet by fasting.					\square_3	\square_{4}	5		
15 I vomit to control my weight.					\square_3	4	5	6	
16 Lately nothing seems enjoyab	ole anymore.				\square_3	\square_{4}	5	6	
17 Laxatives help keep you slim.					\square_3	4	5		
18 I don't eat red meat.					\square_3	4	5		
19 I eat so rapidly I can't even to	aste my food.				3	4		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:	irst 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.				4	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	5	6	
25 I would be very upset if I gain	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.				4	5		7
34 Some foods should be totally	avoided.			\square_3	4	5	6	
35 I use laxatives to control my	weight.				4	5		7
36 I am terrified by the thought	of being overweight.			3	4	5	6	
37 Purging is a good way to lose	e weight.			\square_3	4	5	6	7
38 I avoid fatty foods.						5	6	

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	Center Number:	Participant No	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
39 Recently I have felt pretty blu	е.						6	
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.				\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	6	
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		7
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 N	Number: _		Par	ticipant's I	nitials:	middle last
Dat	e completed:/OR Not done → Specify re	ason (use	codelist b	elow):			
Во	dy Shape Questionnaire (BSQ)						
	would like to know how you have been feeling about your appearance or use read each question and check the box for the appropriate choice. Plea						
Ove	er the Past Four Weeks	Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you brood about your shape?			3	4	5	
2	Have you been so worried about your shape that you have been feeling that you ought to diet?			\square_3	\square_{4}	5	
	Have you thought that your thighs, hips, or bottom are too large for the rest of you?			\square_3	4	5	
	Have you been afraid that you might become fat (or fatter)?			\square_3	\square_{4}	5	6
	Have you worried about your flesh not being firm enough?			\square_3	4	5	
	Has feeling full (e.g., after eating a large meal) made you feel fat?			3	4	5	6
	Have you felt so bad about your shape that you have cried?			\square_3	4	5	
	Have you avoided running because your flesh might wobble?			\square_3	\square_{4}	5	6
	Has being with thin women/men made you feel self-conscious about your shape?			\square_3	4	5	
	Have you worried about your thighs spreading out when sitting down?			\square_{3}	\square_{4}	5	6
	Has eating even a small amount of food made you feel fat?			\square_3	4	5	
	Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?			3	4	5	6
	Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?			\square_3	4	5	6
	Has being naked, such as when taking a bath, made you feel fat?			\square_3		5	
15	Have you avoided wearing clothes which make you particularly aware of the shape of your body?			\square_3		5	
	Have you imagined cutting off fleshy areas of your body?			\square_3	4	5	
No	Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuff	icient time	4 Instru	ument failu	re 5 N	lot require	d
				Par	ticipant's I	nitials:	t middle last



	Center Number: Participant N	Number: _		Pai	rticipant's	Initials: _	irst middle last
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?			3	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				4	5	6
23 Have you thought that you ar because you lack self-control?				3	4	5	6
24 Have you worried about othe flesh around your waist or sto				\square_3		5	6
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	6
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 v your body (e.g., communal changing				\square_3	4	5	
32 Have you taken laxatives in o	rder to feel thinner?			\square_3	4	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:

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: ___ _ _ _

Month 6 Submission

Participant Number:

Center Number:

CR Visit 3

Participant's Initials: first middle last

Were you employed in the last seven days? If Yes: Which days (check all that apply)? Which days do you consider your weekend, Day of Date In Be In Be O0000 to 23	Were you employed in the last seven days? If Yes: Which days (check all that apply)? Which days do you consider your weekend, day —	Se Tod	Seventual Today's date: _	/ Physical Acti	vity Reca	(PAR) check only one):	Mon Tue	es Med	Thurs	Fri	at Sur	OR No	done ↓	Spe	aify r	aify reason (use	scall (PAR) Day (check only one):
If Yes: Which days (check all that apply)? Which days do you consider your weekend, or non-work, days? Mon Tues Wed Thurs Fri Sat Day of Week Date In Bed Up Start Stop Mod. Hard Very Mod. Hard	Which days (check oil that opply)? Fig. Script	_	Were y	day month ye rou employed in the last seve	ear en days?		°Z °C	→ Skip to que		Yes					Interv	Interviewer in	Interviewer initials: first middle last
Which days do you consider your weekend, or non-work, days? Mon Intes Thurs Fri Sate Day of Week Date In Bed Up Start Stop Mod. Hard Very Mod. Mod. Hard Very Mod.	Day of veek Date In Bed Up Start Non Time Thurs Fri Start Week Date In Bed Up Start Stop Mod. Hard Very Mod. Week Date In Bed Up Start Stop Mod. Hard Very Mod. Week Date In Bed Up Start Stop Mod. Hard Very No. Mod. Hard Very No. No. <th>7</th> <th>If Yes: V</th> <th>Which days (check all that apply)</th> <th>٠.</th> <th></th> <th>Mon</th> <th>Tues</th> <th>Med</th> <th></th> <th></th> <th></th> <th>Sun</th> <th></th> <th></th> <th></th> <th></th>	7	If Yes: V	Which days (check all that apply)	٠.		Mon	Tues	Med				Sun				
Day of Week Date In Bed Up Start Stop Mod. Hard Very Mod. Hard Very Mod. Hard Very Mod. Hard Very Mod. Hard	Day of Veek Date Sleep Time Work Time Morning (in minutes) Week In Bed Up Start Stop Mod. Hard Very Mod. day	က	Which c	days do you consider your v	weekend, or no	on-work, days		Tues			i.E.	ш	Sun				
Date In Bed Up Start Stop Mod. Hard Very Mod.	Date Date Lin Bed Up Start Stop Mod. Hard Wery Mod. Mod.	200			Sleek	Time	Work	Time	Morr	i ng (in mi	nutes)	Affer	noon (in		minutes)		minutes) Evening (in minutes)
day month : . <t< th=""><th>doy ————————————————————————————————————</th><th>*</th><th></th><th></th><th>In Bed</th><th>Up</th><th>Start</th><th>Stop</th><th>Mod.</th><th>Hard</th><th>Very Hard</th><th>Mod.</th><th>Hard</th><th></th><th>Very Hard</th><th>Very Hard Mod.</th><th></th></t<>	doy ————————————————————————————————————	*			In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard		Very Hard	Very Hard Mod.	
day month year 00.00 to 23.59 00.00 to 23.50 00.0	day month year 00000 to 23.59 00.00 to 23.59 00.0	_				00:00 to 23:59											
100.00 to 23.59	doy ————————————————————————————————————	yester. day)		month		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	00:00 to 23:59									
	day				00:00 to 23:59	00:00 to 23:59 00:00 to 23:59		00:00 to 23:59									
	day month year 00:00 to 23:59 00:00 to 23:59 day month year 00:00 to 23:59 00:00 to 23:59 day month year 00:00 to 23:59 00:00 to 23:59 day month year 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											
day month year 00:00 to 23:59 00:00 to 23:59 :	doy /	_		/ month		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
Act	day month year	-		//-		00:00 to 23:59											
Act				month	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
day month year 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 day month year 00:00 to 23:59 00:00 to 23:59 00:00 to 23:59 day month year 00:00 to 23:59 00:00 to 23:59 day month year 00:00 to 23:59 00:00 to 23:59	doy month year			, , ,	00:00 % 23:59	00:00 4 00:00											
day month year 00:00 to 23:59		.					00:00 to 23:59	00:00 to 23:59									

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

5 Not required

00:00 to 23:59

year

day

week

Dαy #

yesterday)



Month 6 Submission CR Visit 3

		Center Number:	Participant Number:	Participant's Initials: middle la	
S	even-Day Physical Activi	ty Recall (PAR) (continued)		
4	Compared to your physical activity or or about the same (check only one)?	ver the past three mon	ths, was last week's physical a	activity 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-E	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 6 Submission CR Visit 3

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

Comp	lete 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	/	Reliable Unreliable Unreliable Missing	8	/	Reliable Unreliable Missing
2	/	Reliable Unreliable Unreliable Missing	9	/	Reliable Unreliable 3 Missing
3	/	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



Month 6 Submission CR Visit 5/Control Visit 2

		Center Number:	Partic	ipant Number: _	Particip	ant's Initials:
Outcomes	Labs					
Date and time of	last meal:	/	/	:_		
Date and time sa	imple 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 c	obtained, indicate with a No	ot Done.				
Core Temp	erature					
Staff Initials		de Date of ection/Procedure			e of Sample on/Procedure	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 I	Discharge				
-		/				
Not Done Codeli	st: 1 Participant refused	2 Clinician unable to	obtain 3	Insufficient time	4 Instrument failure	5 Not required



Month 6 Submission CR Visit 5

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 thin	rd time):
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	
	year
Results: 1 Negative 2 Positive	



Month 6 Submission CR Visit 5

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	Center Number:	Participant Number:	Particip	ant's Initials:
DXA Scan				
 Has the participant taken a calcium □ No □ 1 Yes → If Yes: Proceed Were any studies involving barium o □ No □ 1 Yes 	with scan and document in			
DXA Scan			DXA Rescan OR	, NA
Date of scan:/		Date of rescan:	/	 vear
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Area Scanned Check all that appl	у
☐ 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 ☐ WASH U-002		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

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Participant's Initials: first middle last

Participant Number:

Center Number:

5				/22.2.1											
	Today's date:	/////	Day	Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Tue	se Dew Sed] Thurs	Fri S	at Sur	OR No	+ done →	Specify re	eason (use	codelist bel	
-	Were yo	oyed in the last sev	ın days?		o Z O	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	stion 3	Yes				Interv	Interviewer initials:	ials: first	middle last
4	If Yes: W	If Yes: Which days (check all that apply)?	٥.		Mon	Mon Tues Wed Thurs	Wed	Thurs	Ë	Sat	Sun				
ო	Which d	Which days do you consider your weekend, or non-work, days?	reekend, or n	on-work, daysî		Mon Tues Wed Thurs	Wed		Fri	Sat	Sun				
200	Day of		Slee	Sleep Time		Work Time	Mori	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
#		Date	In Bed	ηυ	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
(yester-		day /		00:00 to 23:59											
•		day /			00:00 to 23:59										
10					00:00 to 23:59	00:00 to 23:59									
4		day /				00:00 to 23:59									
ო					00:00 to 23:59	00:00 to 23:59									
71		day / month year			00:00 to 23:59	00:00 to 23:59									
1 (1 week ago)	<u></u>			00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									

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

5 Not required

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Month 6 Submission CR Visit 5

		Center Number:	Participant Number:	Participant's Initials: middle last
S	even-Day Physical Ac	tivity Recall (PAR)	(continued)	
4	Compared to your physical active or about the same (check only on a large less large). About the same	•	ths, was last week's physical	activity more, less,
In	terviewer: Please answer questi	ons below and note any co	mments on interview.	
5	Were there any problems with to \square_0 No \square_1 Yes	ne Seven-Day PAR interviev	v?	
6	Do you think this was a valid Se	ven-Day PAR interview?		
7	Were there any activities reported No 1 Yes	ed by the participant that y	ou don't know how to classify	?

Month 9 Submission

		Center Number: _	Participant Nu	mber:	_ Participant's Initials:
C	linic Weight				
W	eight date and time:/ _{mont}	/			Staff initials:
	R Not done → Specify reason (use 0	·			first middle last
Cli	nic weight (if the first two measuremen	ts are more than 0.1 kg	g apart, measure weigh	t a third time):	
We	eight 1:				
We	eight 2:	kg			
W	eight 3:	kg			
W	eight of gown:	kg			
	ital Signs				
As	sessment date and time:/_	/	:: 00:00 to 23:59		
1	If waist measurement not done — Natural waist measurement (if the first two measurements are more to			sence 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 umbilical point waist circumference a thin		ments are more than 1.0 c	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): _	s	staff initials:
4	Temperature: ° (OR Not done → S	pecify reason (use codelis	t below): S	itaff initials: First middle last
5	Respirations: per minute 0	OR Not done → Spe	ecify reason (use codelis	t below): S	taff initials:
6	Blood pressure (check only one):		ht arm	S	taff initials: first middle last
	6a Blood pressure 1:	/ mm Hg	Time: : : : : : : : : : : : : : : : : : :	OR Not done → Specify reason	n (use codelist 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 Insuffici	ent time 4 Instrum	ent failure 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
/	☐ ₁ N ☐ ₂ A	bnormal, not clinico	ully significant (specify): significant (specify):	· · · · · · · · · · · · · · · · · · ·	first middle last
Safety Labs					
Date and time of last meal: Date and time of sample collection: date	/		23:59 23:59		
Sample	Samp	le 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 code	list below):				
Contraception method (females only):	None		apply: ceptive → Specify: Record on Con pecify (e.g., barrier, IUD):	comitant Medi	cations page
Not Done Codelist: 1 Participant refused	2 Clinician unable	to obtain 3 Insul	ficient time 4 Instrument f	ailure 5 No	t required

Month 9 Submission

	Center Number:	Participant Number:	Participa	nt's Initials: first middle last
Date completed:/	onth / OR Not done	→ Specify reason (use o	odelist below):	
BDI-II				
pick out the on weeks, includir	aire consists of 21 groups of statem te statement in each group that bes ng today. Check the box beside the each group, including item 16 and i	t describes the way you statement you have pic	have been feeling du	ring the past two
1 Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the time \square_2 I am sad all of the time \square_3 I am so sad or unhappy t			
2 Pessimism:	\square_0 I am not discouraged about \square_1 I feel more discouraged at \square_2 I do not expect things to \square_3 I feel my future is hopeles	oout my future than I us work out for me		
3 Past failure:	 □₀ I do not feel like a failure □₁ I have failed more than I □₂ As I look back, I see a lo □₃ I feel I am a total failure 	should have t of failures		
4 Loss of pleasure:	o I get as much pleasure as much pleasure as much pleasure for a get very little pleasure for a local can't get any pleasure for a local can't get a local can't get any pleasure for a local can't get a local c	uch as I used to rom the things I used	to enjoy	
5 Guilty feelings:	\square_0 I don't feel particularly g \square_1 I feel guilty over many thi \square_2 I feel quite guilty most of \square_3 I feel guilty all of the time	ings I have done or sl the time	hould have done	
6 Punishment feelings:	 □₀ I don't feel I am being pu □₁ I feel I may be punished □₂ I expect to be punished □₃ I feel I am being punished 			
7 Self-dislike:	 □₀ I feel the same about mys □₁ I have lost confidence in □₂ I am disappointed in mys □₃ I dislike myself 	myself		
Not Done Codelist: 1 Participa	ant refused 2 Clinician unable to ob	tain 3 Insufficient time	4 Instrument failure	5 Not required

Participant's Initials: first middle last

Month 9 Submission

	Center Number: Participant Number: Participant's Initials:
BDI-II (continued)	
8 Self-criticalness:	 □₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9 Suicidal thoughts or wishes:	 □₀ I don't have any thoughts of killing myself □₁ I have thoughts of killing myself but I would not carry them out □₂ I would like to kill myself □₃ I would kill myself if I had the chance
10 Crying:	☐ I don't cry any more than I used to ☐ I cry more than I used to ☐ I cry over every little thing ☐ I feel like crying, but I can't
11 Agitation:	 □₀ I am no more wound up or restless than usual □₁ I feel more restless or wound up than usual □₂ I am so restless or agitated that it's hard to stay still □₃ I am so restless or agitated that I have to keep moving or doing something
12 Loss of interest:	 □₀ I have not lost interest in other people or activities □₁ I am less interested in other people or things than before □₂ I have lost most of my interest in other people or things □₃ It's hard to get interested in anything
13 Indecisiveness:	 □₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14 Worthlessness:	 □₀ I do not feel I am worthless □₁ I don't consider myself as worthwhile and useful as I used to □₂ I feel more worthless as compared to other people □₃ I feel utterly worthless
15 Loss of energy:	 □₀ I have as much energy as ever □₁ I have less energy than I used to have □₂ I don't have enough energy to do very much □₃ I don't have enough energy to do anything

Month 9 Submission

	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	\square_1 I sleep somewhat more \square_2 I sleep somewhat less t \square_3 I sleep a lot more than \square_4 I sleep a lot less than us \square_5 I sleep most of the day	e than usual rhan usual usual sual		
17 Irritability:	\square_0 I am no more irritable to \square_1 I am more irritable than \square_2 I am much more irritable \square_3 I am irritable all of the	n usual le than usual		
18 Changes in appetite:	☐₀ I have not experienced ☐₁ My appetite is somewh ☐₂ My appetite is somewh ☐₃ My appetite is much le ☐₄ My appetite is much gr ☐₅ I have no appetite at a ☐₀ I crave food all of the te	nat greater than usual ss than before reater than usual II		
19 Concentration difficulty:	\square_1 I can't concentrate as v	well as usual nd on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatigue	atigued than usual gued more easily than usual ed to do a lot of the things I us ed to do most of the things I us		
21 Loss of interest in sex:	\square_0 I have not noticed any \square_1 I am less interested in s \square_2 I am much less interested \square_3 I have lost interest in se	ed in sex now	n sex	



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

			tirst middle las
Cl	inic Weight		
We	right date and time:/	Staff initials:	
	Not done → Specify reason (use Codelist below):		first middle last
Clir	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	eight of gown: kg		
	ital Signs		
Ass	sessment date and time://::::_		
	If waist measurement not done → Specify reason (use codelist below):		
1	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):	Staff initials:	st middle last
	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: $\frac{1}{fir}$	st middle last
4	Temperature: °C OR Not done → Specify reason (use codelist below):	Staff initials: $\frac{1}{fir}$	st middle last
5	Respirations: per minute OR Not done → Specify reason (use codelist below):	Staff initials:	st middle last
6	Blood pressure (check only one): Left arm Right arm	Staff initials:	st middle last
	6a Blood pressure 1:/ mm Hg Time:: OR Not done =	•	
	Specify reas	son (use codelist belo	ow):
	6b Blood pressure 2: / mm Hg Time: :		
	6c Blood pressure 3: / mm Hq 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



12-Lead ECG			
Date and Time		Findings	Staff Initials
	Is ECG (check only one): 1 Normal 2 Abnormal, not clinically significant (specify): 3 Abnormal, clinically significant (specify):		
Safety Labs Date and time of last meal:/	/		
Date and time of sample collection:/	: th year 00:00 to to the year 00:00 to to the year 00:00 to to the year 00:00 to th		
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	



		Center Number:	Participant N	lumber:	Participa	nt's Initials:
D	oubly Labeled V	Water (DLW)				
ı	Date and time of DLW d	losing:/ _{month} /	: :	23:59	Staff initio	ls:
	OR Not done → Specify	reason (use codelist below): _				
2	DLW dose mixture ID ar	nd bottle number:		CA	1	
3	Exact weight of DLW mix	xture:(grams			
4	Urine samples:					
	Collection	Sample		Date and	Time Collected	
	Pre dosing (PD)	PDa	/.	//	year 00:00	: to 23:59
		PDb	/.	//	year 00:00	: to 23:59
	Day 0 (Visit 1)	DOa	/.	/ month	year 00:00	: to 23:59
		DOP	/.	/ /	year 00:00	: to 23:59
	Day 7 (Visit 2)	D7α	//	/ month	year 00:00	: to 23:59
		D7b	/.	/ month	year 00:00	: to 23:59
	Day 14 (Visit 4)	D14a	/.	/ month	year 00:00	: to 23:59
		D14b	/.	/ month	year 00:00	: to 23:59
_	Affice CDE mana labolis	covered in a to this union of	mmulo coto r	,	,	
5	Allix CKr page label(s)	corresponding to this urine s	i A	ffix	Affix	
				ample Here	Retest Sample Label Here	
			Labe		Lubel Here	

3 Insufficient time

4 Instrument failure

5 Not required

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



	Center Nu	mber:	Participant Nu	mber: Participant's Initials:
Physical Examination				
Date of examination:/	_/	_		Staff initials:
OR Not done → Specify reason (use co				
Rady Systom		Assessments	3	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	\square_{o} \rightarrow	□ 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	\square_{o} \rightarrow	□ 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 sup □ ₀ No □ ₁ Yes → If Yes: Proceed wit	'	n the Subject Scan Log to inform th	e QA Center.	
2 Were any studies involving barium or re □ No □ Yes	adioisotopes performed	d within 4 weeks prior to the sched	luled DXA exam?	
DXA Scan		DXA Rescan O	PRNA	
Date of scan:/	_	Date of rescan:/	/	
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		☐ Hip		



	Center N	Number: Participant Numb	er:	Participant's Ini	first middle last
Da	ite completed:/	OR Not done → Specify reason	(use codelist belov	w):	
R	AND SF-36				
In	structions: This survey asks for your views about o do your usual activities. Please a unsure about how to answer a quest	nswer every question by placing	a check "X" in th		•
1	In general, would you say your health is:		good 🔲 Go	ood □₄ Fair	□₅ Poor
2	Compared to one year ago, how would you rate your health in general now?	☐₁ Much better now than ☐₂ Somewhat better now ☐₃ About the same ☐₄ Somewhat worse now ☐₅ Much worse now than	than 1 year ag		
ty	ne following items are about activities pical day. Does your health now limit so, how much?		Yes, Limited A Lot	_	No, Not Limited At All
3	Vigorous activities, such as running participating in strenuous sports	ng, lifting heavy objects,			
4	Moderate activities , such as movi vacuum cleaner, bowling, or playing				\square_3
5	Lifting or carrying groceries				
6	Climbing several flights of stairs				
7	Climbing one flight of stairs				
8	Bending, kneeling or stooping				\square_3
9	Walking more than a mile				\square_3
10	Walking several blocks				\square_3
11	Walking one block				\square_3
12	Bathing or dressing yourself				\square_3
N	ot Done Codelist: 1 Participant refused 2 Clinici	ian unable to obtain 3 Insufficient	t time 4 Instrume	nt failure 5 No	ot required

Participant's Initials: first middle last



	Center Number:	Participant Number: F	Participant's Initials:	first middle last
Rand SF-36 (contin	ued)			
<u> </u>	eeks, have you had any of the f ther regular daily activities as	-		
physical health?		,	Yes	No
13 Cut down on the	amount of time you spent on	work or other activities		
14 Accomplished I	ess than you would like			
15 Were limited in th	ne kind of work or other activiti	es		
16 Had difficulty p (for example, it too	erforming the work or other act k extra effort)	ivities		
<u> </u>	eeks, have you had any of the fregular daily activities as a res	-		
problems (such as fee	eling depressed or anxious)		Yes	No
17 Cut down on the	amount of time you spent on w	ork or other activities		
18 Accomplished les	s than you would like			
19 Didn't do work o	r other activities as carefully as	usual		
_	I weeks, to what extent has you ed with your normal social activ ups?		☐, Not at a ☐, Slightly ☐, Moderat ☐, Quite a ☐, Extremel	tely bit
21 How much bodily	pain have you had during the	past 4 weeks?	None Very mild Moderat Severe 6	te
	l weeks, how much did pain ur normal work (including both we	ork outside the home	Not at a A little bi Moderat Quite a stremel	it tely bit



	Center Number:	Part	icipant Numbe	er:	Part	icipant's Initials	first middle last
RAND SF-36 (continued)							
These questions are about how weeks. For each question, pleas been feeling.	_	_		_		-	
How much of the time during the pas	st 4 weeks	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23 Did you feel full of pep?				\square_3	4	5	6
24 Have you been a very nervo	us person?			\square_3	4	5	6
25 Have you felt so down in the nothing could cheer you up?	dumps that			\square_3	4	5	6
26 Have you felt calm and peace	eful?			\square_3	4	5	6
27 Did you have a lot of energy	?			\square_3	4	5	6
28 Have you felt downhearted o	ınd blue?			\square_3	4	5	6
29 Did you feel worn out?				\square_3	4	5	6
30 Have you been a happy pers	on?			$\square_{_3}$		5	6
31. Did you feel tired?				\square_3	4		
32 During the past 4 weeks, how a your physical health or emoti interfered with your social ac	onal problems		All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
relatives, etc)?	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			2	3	4	5
How true or false is each of the follo	wing statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easie	er than other po	eople.				4	5
34 I am healthy as anybody I kn	ow.						5
35 I expect my health to get wor	rse.				3	4	5
36 My health is excellent.							

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	Center Number:	_ Participant Number:	Participant's Initials:	dle last
Date completed:/_	OR Not done	e → Specify reason (use o	odelist below):	
BDI-II				
pick out the weeks, incl	e one statement in each group that be	est describes the way you se statement you have pic	group of statements carefully and then have been feeling during the past two ked. Be sure that you check only one	
1 Sadness:	 □₀ I do not feel sad □₁ I feel sad much of the tine □₂ I am sad all of the time □₃ I am so sad or unhappy 			
2 Pessimism:	 □₀ I am not discouraged al □₁ I feel more discouraged of □₂ I do not expect things to □₃ I feel my future is hopele 	about my future than I u work out for me		
3 Past failure:	 □₀ I do not feel like a failur □₁ I have failed more than □₂ As I look back, I see a look □₃ I feel I am a total failure 	I should have ot of failures		
4 Loss of pleasure:	 □₀ I get as much pleasure of the pleasure of the	nuch as I used to from the things I used	to enjoy	
5 Guilty feelings:	\square_0 I don't feel particularly \square_1 I feel guilty over many the \square_2 I feel quite guilty most o \square_3 I feel guilty all of the time	nings I have done or s f the time	hould have done	
6 Punishment feelin	gs: I don't feel I am being p I feel I may be punished I expect to be punished I feel I am being punishe			
7 Self-dislike:	 □₀ I feel the same about my □₁ I have lost confidence in my □₂ I am disappointed in my □₃ I dislike myself 	myself		
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:
В	DI-II (continued)	
8	Self-criticalness:	□₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9	Suicidal thoughts or wishes:	 □₀ I don't have any thoughts of killing myself □₁ I have thoughts of killing myself but I would not carry them out □₂ I would like to kill myself □₃ I would kill myself if I had the chance
10	Crying:	☐ I don't cry any more than I used to ☐ I cry more than I used to ☐ I cry over every little thing ☐ I feel like crying, but I can't
11	Agitation:	\square_0 I am no more wound up or restless than usual \square_1 I feel more restless or wound up than usual \square_2 I am so restless or agitated that it's hard to stay still \square_3 I am so restless or agitated that I have to keep moving or doing something
12	Loss of interest:	\square_0 I have not lost interest in other people or activities \square_1 I am less interested in other people or things than before \square_2 I have lost most of my interest in other people or things \square_3 It's hard to get interested in anything
13	Indecisiveness:	 □₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14	Worthlessness:	☐ I do not feel I am worthless ☐ I don't consider myself as worthwhile and useful as I used to ☐ I feel more worthless as compared to other people ☐ I feel utterly worthless
15	Loss of energy:	 □₀ I have as much energy as ever □₁ I have less energy than I used to have □₂ I don't have enough energy to do very much □₃ I don't have enough energy to do anything



	Center Number:	Participant Number:	Participant's Initials:	first middle las
BDI-II (continued)				
16 Changes in sleeping pattern:	☐₁ I sleep somewhat more ☐₂ I sleep somewhat less ☐₃I sleep a lot more than ☐₄I sleep a lot less than u ☐₅ I sleep most of the day	e than usual than usual usual usual		
17 Irritability:	 □₀ I am no more irritable □₁ I am more irritable tha □₂ I am much more irritable □₃ I am irritable all of the 	n usual ole than usual		
18 Changes in appetite:	☐₀ I have not experienced ☐₁ My appetite is somew ☐₂ My appetite is somew ☐₃ My appetite is much le ☐₄ My appetite is much g ☐₃ I have no appetite at c ☐₀ I crave food all of the	hat greater than usual ess than before preater than usual all		
19 Concentration difficulty:	1 I can't concentrate as	well as usual ind on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatigu	fatigued than usual gued more easily than usual ued to do a lot of the things I used to do most of the things I u		
21 Loss of interest in sex:	☐ I have not noticed any ☐ I am less interested in ☐ I am much less interest ☐ I have lost interest in so	ted in sex now	in sex	



	Center Number:	Participant I	Number:	Participant's II	nitials:
Date completed:/	OR Not dor	ne → Specify re	ason (use codelist be	:low):	
Profile of Mood States	7				
Instructions: Please describe how yo	u feel right now by c	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				\square_3	4
2 Tense			\square_2	\square_3	4
3 Angry					4
4 Worn out					4
5 Unhappy				\square_3	4
6 Clear-headed			\square_{2}	\square_3	4
7 Lively				\square_3	4
8 Confused			\square_{2}	\square_3	4
9 Sorry for things done					4
10 Shaky				\square_3	
11 Listless					4
12 Peeved			\square_{2}	\square_3	
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					
19 Energetic					4
20 Panicky					4
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Not Done Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insuff	ficient time 4 Instru		ot required
				Participant's I	nitials:



	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_{2}	\square_3	4
31 Annoyed				\square_3	4
32 Discouraged	\square_{o}			\square_3	4
33 Resentful					4
34 Nervous				3	4
35 Lonely					4
36 Miserable					4
37 Muddled					4
38 Cheerful				\square_3	4
39 Bitter					4
40 Exhausted					4
41 Anxious					4
42 Ready to fight					4
43 Good-natured				\square_3	4

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	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
44 Gloomy					4
45 Desperate					4
46 Sluggish					4
47 Rebellious					4
48 Helpless					4
49 Weary					4
50 Bewildered					4
51 Alert					4
52 Deceived					4
53 Furious					4
54 Efficient				\square_3	
55 Trusting					4
56 Full of pep				\square_3	
57 Bad-tempered					4
58 Worthless					
59 Forgetful					4
60 Carefree				\square_3	4
61 Terrified				\square_3	4
62 Guilty					
63 Vigorous					4
64 Uncertain about things					
65 Bushed					4

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Center Numbe	er: Participant N	umber:		Participant'	s Initials:	first middle last						
Date completed:/Onth	Not done → Specify rec	son (use code	list below):									
Perceived Stress Scale (PSS)												
Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.												
		Never	Almost Never	Some- times	Fairly Often	Very Often						
In the last month, how often have you fe unable to control the important things in	•					4						
2 In the last month, how often have you fe your ability to handle your personal prob					\square_3	4						
3 In the last month, how often have you fe going your way?	It that things were				\square_3	4						
4 In the last month, how often have you fe piling up so high that you could not over					\square_3							
Not Done Codelist: 1 Participant refused 2 Clinician un	able to obtain 3 Insuffi	cient time 4	Instrument f	ailure 5	Not requi	red						

Participant's Initials: first middle last



	Cent	er Number: Particip	oant Number:	Partic	cipant's Initials	first middle last
Da	te completed:/ _{month} / _{year}	_ OR Not done → Specif	fy reason (use code	elist below):		
P	ttsburgh Sleep Quality Inde	e X (PSQI)				
	structions: The following questions relate to the most accurate reply for the i	o your usual sleep habits d		-		
Du	ring the past month					
1	When have you usually gone to b	ed?::				
2	How long (in minutes) has it taken	•		minutes	5	
3	When have you usually gotten up	in the morning?	: :00 to 23:59			
4	How many hours of actual sleep did (This may be different than the number of hours you sp	, ,				
5	During the past month, how often sleeping because you (check only or	•	e 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 m	ninutes				\square_3
	b Wake up in the middle of the ni	ght or early morning				\square_3
	• Have to get up to use the bathr	oom				\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 describ you have had trouble sleeping reason(s):	•	n 			\square_3
6	During the past month, how often medicine (prescribed or "over the counter")					\square_3
	89,with permission from Elsevier Science. >> Done Codelist: 1 Participant refused 2 Cli	nician unable to obtain 3	Insufficient time 4	Instrument failure	e 5 Not re	quired



	Center Number: Participan	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?	o			
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?	\Box_{0}			\square_3



Month 12 Submission

								VI	SIT I		
Cent	er Number:	Partici	pant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last		
Date completed:/OR I	Not done → Spec	ify reaso	on (use co	delist bel	ow):						
Derogatis Interview for Sexu	al Function	DISF-S	R) (F) Fe	male Ve	rsion						
Instruction: Below you will find a brief set of a sections that ask about different aspects of you while another inquires about the kinds of sexusexual arousal and the quality of your organ relationship.	r sexual experiences	ces. One 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	ams, ur		
activities asked about in that section. Some free frequency scales range from "0 = never" to "4 of a satisfaction scale. This type of scale tells ha Some satisfaction scales range from "0 = could	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	on who gave you	the inve	ntory for	help.							
Section 1—Sexual Cognition/Fantasy	,										
During the past 30 days or since the last t you filled out this inventory, how often he you had thoughts, dreams, or fantasies al	ive	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		6		8		
1.2 Erotic parts of a man's body (e.g., shoulders, legs)	face,			\square_3	4	5	6		8		
1.3 Erotic or romantic situations	o			\square_3	4	5			8		
1.4 Caressing, touching, undressing, of foreplay	or				4	5	6		8		
1.5 Sexual intercourse, oral sex, touc to orgasm	hing			3	4	5			8		
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5 Not required

4 Instrument failure

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused

3 Insufficient time



Center	Number:	Po	articipant N	umber: _		Par	ticipant's	Initials:	st middle last
Derogatis Interview for Sexua	l Functi	on (DIS	F-SR) (F)	Female \	/ersion (d	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				3	4		6	7	8
2.2 Actively seek sexual satisfaction				3	4		6	7	8
2.3 Feel sexually aroused with a partner				3	4		6	7	8
	Never	Rarely	Sometimes	Usually	Always				
2.4 Have normal lubrication with masturbation				3	4				
2.5 Have normal lubrication									

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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	o			\square_3	4	5	□ ₆		8
3.2 Masturbation	По			3	□ 4	5	□ ₆		
3.3 Casual kissing and petting					4	5	□ ₆		8
3.4 Sexual foreplay					□ ₄	5	□ ₆		
3.5 Sexual intercourse, oral sex, etc.	o				4	5	<u></u> 6	\square_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	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)	o				4				
4.4 Feelings of closeness and togetherness with your partner	o			\square_3	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					

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Ce	P	articipant's	Initials:	irst middle last					
Derogatis Interview for Sex	ual 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 intercourse.				\square_3	4	5		7	8
	Not at	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex	? □₀			\square_3	4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	d .				4				
	Could	Very	Poor	Somewhat	Adequate	Above	Good	Very	Could

not be

worse

poor

inadequate

average

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

of your sexual functioning?

good

not be

better

Month 12 Submission Visit 1

	Center Number	:	Partici	pant Numl	ber:		_ Partic	cipant's In	itials:	t middle last		
Date completed:day /month/	OR Not done	→ Spec	ify reaso	on (use co	delist bel	ow):						
Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version												
Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.												
On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied." In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.												
follow. Although it is briet, 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/Fant	asy											
During the past 30 days or since the lo you filled out this inventory, how often you had thoughts, dreams, or fantasie	n 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		o				4	5	□ ₆				
1.2 Erotic parts of a woman's bod face, genitals, legs)	y (e.g.,	\square_{o}		\square_2	\square_3	□ ₄	5	□ ₆		□ ₈		
1.3 Erotic or romantic situations		По			\square_3	4	5	□ ₆		□ ₈		
1.4 Caressing, touching, undressin foreplay	g, or	\Box_{o}		\square_2	\square_3	\square_4	5	□ ₆	\square_7	□ ₈		
1.5 Sexual intercourse, oral sex, to to orgasm	ouching	О					5	□ ₆		□ ₈		

5 Not required

4 Instrument failure

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

3 Insufficient time



	Center Number:	Participant Number:	Participant's Initials:	first middle last
Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)				

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

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Participant's Initials: first middle last

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Center Num	ber:	Pai	rticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DISI	F-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	6		8
3.2 Masturbation	По			\square_3	4	5	6		8
3.3 Casual kissing and petting	По			\square_3	4	5	6		8
3.4 Sexual foreplay	По			\square_3	4	5			8
3.5 Sexual intercourse, oral sex, etc.	По			\square_3	4	5	6		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	О			3	4				
4.2 The intensity of your orgasm	По			\square_3	4				
4.3 The length or duration of your orgasm	По			\square_3	4				
4.4 The amount of seminal liquid that you ejaculate	o			\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	_4				

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Cente	ter Number: Participant Number:					Participant's Initials: initials: last				
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	_ ₇	□ 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?	\Box_0			\square_3						
	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			

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	Center Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:/	OR Not done →	Specify reason (use codelist below):		
Food Cravinas Questio	nnaire—State (FCO_S	;1		

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].				4	5
2	I'm craving [one or more specific foods].			\square_3	\square_{4}	
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	4	5
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	
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	\square_{4}	
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		
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.					
15	I feel weak because of not eating.			\square_3		
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time	4 Instrume	nt failure	5 Not req	uired

Participant's Initials:



	Center Number:	Participant Number: Participant's 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 often	an .	Danala			Always/Almost					
have you experienced a craving		(once or twice)	Sometimes	Often	Every Day					
1 Cake			\square_3							
2 Pizza			\square_3	4						
3 Fried chicken			\square_3	4						
4 Gravy										
5 Sandwich bread				4						
6 Sausage			\square_3							
7 French fries				4						
8 Cinnamon rolls				4						
9 Rice				4						
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 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: first middle last
Date o	completed:/	year OR Not done —	Specify reason (use codelist below):		
Eati	ng Inventory				
1	When I smell a sizzling sto difficult to keep from eatin			☐₁ 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 th	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	because I just get too	hungry.	₁ True	o False
6	I deliberately take small h	nelpings as a means	of controlling my weight.	, True	o False
7	Sometimes things just tast I am no longer hungry.	e so good that I kee _l	p on eating even when	₁ True	o False
8	Since I am often hungry, I expert would tell me that something more to eat.		<u> </u>	, True	o False
9	When I feel anxious, I find	d myself eating.		☐₁ True	o False
10	Life is too short to worry	about dieting.			o False
11	Since my weight goes up more than once.	and down, I have go	one on reducing diets	₁ True	□₀ False
12	I often feel so hungry tha	t I just have to eat so	omething.	, 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 ca	lories in common food.	, True	o False
15	Sometimes when I start e	ating, I just can't see	m to stop.	ղ 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 to eating then.	y, I get hungry becau	use I have gotten used	, True	o False
18	While on a diet, if I eat fo for a period of time to mo		d, I consciously eat less		□₀ False
Not D	Anna Cadaliste 1 Participant refused	2 Clinician unable to obto	rin 3 Insufficient time 4 Instrument	failure 5 N	lot required

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

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calerie Phase 2

Month 12 Submission Visit 1

	Center Number:	Participant Number: Participant's Initials: First middle last
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?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult
42	How conscious are you of what you are eating?	☐₁ Not at all ☐₂ Slightly ☐₃ Moderately ☐₄ Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐₁ Almost never ☐₂ Seldom ☐₃ Usually ☐₄ Almost always
44	How likely are you to shop for low calorie foods?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
45	Do you eat sensibly in front of others and splurge alone?	□₁ Never □₂ Rarely □₃ Often □₄ Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
47	How frequently do you skip dessert because you are no longer hungry?	☐₁ Almost never ☐₂ Seldom ☐₃ At least once a week ☐₄ Almost every day
48	How likely are you to consciously eat less than you want?	☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely
49	Do you go on eating binges though you are not hungry?	☐₁ Never ☐₂ Rarely ☐₃ Sometimes ☐₄ At least once a week
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	 Not like me 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?	o Eat whatever you want, whenever you want it I Usually eat whatever you want, whenever you want it Often eat whatever you want, whenever you want it Often limit food intake, but often "give in" Usually limit food intake, rarely "give in" Constantly limiting food intake, never "giving in"



			Center N	Number:	Participant Number:	Participant's Initials:	first middle last
Date completed:	/	/ month	/year	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		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			8		
4	I can resist eating when I feel physically run down.	o			\square_3	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).				\square_3	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	

Participant's Initials: first middle last



	nber:			mber:			Particip	oant's Init	ials:	middle last
Weight Efficacy Lifestyle Question	Note	onfide	e nt at a		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	\square_4		6		8	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.				\square_3		5	6		8	9
13 I can resist eating even when others are pressuring me to eat.	e				4	5			8	9
14 I can resist eating when I am in pain.				\square_3	4	5	6		8	9
15 I can resist eating just before going to bed.									8	9
16 I can resist eating when I have experienced failure.				\square_3		5	6		8	9
17 I can resist eating when high-calorie for are available.	ods						6		8	9
18 I can resist eating even when I think others will be upset if I don't eat.						5	6		8	9
19 I can resist eating when I feel uncomfortable.					4	5	6		8	9
20 I can resist eating when I am happy.				\square_3		5	6		8	9



	Center Number:	Participa	nt Numbe	er:		Participant's Initials:			
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	\square_4	5		
5 I can't keep certain foods in my binge on them.	house because I will				\square_3	4		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		
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	6	
16 Lately nothing seems enjoyab	le anymore.				\square_3	\square_4	5		
17 Laxatives help keep you slim.					\square_3	4	5	6	
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	lumber: _		Pa	rticipant's	Initials: _	irst middle last
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.	omething to rid myse				4	5		
22 I overeat too frequently.				\square_3		5		
23 It's okay to be overweight.				\square_3	4	5	6	
24 Recently I have felt that I am o	worthless person.			\square_3	4	5	6	
25 I would be very upset if I gain	ed 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.				\square_3	4	5	6	7
28 Being fat would be terrible.				3	4	5		
29 I have thought seriously abou	t suicide lately.			\square_3	4	5	6	7
30 I don't have any energy anymo	re.			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	ited.			\square_3		5		
34 Some foods should be totally	avoided.			\square_3		5	6	
35 I use laxatives to control my w	veight.			\square_3	4	5		
36 I am terrified by the thought o	f being overweight.			\square_3	4	5	6	
37 Purging is a good way to lose	weight.			\square_3	4	5	6	7
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	

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		Center Number: Participan	t Number: _		Par	ticipant's I	nitials:	
Da	te completed:/ _{month} / _{year}	OR Not done → Specify ı					firs	t middle last
	ody Shape Questionnaire							
	e would like to know how you have been case read each question and check the bo		_					
Ov	er the Past Four Weeks		Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you bro	ood about your shape?			\square_3		5	
2	Have you been so worried about have been feeling that you ough					4	5	6
3	Have you thought that your thig too large for the rest of you?	ghs, hips, or bottom are				4	5	6
4	Have you been afraid that you fatter)?	might become fat (or					5	6
5	Have you worried about your fl enough?	lesh not being firm				4	5	6
6	Has feeling full (e.g., after eating a lar	rge meal) made you feel				4	5	
7	Have you felt so bad about you cried?	r shape that you have				4	5	6
8	Have you avoided running beco wobble?	ause your flesh might				4	5	6
9	Has being with thin women/me self-conscious about your shape					4	5	6
10	Have you worried about your the sitting down?	highs spreading out when					5	
11	Has eating even a small amount fat?	t of food made you feel				4	5	6
12	Have you noticed the shape of a felt that your own shape compa				\square_3	4	5	6
13	Has thinking about your shape in ability to concentrate (e.g., while want to conversations)?	•				4		6
14	Has being naked, such as when feel fat?	taking a bath, made you				4	5	6
15	Have you avoided wearing clot particularly aware of the shape				\square_3	4	5	6
16	Have you imagined cutting off f body?	leshy areas of your			\square_3	\Box_4	5	

5 Not required

4 Instrument failure

CRF, page 196

3 Insufficient time

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused



	Center Number: Par	ticipant N	umber: _		Par	rticipant's	Initials: _	rst middle last
Body Shape Questionno	aire (BSQ) (continued)							
Over the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes o you feel fat?	r other high calorie food r	nade			\square_3	4	5	
18 Have you not gone out on because you have felt bad	social occasions (e.g., parties, about your shape?)			\square_3		5	6
19 Have you felt excessively lo	arge and rounded?				\square_3	4	5	
20 Have you felt ashamed of y	our body?				3	4	5	6
21 Has worry about your shap	pe made you diet?				\square_3	4	5	6
22 Have you felt happiest abo stomach has been empty?	ut your shape when your				\square_3	4	5	6
23 Have you thought that you because you lack self-control					\square_3	4	5	
24 Have you worried about of flesh around your waist or		:			\square_3	4	5	
25 Have you felt that it is not f thinner than you?	air that other women/me	n 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 soft		p too			\square_3	4	5	
28 Have you worried about yo	our flesh being dimply?				\square_3	4	5	
29 Has seeing your reflection (you feel bad about your sh		nade			\square_3	4	5	6
30 Have you pinched areas of fat is there?	your body to see how m	uch			\square_3	4	5	6
31 Have you avoided situation your body (e.g., communal change		•			\square_3	4	5	6
32 Have you taken laxatives in	n order to feel thinner?				\square_3	4	5	6
33 Have you been particularly shape when in the compan		r				4	5	6
34 Has worry about your shap to exercise?	oe made you feel you oug	ıht					5	6



		Center Number	: Participant Num	ber: Part	icipant's Initials:				
Hai	ndgrip Strength								
Date	and time of assessment:	/	::: _:	Staff	initials:				
OR N	ot done → Specify reaso	n (use codelist below):							
1 D	ynometer handle positior	n:							
2 D	2 Dominant hand (check only one): \square_1 Left \square_2 Right \square_3 Ambidextrous								
3 H	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 failu	re 5 Not required				



			Center Number:	Participant Number:	Particip	first middle las
Is	sometric/Isokine	tic Kne	e Extension and	d Flexion		
	ate and time of assessment				Staff ini	tials:
	Decembrication of the state of		□ N ₁ . □ V ₂ .			
1	Recent injury or pain—rig					
2	Recent injury or pain—le		· .			
3	Specify machine used (Pl	BRC only):	□ ₀ Cybex □ ₁ Biolex			
	All values corrected	for 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 Particip	oant refused	2 Clinician unable to ob	otain 3 Insufficient time	4 Instrument failure	5 Not required



	Center Number:	Participant Number: Parti	icipant's Initials:
Clinic Weight			
Weight date and time	/	Staff i	initials:
OR Not done → Spec	fy reason (use codelist below):		
Clinic weight (if the two	measurements are more than 0.1 kg apart, med	asure 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

calerie

Month 12 Submission Visit 2

Participant's Initials: first middle last

Participant Number:

Center Number:

Phase 2

Se	ven-L	Seven-Day Physical Activity Recall (PAR)	rity Reca	II (PAR)											
Toda	Today's date:	/		Day (check only one):	Mon Tues Wed Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	se Wed	Thurs	Fri Sc	at Sun	OR No	done 🕇	Specify re	esn) uospa	codelist belo	.w):
_	Were yo	oyed in the last sev	ven ven days?		°Z °C	$\Box_{\rm o}$ No \rightarrow Skip to question 3		Ty Yes				Interv	Interviewer initials:		first middle last
4	f Yes: M	If Yes: Which days (check all that apply)?	۵.		Mon	Tues Wed		Thurs	i.E	Sat] Sun				
<u>ر</u>	Which d	Which days do you consider your weekend, or non-work, days?	veekend, or n	on-work, daysî	Mon	Tues	Med] Thurs	Fi	Sat	Sun				
-	Pay of		Sleek	Sleep Time	Work	Work Time	Morn	Morning (in minutes)	nutes)	Affen	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
7		,													
rester- day)		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
٠		day /	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
ro.		dey month year	00:00 6 23:59	00:00 to 23:59		00:00 10:23:59									
			00:00 to 23:59	00:00 to 23:59											
4		day / /		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
n		day / /		00:00 to 23:59 00:00 to 23:59 00:00 to 23:59	00:00 % 23:59	00:00 to 23:59									
7		day /	00:00 to 23:59	00:00 to 23:59 00:00 to 23:59											
T week ago)		day /		00:00 to 23:59	00:00 % 23:59	00:00 to 23:59									

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

5 Not required

Dαy #



	Center Number: Participant Number: Participant's Initials: first_middle_last
Seve	en-Day Physical Activity Recall (PAR) (continued)
or o	mpared to your physical activity over the past three months, was last week's physical activity more, less, about the same (check only one)? More Less About the same
Interv	iewer: Please answer questions below and note any comments on interview.
	re there any problems with the Seven-Day PAR interview? No Yes
	you think this was a valid Seven-Day PAR interview? No Yes
	re there any activities reported by the participant that you don't know how to classify? No Yes



Month 12 Submission

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



		Center Number:	Participant Number:	Participant's Initials: first middle las
V	O ₂ Max			
1	Date and time of test:/	/	00:00 to 23:59	Staff initials:
	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	Rest ECG: Rhythm (check only one): Ventricular conduction (ch		rmal 2 LBBB	
4	Heart rate (HR) data: Resting heart r Age-predicted Heart rate (ma	heart rate:	bpm	
5	Reason(s) for termination of testing (Symptom limited (dyspnea, fatigue) Angina/ischemia → Complete all t	hat apply: HR when t		: bpm or ₉₆ NA r ed: bpm or ₉₆ NA
	Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress Orthopedic/extremity complaints (po	image study, complete v nins/cramps)	entricular episode report)	Spiii Ok
6	Did frequent ventricular ectopy occur No Yes → If Yes: When did it occur (_		
7	Peak VO ₂ : mL/kg/min	L/min		
8	Did the participant meet at least 2 of \square_0 No \square_1 Yes \rightarrow If Yes: VO ₂ max:	_	betwe	ve a plateau in VO ₂ (change ≤ 150 mL) een the final two stages ≥ 1.1 ax ± 5 bpm of age-predicted maximum
9	Exercise time: : : :			
10	Blood pressure at VO ₂ peak/VO ₂ mo	systolic diastolic	mm Hg	
11	Borg RPE score at VO ₂ peak/VO ₂ mo	ax:(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		

3 Insufficient time

5 Not required

4 Instrument failure

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



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

Month 12 Submission Visit 3

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

3 Insufficient time

4 Instrument failure

Core Tem	perature		tirst middle last
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	
	/ _{month} /	00:00 to 23:59	
Inpatient	Admission and Discharge		
1 Inpatient a	dmission date and time:/	:: : ::	
2 Inpatient d	ischarge date and time:/ _{month} /	::::::	



) 6							
1	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					
	Arm injected:	Left					
5 DTH results: Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. A = Largest diameter						_	
	•	perpendicular to A			T		
	A = Largest diameter	perpendicular to A		Read By:	T	Hour (@ Visit 5) B (diameter)	Read By:
	A = Largest diameter B = Second diameter	perpendicular to A	Hour (@ Visit 4)		48	Hour (@ Visit 5)	
	A = Largest diameter B = Second diameter Antigen	perpendicular to A 24 A (diameter)	Hour (@ Visit 4) B (diameter)		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)	Read By:	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



	Center Number:	Participant Number: _	Particip	pant's Initials: first middle last		
Clinic Weight						
Weight date and time: _	/	: 0 to 23:59	Staff init	tials:		
OR Not done → Specify reason (use codelist below):						
Clinic weight (if the two m	easurements are more than 0.1 kg apart,	measure weight a third tim	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 co	ollection started://	year 00:00 to 23:	- <u></u>			
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Ca	techolamines	O No		first middle last		
	Blood	□ ₀ No □ ₁ Yes		first middle last		
Oral glucos	e tolerance test (OGTT)	O No		first middle last		
If a sample is not obtained,						
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		
	/					

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



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):			: → Specify: Record on Cor (e.g., barrier, IUD):	ncomitant	Medico	
Day 1		Date	Time	If Not I Reas (use co	son [*]	Staff Initials
Day 1 of menses (females only)						
Date and time of last meal (males only	7)	/	00:00 to 23:59			
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 I Reas (use co	son	Staff Initials
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, Re (Use codelist be		Staff	Initials
Resting Metabolic Rate (RMR)—Visit 4	c	/			first	middle last
Cart ID		-003 (623-002)		PBRC-01		
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	ime 4 Instrument	failure	5 Not re	equired

Month 12 Submission

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Tod	Today's date:	/	Day	Day (check only one):	Mon Tues Wed Thurs Fri Sat	beW Si] Thurs	Fri	II Sun	OR No	done 1	Specify re	Sun OR Not done → Speafy reason (use codelist below):	codelist bel	ow):
_	Were yo	oyed in the last se	ın days?		°Z °	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$		Tes				Interv	Interviewer initials:		first middle last
7	If Yes: W	If Yes: Which days (check all that apply)?	۲.		Mon	Tues	Med] Thurs	i.E	Sat	Sun				
က	Which d	Which days do you consider your weekend, or non-work, d	veekend, or no	on-work, days?	Mon	Tues] Wed	Thurs	Fri	Sat	Sun				
200	Day of		Sleek	Sleep Time	Work Time	Time	Morn	Morning (in minutes)	intes)	After	Afternoon (in minutes)	inutes)	Ever	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	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									
IO.		day month year	00:00 to 23:59	00:00 to 23:59											
4		day month year	00:00 to 23:59	00:00 to 23:59											
က			00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59										
4															
■ 1 week ago)			00:00 to 23:59	00:00 to 23:59	. :	. :									

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

3 Insufficient time

4 Instrument failure



		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)? More Less About the same	over the past three mont	ns, was last week's physical	activity more, less,	
In	terviewer: Please answer questions l	below and note any con	nments on interview.		
5	Were there any problems with the So \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	u don't know how to classif	y?	



	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



Month 18 Submission Month 17 Visit

Participant's Initials: ___

Clinic Weight				
Weight date and times	:/	: ::	Staff init	ials:
	ify reason (use codelist below)			
Clinic weight (if the two	o measurements are more than (0.1 kg apart, measure weight a th	nird time):	
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			
Pregnancy Te	st			
Complete only for fo	emales.			
Does participant h	nave reproductive potential? Date urine pregnancy test pe	erformed:/ _{month} /_		
Does participant h No Yes → If Yes: [Date urine pregnancy test pe Results: 1 Negative 2 Positive			
Does participant h ONO Tyes → If Yes: I	Date urine pregnancy test pe Results: 1 Negative 2 Positive	erformed:/		
Does participant h one of the composition of the	Date urine pregnancy test pe Results: 1 Negative 2 Positive			Staff Initials
Does participant h o No o No o Yes → If Yes: I Outcomes Lak Date and time sample If a sample is not obtain	Date urine pregnancy test per Results: 1 Negative 2 Positive Collection started: 4 day Cample	//	: 	Staff Initials First middle last
Does participant h o No o No o Yes → If Yes: I Outcomes Lak Date and time sample If a sample is not obtain	Date urine pregnancy test pe Results:	Sample Complete? One of the complete of the c	: 	

Center Number: ___ _ Participant Number: ___ _ _



Month 18 Submission CR Visit 1/Control Visit

		Center Number:	Participant Number:	Participant's Initials:
C	linic Weight			
We	eight date and time:/ _{month}	/	:	Staff initials:
	R Not done → Specify reason (use Cod			first middle last
Cli	nic weight (if the first two measurements o	are more than 0.1	kg apart, measure weight a third time):	
We	eight 1:	_ kg		
We	eight 2:	_ kg		
We	eight 3:	_ kg		
We	eight of gown:	_ kg		
V	ital Signs			
As	sessment date and time:/	/	: 00:00 to 23:59	
	If waist measurement not done → Sp	pecify reason (use	codelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, meas	sure 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 umbilical point waist circumference a third til		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 do	ne → Specify red	ason (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 → Sp	pecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):1	Left arm	ght 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		
	6c Blood pressure 3:/	mm Hg	Time::::	
No	ot Done Codelist: 1 Participant refused	2 Clinician unab	le to obtain 3 Insufficient time 4 Instru	ument 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
/		(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	Sample		of Done, Reason e 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:	/	/ : : : :	3:59	
Date and time sample collection started:	/	/ :	3:59	
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



		Center Number:	Participant Number:	Participant's Initials: middle las
D	oubly Labeled V	Vater (DLW)		
1	Date and time of DLW d	osing:/ _{month} / _{year}	:: ::	Staff initials: First middle lost
	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 T	ime Collected
	Pre dosing (PD)	PDa	/	year : : : : : : : : : : : : : : : : : : :
		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 : : : : : : : : : : : : : : : : : : :
		D7b	/	year 00:00 to 23:59
	Day 14 (Visit 4)	D14a	/	year 00:00 to 23:59
		D14b	/	year : 00:00 to 23:59
5	Affix CRF page label(s)	corresponding to this urine sample set	Attix	Affix
			i 'i i	Retest Sample
			Label Here	Label Here
,				

3 Insufficient time

4 Instrument failure

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



Ce	enter Number:	Participant Number:	Participant's Initials:					
Pregnancy Test								
Complete only for females.	Complete only for females.							
Does participant have reproductive potential? □ ₀ No □ 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 rad □ No □ Yes 	scan and document in							
DXA Scan		DXA Rescan O	R \square_{96} NA					
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



Cent	er Number:	Participant Number:	Participant's Initials:
Clinic Weight			
Weight date and time:/ _{month} /	: year	23:59	Staff initials: first middle last
OR Not done → Specify reason (use Codelist be	elow):		
Clinic weight (if the first two measurements are mo	re than 0.1 kg apar	t, measure weight a third time):	
Weight 1: kg			
Weight 2: kg			
Weight 3: kg			
Weight of gown: kg			
Contraception			
If Not Done → Specify reason (use codelist belo	w):		
Contraception method (females only):	□ None OR C	_	: I on Concomitant Medications page r, IUD):
Not Done Codelist: 1 Participant refused 2 Cl	nician unable to ob	tain 3 Insufficient time 4 Ins	trument failure 5 Not required

Month 18 Submission CR Visit

Participant's Initials: first middle last

Participant Number:

Center Number:

Phase 2	
erie	
Cal	

Se	ven-D	Seven-Day Physical Activity Recall (PAR)	cal Activ	ity Recal	(PAR)											
် ဝ	oday's date: _	/	/ - #		Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Tue	pewss	Thurs	Fri S	at Sur	OR No	† done →	Specify re	eason (use	codelist beld). /wo
_	Were yo	oyed	the last seven	n days?		°Z °	$\bigcup_0 \mathbb{N}_0 \to Skip$ to question 3	stion 3	, Yes				Interv	Interviewer initials:		first middle last
2	If Yes: W	If Yes: Which days (check all that apply)?	k all that apply).	•		Mon	Tues Wed Thurs Fri	Ved	Thurs	ш	Sat Sun	Sun				
_	Which d	Which days do you consider your weekend, or non-work, days?	nsider your w	reekend, or no	on-work, days?	Mon	Tues Wed	Ved	Thurs		Sat	Sun		l		
>	Day of			Sleep	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	ninutes)	Even	Evening (in minutes)	utes)
5 #	Week	Date	Φ.	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
sster. lay)	·	day / month	./	00:00 to 23:59 00:00 to 23:59												
9	·	day / month	/year		: : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59									
10	·	day / month	/year	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59 00:00 to 23:59											
4	·	day month	/year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
m	·	day month	/year			00:00 to 23:59	00:00 to 23:59									
2		day month	/year		: : : : : : : : : : : : : : : : : : :											
■ week ago)	·	day / month	/ year		00:00 to 23:59	. :	. :									

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



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	Interviewer: Please answer questions below and note any comments on interview.								
5	Were there any problems with the Se	even-Day PAR interviev	v?						
6	Do you think this was a valid Seven-Do No	Day PAR interview?							
7	Were there any activities reported by No	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: middle last
6-D	ay Food Record				
Comp	olete below OR Not done → Speci	ify reason (use Codelist b	pelow): _	Staff in	itials:
				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 Description 1 Reliable Description 3 Missing
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	Reliable Description 1 Reliable Description 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 Lackground Delta Control Lackground D
5	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	12	/	Reliable Description 1 Reliable Description 3 Missing
6	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	13	/	Reliable Description 1 Reliable Description 3 Missing
Not D	Oone Codelist: 1 Participant refused	2 Clinician unable to ob	otain 3	Insufficient time 4 Instrument failure	5 Not required



		Center Number: Participant Number: Participant's Initials: isst last
Da	te completed:/	/ OR Not done → Specify reason (use codelist below):
В	DI-II	
Ins	pick out the one weeks, includin	ire consists of 21 groups of statements. Please read each group of statements carefully and then e statement in each group that best describes the way you have been feeling during the past two g today. Check the box beside the statement you have picked. Be sure that you check only one ach group, including item 16 and item 18.
1	Sadness:	 □₀ I do not feel sad □₁ I feel sad much of the time □₂ I am sad all of the time □₃ I am so sad or unhappy that I can't stand it
2	Pessimism:	 □₀ I am not discouraged about my future □₁ I feel more discouraged about my future than I used to be □₂ I do not expect things to work out for me □₃ I feel my future is hopeless and will only get worse
3	Past failure:	 □₀ I do not feel like a failure □₁ I have failed more than I should have □₂ As I look back, I see a lot of failures □₃ I feel I am a total failure as a person
4	Loss of pleasure:	☐ I get as much pleasure as I ever did from the things I enjoy ☐ I don't enjoy things as much as I used to ☐ I get very little pleasure from the things I used to enjoy ☐ I can't get any pleasure from the things I used to enjoy
5	Guilty feelings:	 □₀ I don't feel particularly guilty □₁ I feel guilty over many things I have done or should have done □₂ I feel quite guilty most of the time □₃ I feel guilty all of the time
6	Punishment feelings:	□₀ I don't feel I am being punished □₁ I feel I may be punished □₂ I expect to be punished □₃ I feel I am being punished
7	Self-dislike:	 □₀ I feel the same about myself as ever □₁ I have lost confidence in myself □₂ I am disappointed in myself □₃ I dislike myself
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required
		Participant's Initials:
		first middle last



		Center Number:	_ Participant Number:	_ Participant's Initials: middle last
BD	-II (continued)			
8 S	self-criticalness:	\square_1 I am more critical \square_2 I criticize myself for	blame myself more than usual of myself than I used to be or all of my faults everything bad that happens	
9 S	iuicidal thoughts or wishes:	•	•	carry them out
10 (Crying:	☐ l don't cry any mo ☐ l cry more than l ☐ l cry over every li ☐ l feel like crying,	used to ttle thing	
11 /	Agitation:	\Box_1 I feel more restles \Box_2 I am so restless or	und up or restless than usual s or wound up than usual agitated that it's hard to stay agitated that I have to keep n	
12 L	oss of interest:	, I am less intereste	erest in other people or activition d in other people or things that f my interest in other people or erested in anything	n before
13 l	ndecisiveness:		cult to make decisions than usu ter difficulty in making decisior	
14 V	Vorthlessness:		nyself as worthwhile and useful ess as compared to other peop	
15 L	oss of energy:		-,	



	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	☐ I sleep somewhat more ☐ I sleep somewhat less to a lot more than ☐ I sleep a lot less than u ☐ I sleep most of the day	e than usual than usual usual sual		
17 Irritability:	\square_0 I am no more irritable in \square_1 I am more irritable that \square_2 I am much more irritable \square_3 I am irritable all of the	n usual le than usual		
18 Changes in appetite:	☐ I have not experienced ☐ My appetite is somewh ☐ My appetite is somewh ☐ My appetite is much le ☐ My appetite is much go ☐ I have no appetite at a ☐ I crave food all of the food	nat greater than usual ess than before reater than usual Ill		
19 Concentration difficulty:	☐₀ I can concentrate as w ☐₁ I can't concentrate as v ☐₂ It's hard to keep my mi ☐₃ I find I can't concentrate	well as usual ind on anything for very long		
20 Tiredness or fatigue:	\square_2 I am too tired or fatigu	atigued than usual gued more easily than usual ed to do a lot of the things I us ed to do most of the things I us		
21 Loss of interest in sex:	\square_0 I have not noticed any \square_1 I am less interested in s \square_2 I am much less interest \square_3 I have lost interest in se	ed in sex now	ı sex	



	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	t middle last
Date completed:/ _{month} /	OR Not done –	→ Specify	/ reason	(use cod	elist belo	w):			
Multiaxial Assessment of	Eating Disorder	Sym	ptom	S (MAE	DS)				
Instructions: Using the scale shown, plea	se rate the following items	on a sca	le from 1	to 7. Ple		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		
2 My sleep isn't as good as it u	sed to be.				$\square_{_3}$	4	5	6	
3 I avoid eating for as long as	l can.				\square_3	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				\square_3	4		6	
6 I can easily make myself vom	it.				$\square_{_3}$	4	5	6	
7 I can feel that being fat is term	ible.				\square_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}	\square_4	5	6	
11 I think I am a good person.					\square_3	4	5	6	
12 My eating is normal.					\square_3	4	5	6	
13 I can't seem to concentrate la	tely.				\square_{3}	4	5	6	
14 I try to diet by fasting.					$\square_{_3}$	\square_4	5	6	
15 I vomit to control my weight.					\square_3	4	5	6	
16 Lately nothing seems enjoyal	ole anymore.				$\square_{_3}$	\square_{4}	5		
17 Laxatives help keep you slim.	,					4	5	6	
18 I don't eat red meat.					\square_3		5	6	
19 I eat so rapidly I can't even to	aste my food.				\square_3	4	5	6	
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	in 3 In:	sufficient	time 4	Instrume	nt failure	5 No	t require	ed



	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		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	6	
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	6	
35 I use laxatives to control my	weight.			\square_3	4	5	6	
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	4	5		
38 I avoid fatty foods.								



	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		5	6	
41 I don't eat fried foods.				\square_3		5	6	
42 I skip meals.				3	4	5	6	7
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			3	4	5	6	7
45 I feel good when I skip meals	•			3	4	5	6	
46 I avoid foods with sugar.				\square_3	4	5	6	7
47 I hate it when I feel fat.				\square_3				
48 I am too fat.					4	5		7
49 I eat until I am completely stu	ffed.			3	4	5		
50 I hate to eat.				3	4	5	6	7
51 I feel guilty about a lot of thin	gs these days.			\square_3	4	5		
52 I'm very careful of what I eat				\square_3	4	5	6	7
53 I can "hold off" and not eat e	even if I am hungry.			\square_3		5	6	
54 I eat even when I am not hun	gry.			\square_3	4	5	6	
55 Fat people are disgusting.				\square_3		5		
56 I wouldn't mind gaining a fev	v pounds.							



Month 18 Submission **CR Visit 4**

5 Not required

CRF, page 226

4 Instrument failure

	Center Number: Participant Number	: Particip	ant's Initials:					
Inpatient Admission and	Discharge							
1 Inpatient admission date and time:	//	3:59						
2 Inpatient discharge date and time:	/	2:59						
Clinic Weight								
Weight date and time:/ _{month}	_/; year::: 00:00 to 23:59	Staff init	ials:					
OR Not done → Specify reason (use coa	lelist 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								
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 (623-002) ☐ WASH U-00 ☐ Tufts-006 (623-006) ☐ WASH U-00		016 (623-005) 017 (623-001)					

2 Clinician unable to obtain

3 Insufficient time

Not Done Codelist: 1 Participant refused

Month 18 Submission CR Visit 4

Participant's Initials: first middle last

Participant Number:

Center Number:

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ν Θ	Vent	Seven-Day Physical Activity Recall (PAR)	Activ	rity Reca	II (PAR)											
<u> </u>	Today's date:	e:			Day (check only one):	Won	ss Wed	Thurs	Fri S	at Sur	OR No	done +	Spedily n Interv	eaity reason (use codelis Interviewer initials:	codelist bel	ow):
_	Were yo	Were you employed in the last seven days?	last seve	en days?		o N O	$_{0}$ No \rightarrow Skip to question 3	estion 3	, Yes							first middle last
N	If Yes: W	If Yes: Which days (check all that apply)?	that apply)	۲٠		Mon	Tues	Med	Thurs	Œ	Sat	Sun				
က	Which d	Which days do you consider your weekend, or non-work, days?	er your v	weekend, or no	on-work, days	Mon	Tues	Wed	Thurs	Ш	Sat	Sun		-		
Dav	Day of			Sleek	Sleep Time	Work Time	Time	Mor	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	ninutes)	Ever	Evening (in minutes)	iutes)
#	Week	Date		In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
N		`		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									
0		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												
n		day month	year	00:00 % 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
		/			00:00 to 23:59											
4		day month	year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
ຕ				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	 	 									
.		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	 	 									
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



Month 18 Submission CR Visit 4

		Center Number:	Participant Number:	Participant's Initials: middle la	
S	even-Day Physical Activi	ty Recall (PAR) (continued)		
4	Compared to your physical activity or or about the same (check only one)?	ver the past three mon	ths, was last week's physical a	activity 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-E	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

Participant's Initials: _____

			tirst middle las
Clinic Weight			
Weight date and time:/ _{month} / _{year}	: 00:00 to 23:59	Staff initio	als:
OR Not done → Specify reason (use codelist below):			date
Clinic weight (if the two measurements are more than 0	.1 kg apart, measure weight a thir	rd time):	
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 per Results: □₁ Negative □₂ Positive Outcomes Labs Date and time sample collection started: — day /_			
Sample If a sample is not obtained, indicate with a Not Done.	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□ ₀ No □ ₁ Yes		first middle last
Vaccine Administration NOTE: Before any vaccine is administered, review and protocol for participant eli	the vaccine questionnaire	If Not Done, Reason (Use codelist below)	Staff Initials
Vaccine(s) given:	Hepatitis A		first middle last

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

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:
C	linic Weight			
W	eight date and time:/ _{month}	/	:	Staff initials:
	R Not done → Specify reason (use Coo			first middle last
Cli	nic weight (if the first two measurements o	are more than 0.1 kg	g 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:/	/	::	
	If waist measurement not done → S _I	pecify reason (use c	odelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, measu	ure natural waist circumference a third time):	Staff initials:
	Natural waist measurement 1:	·		
	Natural waist measurement 2:		cm	
	Natural waist measurement 3:	·	cm	
2	Umbilical point waist measurement (if umbilical point waist circumference a third ti		ments are more than 1.0 cm apart, measure	
	Umbilical point waist measurement 1	:	cm	
	Umbilical point waist measurement 2	2:	cm	
	Umbilical point waist measurement 3	3:	cm	
3	Pulse: bpm OR Not do	ne → Specify reas	son (use codelist below):	Staff initials:
4	Temperature:°C (OR Not done → S	pecify 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):1	Left arm Rigl	ht arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time:: OR Not done =	→ son (use codelist below):
	6b Blood pressure 2:/		Spot, 102	Soft (use codelisi below).
	6c Blood pressure 3:/			
No	ot Done Codelist: 1 Participant refused	2 Clinician unable	e to obtain 3 Insufficient time 4 Instr	ument failure 5 Not required



Center N	Number: Participant I	Number: Pa	rrticipant's Initials: middle last			
12-Lead ECG						
Date and Time		Findings	Staff Initials			
	Is ECG (check only one):	first middle last				
Safety Labs	,					
Date and time of last meal:/						
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials			
Blood	□ ₀ No □ ₁ Yes		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:/						
Results:						
Not Done Codelist: 1 Participant refused 2 Clinici	ian unable to obtain 3 Insuff	ficient time 4 Instrument fail	lure 5 Not required			



		Center Number	: Participant Number: Participant's Initials: list middle last					
D	oubly Labeled W	Vater (DLW)						
1	Date and time of DLW do	osing:/ _{month} /_	year O0:00 to 23:59 Staff initials: first middle lost					
	OR Not done → Specify	reason (use codelist below):						
2	DLW dose mixture ID an	d bottle number: –						
3	Exact weight of DLW mix	cture:	grams					
4	Urine samples:							
	Collection	Sample	Date and Time Collected					
	Pre dosing (PD)	PDa	//					
		PDb	//					
	Day 0 (Visit 1)	DOa	/					
		D0b	/					
	Day 7 (Visit 2)	D7α	/					
		D7b	/					
	Day 14 (Visit 4)	D14a	/					
		D14b	/					
5	5 Affix CRF page label(s) corresponding to this urine sample set: [
			Affix Affix Test Sample Retest Sample Label Here Label Here					
			·					

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 of								
Body System		Assessments	i	If Abnormal or Not Done: Explain				
Body System	Normal	Abnormal	Not Done	ii Abiioi iiidi of Noi Boile. Expidiii				
General appearance:		□₀→						
2 Head, Ears, Eyes, Nose, Throat:		□₀→	□ ₉₇ →					
3 Neck:		□₀→	□ ₉₇ →					
4 Heart:		□₀→	₉₇ →					
5 Lungs:		\square_{o} \rightarrow	₉₇ →					
6 Abdomen:		□₀→	□ ₉₇ →					
7 Lymph nodes:		□₀→	□ ₉₇ →					
8 Extremities/Skin:		o→	□ ₉₇ →					
9 Neurological:		□₀→	□ ₉₇ →					
10 Musculoskeletal:		□₀→	□ ₉₇ →					
	Normal	Abnormal	Not Done*					
11 Genitourinary:		□₀→	□ ₉₇ →					
12 Breast:		□₀→	₉₇ →					
Physician's Signature								
Investigator:				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: ___ _ _

		tirst 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 □ ₉₆ NA					
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			
ПНір		☐ Hip			
Not Done Codelist: 1 Participant refused 2 (Clinician unable to obtain	a 3 Insufficient time 4 Instrument failure 5 Not required			



	Ce	enter Number: Participant Num	nber:	Participant's In	itials:		
Dat	te completed:/	OR Not done → Specify reaso	on (use codelist below	·):			
R/	AND SF-36						
Ins	Instructions: This survey asks for your views about your health. This information will help keep track of how well you are able to do your usual activities. Please answer every question by placing a check "X" in the appropriate box. If you are unsure about how to answer a question, give the best answer you can.						
1	In general, would you say your health is:		good 🔲 3 Go	od □₄ Fair	Poor		
2	Compared to one year ago, how would you rate your health general now?	in Much better now tha Somewhat better now About the same Somewhat worse now Much worse now the	w than 1 year ag				
ty	The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? Yes, Limited Yes, Limited No, Not A Little Limited At All						
3	Vigorous activities, such as ruparticipating in strenuous sports	unning, lifting heavy objects,					
4	Moderate activities , such as n vacuum cleaner, bowling, or play				\square_3		
5	Lifting or carrying groceries				\square_3		
6	Climbing several flights of stairs	5	\square_1	\square_{2}	\square_3		
7	Climbing one flight of stairs						
8	Bending, kneeling or stooping			\square_{2}	\square_3		
9	Walking more than a mile				\square_3		
10	Walking several blocks		\square_1	\square_{2}	\square_3		
11	Walking one block				\square_3		
12	Bathing or dressing yourself				\square_3		
No	ot Done Codelist: 1 Participant refused 2 C	Clinician unable to obtain 3 Insufficie	ent time 4 Instrumer	nt failure 5 No	ot required		



	Center Number:	Participant Number: F	Participant's Initials:	first middle last
Rand SF-36 (contin	ued)			
<u> </u>	eeks, have you had any of the f ther regular daily activities as	-		
physical health?		,	Yes	No
13 Cut down on the	amount of time you spent on	work or other activities		
14 Accomplished I	ess than you would like			
15 Were limited in th	ne kind of work or other activiti	es		\square_2
16 Had difficulty p (for example, it too	erforming the work or other act k extra effort)	ivities		
<u> </u>	eeks, have you had any of the fregular daily activities as a res	-		
problems (such as fee	eling depressed or anxious)		Yes	No
17 Cut down on the	amount of time you spent on w	ork or other activities		
18 Accomplished les	s than you would like			
19 Didn't do work o	r other activities as carefully as	usual		
_	I weeks, to what extent has you ed with your normal social activ ups?		☐, Not at a ☐, Slightly ☐, Moderat ☐, Quite a ☐, Extremel	tely bit
21 How much bodily	pain have you had during the	past 4 weeks?	None Very mild Moderat Severe 6	te
	l weeks, how much did pain ur normal work (including both we	ork outside the home	Not at a A little bi Moderat Quite a stremel	it tely bit



Cenfer Number: _	Part	icipant Numbe	er:	Part	icipant's Initials	first middle last
RAND SF-36 (continued)						
These questions are about how you feel and h weeks. For each question, please give the one been feeling.	_		_		-	
How much of the time during the past 4 weeks	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23 Did you feel full of pep?			\square_3	4		
24 Have you been a very nervous person?			\square_3	4	5	6
25 Have you felt so down in the dumps that nothing could cheer you up?			\square_3		5	
26 Have you felt calm and peaceful?			\square_3	4	5	6
27 Did you have a lot of energy?			\square_3	4	5	
28 Have you felt downhearted and blue?			$\square_{_3}$		5	6
29 Did you feel worn out?			\square_3	4	5	6
30 Have you been a happy person?			\square_3		5	6
31. Did you feel tired?			\square_3	4	5	6
32 During the past 4 weeks, how much of the time your physical health or emotional problems		All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
interfered with your social activities (like visiting relatives, etc)?	friends,		\square_{2}		4	5
How true or false is each of the following statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easier than other p	eople.					5
34 I am healthy as anybody I know.						
35 I expect my health to get worse.				3	4	5

36 My health is excellent.



		Center Number: _	Participant Number:	Participar	nt's Initials:	 ast
Do	te completed:/ _{mon}	OR Not	done → Specify reason (use	codelist below):		
В	DI-II					
In	pick out the one weeks, includin	ire consists of 21 groups of sestatement in each group the g today. Check the box besidach group, including item 16	at best describes the way yo de the statement you have p	ou have been feeling du	ring the past two	
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of th \square_2 I am sad all of the ti \square_3 I am so sad or unha	me			
2	Pessimism:	I do not expect thing	ed about my future than I			
3	Past failure:	□ ₀ I do not feel like a fo □ ₁ I have failed more th □ ₂ As I look back, I see □ ₃ I feel I am a total fai	nan I should have e a lot of failures			
4	Loss of pleasure:	☐₁ I don't enjoy things o	ure as I ever did from the as much as I used to ure from the things I used sure from the things I used	d to enjoy		
5	Guilty feelings:	\square_0 I don't feel particula \square_1 I feel guilty over man \square_2 I feel quite guilty mo \square_3 I feel guilty all of the	ny things I have done or est of the time	should have done		
6	Punishment feelings:	\square_0 I don't feel I am bein \square_1 I feel I may be punis \square_2 I expect to be punish \square_3 I feel I am being pun	shed ned			
7	Self-dislike:	☐ ₀ I feel the same abou ☐ ₁ I have lost confidence ☐ ₂ I am disappointed in ☐ ₃ I dislike myself	ce in myself			
N	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable	e to obtain 3 Insufficient time	4 Instrument failure	5 Not required	
				Participa	nt's Initials:	last



	Center Number: Participant Number: Participant's Initials: first middle last
BDI-II (continued)	
8 Self-criticalness:	 □₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9 Suicidal thoughts or wishes:	 □₀ I don't have any thoughts of killing myself □₁ I have thoughts of killing myself but I would not carry them out □₂ I would like to kill myself □₃ I would kill myself if I had the chance
10 Crying:	☐₀ I don't cry any more than I used to ☐₁ I cry more than I used to ☐₂ I cry over every little thing ☐₃ I feel like crying, but I can't
11 Agitation:	\square_0 I am no more wound up or restless than usual \square_1 I feel more restless or wound up than usual \square_2 I am so restless or agitated that it's hard to stay still \square_3 I am so restless or agitated that I have to keep moving or doing something
12 Loss of interest:	 □₀ I have not lost interest in other people or activities □₁ I am less interested in other people or things than before □₂ I have lost most of my interest in other people or things □₃ It's hard to get interested in anything
13 Indecisiveness:	 □₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14 Worthlessness:	 □₀ I do not feel I am worthless □₁ I don't consider myself as worthwhile and useful as I used to □₂ I feel more worthless as compared to other people □₃ I feel utterly worthless
15 Loss of energy:	 □₀ I have as much energy as ever □₁ I have less energy than I used to have □₂ I don't have enough energy to do very much □₃ I don't have enough energy to do anything



	Center Number:	Participant Number:	Participant's Initials:	first middle last
BDI-II (continued)				
16 Changes in sleeping pattern:	☐ I sleep somewhat m ☐ I sleep somewhat le ☐ I sleep a lot more the ☐ I sleep a lot less that ☐ I sleep most of the company o	nore than usual ess than usual an usual n usual		
17 Irritability:	\square_0 I am no more irritable t \square_1 I am more irritable t \square_2 I am much more irritable all of t	than usual table than usual		
18 Changes in appetite:	, My appetite is some	ewhat greater than usual h less than before h greater than usual at all	ite	
19 Concentration difficulty:	☐ l can concentrate as ☐ l can't concentrate as ☐ lt's hard to keep my ☐ l find I can't concen	as well as usual v mind on anything for very lo	ng	
20 Tiredness or fatigue:	\square_2 I am too tired or fat	or fatigued than usual atigued more easily than usu igued to do a lot of the thing igued to do most of the thing	s I used to do	
21 Loss of interest in sex:			est in sex	

Participant's Initials: first middle last



		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				\square_3	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					4
8 Co	onfused	\square_{o}		\square_{2}	\square_3	4
9 Sc	orry for things done	\square_{o}			\square_3	4
10 Sh	naky	\square_{o}		\square_{2}	\square_3	4
11 Lis	stless				\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_3	4
15 A	tive					4
16 O	n edge				3	4
17 G	rouchy					4
18 Bl	ue				\square_3	4
19 En	ergetic				\square_3	4
20 Pc	ınicky				\square_3	4
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Not D	one Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N	ot required

Participant's Initials: 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					
23 Unworthy					4
24 Spiteful				\square_3	4
25 Sympathetic				\square_3	4
26 Uneasy			\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_3	4
31 Annoyed	o			\square_3	4
32 Discouraged					4
33 Resentful					4
34 Nervous				\square_3	4
35 Lonely					4
36 Miserable					4
37 Muddled					4
38 Cheerful					4
39 Bitter					4
40 Exhausted				\square_3	4
41 Anxious				\square_3	4
42 Ready to fight					4
43 Good-natured	o			\square_3	4

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	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
44 Gloomy				\square_3	4
45 Desperate					4
46 Sluggish	\Box_{0}				4
47 Rebellious					4
48 Helpless					4
49 Weary					4
50 Bewildered				\square_3	
51 Alert					4
52 Deceived					
53 Furious					4
54 Efficient				\square_3	
55 Trusting					4
56 Full of pep				\square_3	
57 Bad-tempered					4
58 Worthless					
59 Forgetful					4
60 Carefree					
61 Terrified				\square_3	4
62 Guilty	\square_{o}			\square_3	
63 Vigorous				\square_3	4
64 Uncertain about things	o			\square_3	4
65 Bushed					4

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C	enter Number:	Participant Numb	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 you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.										
			Never	Almost Never	Some- times	Fairly Often	Very Often			
In the last month, how often have unable to control the important.										
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?	ve you felt that thi	ngs were				\square_3	4			
4 In the last month, how often have piling up so high that you could	-					\square_3				
Not Done Codelist: 1 Participant refused 2	Clinician unable to obto	in 3 Insufficient	time 4	Instrument f	ailure 5	Not requi	red			



	Center Number: Participant	Number:	Partici	pant's Initials	first middle last
Da	te completed:/ _{month} / _{year} OR Not done → Specify r	eason (use code	list below):		
Pi	ttsburgh Sleep Quality Index (PSQI)				
Ins	structions: The following questions relate to your usual sleep habits during the most accurate reply for the majority of days and nights in	- T			
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		minutes		
3	When have you usually gotten up in the morning?	23:59			
4	How many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) hours				
5	During the past month, how often have you had trouble sleeping because you (check only one answer per question)	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
	a Cannot get to sleep within 30 minutes				\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	o			\square_3
	f Feel too cold				\square_3
	g Feel too hot	o			\square_3
	h Have bad dreams				\square_3
	i Have pain	o			
	i Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):	\square_{o}			\square_3
6	During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				\square_3
	89,with permission from Elsevier Science.				
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time 4	Instrument failure	5 Not re	quired



	Center Number: Participa	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?				\square_3
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?				\square_3



Center Numb	oer:	Partici	ipant Num	ber:		_ Partic	cipant's Ir	nitials:	it middle last	
Date completed: —_dey /—_month —/—_year — OR Not do	ne → Spec	ify reaso	on (use co	delist bei	low):					
Derogatis Interview for Sexual Fu	unction	(DISF-S	R) (F) Fe	male Ve	rsion					
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 expectations and the quality of your orgasm. The relationship.	ıl experien periences	that you	section of have. You	asks abo ou are a	out sexu Iso aske	a l fant o 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 = alway of a satisfaction scale. This type of scale tells how much										
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					4					
1.2 Erotic parts of a man's body (e.g., face, shoulders, legs)					4	5	6		8	
1.3 Erotic or romantic situations					4	5	6		8	
1.4 Caressing, touching, undressing, or foreplay					4	5	6	7	8	
1.5 Sexual intercourse, oral sex, touching to orgasm				\square_3	4	5			8	

5 Not required

4 Instrument failure

2 Clinician unable to obtain

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Not Done Codelist: 1 Participant refused

3 Insufficient time



Participant's Initials:

	•	Comor I (ombor.		r arneipanii r tombori	·	ramapam s milais.	first middle last
Derogatis	Interview for Se	xual Fun	ction	DISF-SR) (F) Fema	le Version (contir	nued)	

Participant Number

Center Number

Section 2—Sexual Arousal Not at Less 1 or 2 1 per 2 or 3 4 to 6 1 per 2 or 3 4 or During the past 30 days or since the last all than 1 per week per per day per more time you filled out this inventory, how often per month week week day per did you have the following experiences? month day 2.1 Feel sexually aroused while alone 2.2 Actively seek sexual satisfaction 2.3 Feel sexually aroused with a partner Sometimes Usually Always Never Rarely 2.4 Have normal lubrication with masturbation 2.5 Have normal lubrication throughout sexual relations

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Participant's Initials:

first middle last

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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			8
3.3 Casual kissing and petting				3	4	5			8
3.4 Sexual foreplay	По			\square_3	4	5			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	o				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	o			\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}					

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Center Number:	Participant Number:	Participant's initials:	first middle last

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued) Section 5—Drive and Relationship Not at 1 or 2 2 or 3 4 to 6 2 or 3 Less 1 per 1 per 4 or per all than 1 week day per per per more month per week week day 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? Somewhat | Adequate Above Could Could Very Poor Good Very not be inadequate not be poor average good better worse 5.4 In general, what would represent the best description of the quality of your sexual functioning?

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calerie Phase 2

Month 24 Submission Visit 1

									V 1	311 I		
	Center Number	:	Partici	pant Numl	ber:		_ Partic	cipant's Ir	nitials:	t middle last		
Date completed:/	OR Not done	→ Spec	ify reasc	on (use co	delist bel	ow):						
Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version												
nstruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different actions 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 elationship. On some questions you are asked to respond in terms of a frequency scale, that is "how often" do you perform the sexual												
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/Fanto	asy											
During the past 30 days or since the la you filled out this inventory, how often you had thoughts, dreams, or fantasie	n 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		О			\square_3	4	5	□ ₆				
1.2 Erotic parts of a woman's bod face, genitals, legs)	y (e.g.,	\square_{o}		□ ₂	\square_3	4	5	□ ₆		□ ₈		
1.3 Erotic or romantic situations		□ _o			\square_3	□ ₄	₅			8		
1.4 Caressing, touching, undressin foreplay	g, or	\square_{o}			\square_3	□ ₄	5	□ ₆		□ ₈		
1.5 Sexual intercourse, oral sex, to to orgasm	ouching	По				4	5	□ ₆		□ ₈		

Participant's Initials: first middle last

5 Not required

4 Instrument failure

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

3 Insufficient time



Participant's Initials

				Tamelpani Hombon	·	r arneipani 5 iniiais.	first	middle	last		
Derogatis	Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version (continued)										

Participant Number

Center Number

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

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through intercourse and orgasm

Participant's Initials:



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		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					4					
4.4 The amount of seminal liquid that you ejaculate	□ _o									
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						

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Cente	Center Number: Participant Number:					Participant's Initials:			
Derogatis Interview for Sexue	al Fund	tion (DISF-SR) (M) Male \	/ersion (d	continue	4)		
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		□ ₈
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?				3	□ 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?					4				

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	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].				4	5
2	I'm craving [one or more specific foods].			\square_3	4	5
3	I have an urge for [one or more specific foods]			\square_3		5
4	Eating [one or more specific foods] would make things seem just perfect.			\square_3	\square_{4}	
5	If I were to eat what I am craving, I am sure my mood would improve.			\square_3	4	5
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	4	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		5
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		5
13	I am hungry.			\square_3		5
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		
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	nber: Po	articipant Number:		Participant's I	nitials: middle last
Date completed:/O	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					
Note: A craving is defined as an intense desire to cor Over the past month, how often	nsume a particulo	_	ype that is diff	icult to resist.	Always/Almost
have you experienced a craving for	Never	(once or twice)	Sometimes	Often	Every Day
1 Cake			\square_3	4	
2 Pizza					
3 Fried chicken					
4 Gravy					
5 Sandwich bread					
6 Sausage			\square_3		5
7 French fries			\square_3		
8 Cinnamon rolls			\square_3	4	
9 Rice			\square_3		
10 Hot dog			\square_3	4	
11 Hamburger			\square_3		
12 Biscuits			\square_3		
13 lce cream			\square_3		
14 Pasta					
15 Fried fish				4	
16 Cookies			\square_3		5
17 Chocolate			\square_3		
18 Pancakes or waffles			\square_3	4	
19 Corn bread			\square_3		
20 Chips			\square_3	4	
21 Rolls			\square_3	4	
22 Cereal			\square_3	4	5
23 Donuts			\square_3	4	
24 Candy			\square_3	4	
25 Brownies			\square_3		
26 Bacon			\square_3		
27 Steak			\square_3		
28 Baked potato			\square_3		
Not Done Codelist: 1 Participant refused 2 Clinician	unable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	lot 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 toc	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		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.	ınd down, I have go	one 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.		, True	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 D	one Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time	4 Instrument	failure 5 N	lot 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.	, True False
21	I enjoy eating too much to spoil it by counting calories or watching my weight.	☐₁ True ☐₀ False
22	When I see a real delicacy, I often get so hungry that I have to eat right away.	☐₁ True ☐₀ False
23	I often stop eating when I am not really full as a conscious means of limiting the amount I eat.	☐₁ True ☐₀ False
24	I get so hungry that my stomach often seems like a bottomless pit.	, True 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.	☐₁ True ☐₀ False
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.	☐₁ True ☐₀ False
30	I eat anything I want, any time I want.	☐₁ True ☐₀ False
31	Without even thinking about it, I take a long time to eat.	☐₁ True ☐₀ False
32	I count calories as a conscious means of controlling my weight.	☐₁ True ☐₀ False
33	I do not eat some foods because they make me fat.	☐₁ True ☐₀ False
34	I am always hungry enough to eat at any time.	☐₁ True ☐₀ False
35	I pay a great deal of attention to changes in my figure.	☐₁ True ☐₀ False
36	While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods.	, True False

calerie Phase 2

Month 24 Submission

	Center Number:	Participant Number: Participant's Initials: First middle last
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?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	\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?	\square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐, Easy ☐, Slightly difficult ☐, Moderately difficult ☐, 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 □₄ Very likely
45	Do you eat sensibly in front of others and splurge alone?	□₁ Never □₂ Rarely □₃ Often □₄ Always
46	How likely are you to consciously eat slowly in order to cut down on how much you eat?	 □₁ Unlikely □₂ Slightly likely □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?	o Eat whatever you want, whenever you want it usually eat whatever you want, whenever you want it often eat whatever you want, whenever you want it often limit food intake, but often "give in" usually limit food intake, rarely "give in" often limit food intake, rarely "give in" often limit food intake, rarely "give in"



				Center N	lumber:	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	ll that esire 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).				\square_3	4	5				9	
2	I can control my eating on the weekends.				\square_3	4	5			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.	o			\square_3	4		6		8	9	
5	I can resist eating when I am watching TV.					4				8	9	
6	I can resist eating when I am depressed (or down).	o			\square_3	4	5			8	9	
7	I can resist eating when there are many different kinds of food available.					4				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.				\square_3			6	7	8	9	
N	ot Done Codelist: 1 Participant refused 2 Clinician unable	to obta	in 3	nsufficie	ent time	4 Ins	trument	failure	5 Not	required		



	Center Number: _	Participant Number:						Participant's Initials:					
Weight Efficacy Lifestyle Q	uestionna	ire (w	/EL) (co	ntinue	d)								
I am confident that:			onfide an resis		ll that esire to	eat	Very confident that you can resist the desire to eat						
		0	1	2	3	4	5	6	7	8	9		
10 I can resist eating when I am re	eading.				\square_3	4	5	6		8	9		
11 can resist eating when I am continued (or irritable).	ingry				\square_3	4	5	6		8	9		
12 I can resist eating even when I a party.	am at				\square_3	4	5	6		8	9		
13 I can resist eating even when o pressuring me to eat.	thers are				\square_3	4	5	6		8	9		
14 I can resist eating when I am in	n pain.				\square_3	4	5	6		8	9		
15 I can resist eating just before g bed.	oing to					4	5	6		8	9		
16 I can resist eating when I have experienced failure.		□ _o			\square_3	4		6		8	9		
17 I can resist eating when high-coare available.	alorie foods					4	5	6		8	9		
18 I can resist eating even when I others will be upset if I don't ea		o			\square_3	4	5	6		8	9		
19 I can resist eating when I feel uncomfortable.						4	5	6		8	9		
20 I can resist eating when I am h	арру.					4	5	6		8	9		



	Center Number:	Participa	nt Numbe	r:		Partici	ipant's Initials:		
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, plea	se rate the following items	on a sca	e from 1	to 7. Ple	ase ansv	ver as tr	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	6	
2 My sleep isn't as good as it u	sed to be.						5	6	
3 I avoid eating for as long as	can.				\square_3	4	5		
4 Certain foods are "forbidden	" for me to eat.				\square_3		5	6	
5 I can't keep certain foods in my binge on them.	house because I will				\square_3	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.				\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.						5	6	
10 I don't eat certain foods.							5	6	
11 I think I am a good person.					\square_3		5	6	
12 My eating is normal.					\square_3		5		
13 I can't seem to concentrate la	tely.				\square_3	4	5	6	
14 I try to diet by fasting.					\square_3		5		
15 I vomit to control my weight.					\square_3	4	5	6	
16 Lately nothing seems enjoyab	ole anymore.				\square_3	\square_{4}	5		
17 Laxatives help keep you slim.					\square_3		5	6	
18 I don't eat red meat.					\square_3	4	5	6	
19 I eat so rapidly I can't even to	aste my food.				\square_3				
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	in 3 In:	sufficient	time 4	Instrume	nt failure	5 No	t require	d



Center Numb	er: Par	ticipant N	umber:		Pai	ticipant's	Initials: _	rst middle last
Multiaxial Assessment of Eating D	isorder Sy	mpto	ms (/	MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being ove	rweight.				4			
21 When I feel bloated, I must do something to of that feeling.	o rid myself			\square_3	4	5		
22 I overeat too frequently.				\square_3	4			
23 It's okay to be overweight.				\square_3	4	5	6	
24 Recently I have felt that I am a worthless	s person.			\square_3	4		6	
25 I would be very upset if I gained 2 pour	nds.			\square_3	4	5	6	7
26 I crave sweets and carbohydrates.				\square_3	4		6	
27 I lose control when I eat.				\square_3	4	5	6	7
28 Being fat would be terrible.				\square_3	4		6	
29 I have thought seriously about suicide la	ıtely.			\square_3	4		6	
30 I don't have any energy anymore.				\square_3	4		6	
31 I eat small portions to control my weight	t.			\square_{3}	4	5	6	7
32 I eat 3 meals a day.				\square_{3}	4	5		
33 Lately I have been easily irritated.		1		\square_3	4	5	6	7
34 Some foods should be totally avoided.				$\square_{_3}$	4		6	
35 I use laxatives to control my weight.				\square_3	4	5	6	7
36 I am terrified by the thought of being ov	erweight.			\square_3	4	5	6	7
37 Purging is a good way to lose weight.				\square_3	4	5	6	
38 I avoid fatty foods.				\square_3	4	5		



	Center Number:	Participant N	umber: _		Pai	rst middle last		
Multiaxial Assessment of	Eating Disorder	r Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue	е.			\square_3	4	5		
40 I am obsessed with becoming	overweight.			\square_3	4	5	6	
41 I don't eat fried foods.				\square_3	4	5		
42 l skip meals.				\square_3	4	5	6	
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned wit	h the way I eat.			\square_3	4	5		
45 I feel good when I skip meals				3	4	5		
46 I avoid foods with sugar.				\square_3	4	5		
47 I hate it when I feel fat.				3	4	5		
48 I am too fat.				\square_3	4	5		
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 thin	gs these days.			\square_3	4	5		
52 I'm very careful of what I eat.				\square_3	4	5		
53 I can "hold off" and not eat e	ven 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		
56 I wouldn't mind gaining a few	pounds.				4	5		



	Center Number: Participant I	Number: _		Par	ticipant's I	nitials:	t middle last
Da	te completed:/ _{month} / _{year} OR Not done → Specify re	ason (use	codelist b	elow):		5	
В	ody Shape Questionnaire (BSQ)						
	would like to know how you have been feeling about your appearance or ase read each question and check the box for the appropriate choice. Plea						
Ov	er the Past Four Weeks	Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you brood about your shape?					5	
2	Have you been so worried about your shape that you have been feeling that you ought to diet?				4	5	
3	Have you thought that your thighs, hips, or bottom are too large for the rest of you?				4	5	
4	Have you been afraid that you might become fat (or fatter)?				4	5	
5	Have you worried about your flesh not being firm enough?					5	
6	Has feeling full (e.g., after eating a large meal) made you feel fat?					5	6
7	Have you felt so bad about your shape that you have cried?					5	
8	Have you avoided running because your flesh might wobble?				4	5	
9	Has being with thin women/men made you feel self-conscious about your shape?			3	4	5	
10	Have you worried about your thighs spreading out when sitting down?			\square_3	4	5	
11	Has eating even a small amount of food made you feel fat?			\square_3	4	5	
	Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?			3	4	5	6
13	Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?			\square_3	4	5	6
14	Has being naked, such as when taking a bath, made you feel fat?			\square_3	4	5	6
15	Have you avoided wearing clothes which make you particularly aware of the shape of your body?			\square_3		5	6
16	Have you imagined cutting off fleshy areas of your body?					5	6
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuff	ricient time	4 Instru	ument failu	re 5 N	lot require	ed



	Center Number:	Participant N	lumber: _		Pai	rticipant's	Initials:	rst middle last
Body Shape Questic	onnaire (BSQ) (continued)							
Over the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cal- you feel fat?	ces or other high calorie fo	od made				4	5	
	t on social occasions (e.g., po bad about your shape?	arties)			\square_{3}	4	5	
19 Have you felt excessive	ely large and rounded?				\square_3	4	5	6
20 Have you felt ashamed	d of your body?				\square_3	4	5	6
21 Has worry about your	shape made you diet?						5	6
22 Have you felt happiest stomach has been emp	tabout your shape when yoty?	our				4	5	
23 Have you thought that because you lack self-	you are the shape you are control?	e			\square_3	4	5	6
24 Have you worried abortlesh around your wait	out other people seeing roll st or stomach?	s of			$\square_{_3}$		5	
25 Have you felt that it is thinner than you?	not fair that other women/	men are				4	5	6
26 Have you vomited in a	order to feel thinner?				\square_3	4	5	6
27 When in company, have much room (e.g., sitting on	ve you worried about takin a sofa or bus seat)?	g up too			\square_3	4	5	6
28 Have you worried abo	out your flesh being dimply	?			\square_3	4	5	6
29 Has seeing your reflect you feel bad about yo	tion (e.g., in a mirror or shop windo ur shape?	w) made			\square_3	4	5	6
30 Have you pinched are fat is there?	as of your body to see how	v much			$\square_{_3}$		5	
	changing rooms or swimming pools)				\square_{3}	4	5	6
32 Have you taken laxati	ves in order to feel thinner?	?					5	
33 Have you been particus shape when in the con	ularly self-conscious about ynpany of other people?	your				4	5	6
34 Has worry about your to exercise?	shape made you feel you	ought						



		Center Number	: Participant Num	ber: Part	icipant'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 Dynometer handle position:								
2 D	ominant hand (check only	one): 🔲 1 Left 🔠 2 Right	Ambidextrous					
3 H	andgrip 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	ant's Initials:
ls	ometric/Isokine	tic Kne	e Extension and	l Flexion		
D	ate and time of assessment	:/_	month year	00:00 to 23:59	Staff init	ials:
0	R Not done → Specify rea	son (use cod	delist below):			
1	Recent injury or pain—riç	ght knee?	ONO O1 Yes			
2	Recent injury or pain—lef	ft knee?				
3	Specify machine used (Pl	BRC only): [
	All values corrected	for gravit	y 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	tain 3 Insufficient time	4 Instrument failure	5 Not required



5 Not required

	tirst middle last
Clinic Weight	
	Staff initials:
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: ___

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Tod	Today's date:	Today's date:/ Day (check only		Day (check only one):	Mon Tue	Mon Tues Wed Thurs	Thurs		Sur	OR No	done 1	Specify re	eason (use	Fri Sat Sun OR Not done → Specify reason (use codelist below):	ow):
_	Were yo	oyed	ven days?		°Z °	$\Box_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	stion 3	Ty Yes				Interv	Interviewer initials:		first middle last
4	If Yes: W	If Yes: Which days (check all that apply)?	ا4)خ		Mon	Tues Wed		Thurs	Ë	Sat	Sun				
m	Which d	Which days do you consider your weekend, or non-work, days?	r weekend, or n	on-work, days?	Mon	Tues	Wed	Thurs	Œ	Sat	Sun				
Dav	Pay of		Sleel	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	ninutes)	Ever	Evening (in minutes)	utes)
#		Date	ln Bed	dn	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									
day)			00:00 to 23:59	00:00 to 23:59											
				:											
•		day month year	00:00 to 23:59	00:00 to 23:39	00:00 to 23:59	00:00 to 23:59									
T			00:00 to 23:59	00:00 to 23:59											
u		,	00:00 to 23:59	00:00 to 23:59											
n		day month year		00000 00000	00:00 to 23:59	00:00 to 23:59									
4		day /	00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
ო		day /year	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									
7		day / year	00:00 to 23:59 00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									
1 (1 week ago)		doy /	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									

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

5 Not required



		Center Number:	Participant Number:	Participant's Initials:
S	even-Day Physical Activ	ity Recall (PAR) (continued)	
4	Compared to your physical activity of about the same (check only one)? More	over the past three mon	ths, was last week's physical c	activity 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 interviev	/?	
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:	Partio	ipant Number: Partic	ipant's Initials:
6-D	ay Food Record				
Comp	olete below OR Not done → Spec	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 Deliable Deliable Deliable Deliable
3	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10	/	Reliable Description 1 Reliable Description 3 Missing
4	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	Reliable Description 1 Reliable Description 3 Missing
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	5 Not required



		Center Number:	_ Participant Number:	Participant's Initials: first middle last
V	O ₂ Max			
1	Date and time of test:/	/	: 00:00 to 23:59	Staff initials:
	OR Not done → Specify reason (use of	odelist below):		
2	At what time was the participant's las	t meal/snack eaten?	::	
3			s Atrial fibrillation	□ ₉₈ Other □ ₃ RBBB
4	Heart rate (HR) data: Resting heart rate Age-predicted I Heart rate (max	neart rate:	_ bpm	
5	Reason(s) for termination of testing (c Symptom limited (dyspnea, fatigue) Angina/ischemia → Complete all the Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress in	at apply: HR when tr HR when is	chemic ECG changes occu	ed: bpm or ₉₆ NA urred: bpm or ₉₆ NA
6	Orthopedic/extremity complaints (par Other (specify): Did frequent ventricular ectopy occur onumber No 1 Yes → If Yes: When did it occur (continuous)	(e.g., ≥ 7 PVCs/min, bi/	ftri-geminy, NSVT [≥ 3 beats	
7	Peak VO ₂ : mL/kg/min	L/min		
9	Did the participant meet at least 2 of No Yes → If Yes: VO₂ max: Exercise time: : seconds		bet b REF	nieve a plateau in VO₂ (change ≤ 150 mL) ween the final two stages R ≥ 1.1 max ± 5 bpm of age-predicted maximum
	minutes seconds			
10	Blood pressure at VO ₂ peak/VO ₂ ma	x:/diastolic	_ mm Hg	
11	Borg RPE score at VO ₂ peak/VO ₂ ma	x: (6-20)		
12	Peak RER:			
13	VE at VO ₂ peak/VO ₂ max:	L/min		
14	VE/VO ₂ at VO ₂ peak/VO ₂ max	L/min		

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

5 Not required



Outcomes La ate and time samp	ıbs				
	le collection started:/_			:	
	Sample sined, indicate with a Not Done.	Sample Comple		If Not Done, Reason (Use codelist below)	Staff Initials
	Blood	□ ₀ No □ ₁ Yes			first middle last
ore Temper	ature		·	_	
Staff Initials			Time of Sample Collection/Procedure		If Not Done, Reason (Use codelist below
	Start Date:			Start Time:	
first middle last	Stop Date:	year	Stop Time:		
_	mission and Discha		:		
	ion date and time:/ ge date and time:/				



					ber:	Participant's Init	first middle
е	layed-type Hype	rsensitivity	(DTH)				
	Was the DTH worksheet cor No Yes → If Yes: Were any		-		est Idminister test.		
[Date of injection:/_	/	OR Not done	→ Specify reas	on (use codelist below):	
ı	njection by (initials):	last					
1	Arm injected:1 Right	2 Left					
because the induration may not be in the shape of a circle. If the induration is an oval diameter and then the diameter perpendicular to it. Do not measure erythema. Reactic average diameter is equal to or greater than 5 mm. A = Largest diameter B = Second diameter perpendicular to A							_
Γ	diameter and then the average diameter is e A = Largest diameter	e diameter perpendequal to or greater	dicular to it. Do n than 5 mm.		ı		•
	diameter and then the average diameter is e A = Largest diameter	e diameter perpendequal to or greater perpendicular to A	dicular to it. Do n than 5 mm. Hour (@ Visit 4)	ot measure er	48	Hour (@ Visit 5)	sitive if the
	diameter and then the average diameter is e A = Largest diameter B = Second diameter	e diameter perpendequal to or greater	dicular to it. Do n than 5 mm.		ı		•
	diameter and then the average diameter is e A = Largest diameter B = Second diameter Antigen	e diameter perpendequal to or greater perpendicular to A 24 A (diameter)	dicular to it. Do n than 5 mm. Hour (@ Visit 4) B (diameter)	ot measure er	48 A (diameter)	Hour (@ Visit 5) B (diameter)	sitive if the
	diameter and then the average diameter is e A = Largest diameter B = Second diameter Antigen	e diameter perpendequal to or greater perpendicular to A 24 A (diameter)	dicular to it. Do n than 5 mm. Hour (@ Visit 4) B (diameter) mm	ot measure er	A (diameter) mm	Hour (@ Visit 5) B (diameter) mm	Read By:

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

3 Insufficient time

4 Instrument failure

5 Not required



Clinic Weight				
	reason (use codelist below):	:	Staff init	tials:
Clinic weight (if the two m	easurements are more than 0.1 kg apart	, measure weight a third tim	ne):	
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			
Outcomes Labs				
Date and time of last me	day month	year 00:00 to 23: year 00:00 to 23: year 00:00 to 23:		
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Са	ntecholamines	□₀ No □₁ Yes		first middle last
	Blood	□₀ No □₁ Yes		first middle last
Oral glucos	se 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:		
mL	day month year	00:00 to 23:59		
	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	:	Participo	ant's Initia	first middle last
Sex Hormone							
If Not Done → Specify reason (use code	list below):	:					
Contraception method (females only):		☐ None O R	Check all that apply Oral contraceptive	: → Specify: Record on Co			utions page
			\square Other \rightarrow Specify	(e.g., barrier, IUD):			
Day 1			Date	Time	Rec	Done, ason odelist)	Staff Initials
Day 1 of menses (females enly)							
Date and time of last meal (males only	7)	/	nonth year	00:00 to 23:59			
Hormone level blood draw 1 (males o	nly)	/	nonth year	00:00 to 23:59			first middle last
Hormone level blood draw 2 (females of Progesterone level	o nly)						
Day 2			Date	Time	Rec	Done, ason odelist)	Staff Initials
Date and time of last meal							
Hormone level blood draw 3 (females of Progesterone level	only)						
Metabolic Rate							
Sample		Date of C	ollection	If Not Done, Ro		Staff	Initials
Resting Metabolic Rate (RMR)—Visit 4	d	/	_/			first	middle last
Cart ID		-003 (623-00 -006 (623-00	·	·		16 (623-6 17 (623-6	•
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to d	btain 3 Insufficient ti	ime 4 Instrument	failure	5 Not re	equired

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

2	Sevendos Today's date: _	Physical Act	VITY Keco	÷CCIII (PAR) Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Speafy reason (use codelist below):	Mon Tue	pew S	Thurs	Fri S	at Sun	OR Not	done 1	Specify re	egn) uospe	codelist bela	ow):
_	Were yo	month oyed in the last sev	year ven days?		Ž	$\square_0 \ No \rightarrow Skip to question 3 \qquad \square_1 \ Yes$	stion 3	Types Yes				Interv	Interviewer initials:		first middle last
7	If Yes: M	If Yes: Which days (check all that apply)?)غ		Mon	Tues Wed		Thurs	Fi.	Sat	Sun				
m	Which d	Which days do you consider your weekend, or non-work, days?	weekend, or n	on-work, days?	Mon	Tues	Wed Thurs	Ш	Fri	Sat	Sun				
2	Day of		Slee	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	utes)	Aften	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
#		Date	In Bed	ηN	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
Vester		//-		00:00 to 23:59	 										
day)		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												
0		day month year	- : : : : : : : : : : : : : : : : : : :	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
2		dow moon vob		00:00 to 23:59	:										
			00:00 to 23:59	00:00 to 23:59											
4		day //	00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59										
က		doy / month year			00:00 to 23:59	00:00 to 23:59									
74		day / month year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1 week ago)		day / month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									

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

5 Not required

4 Instrument failure



		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 con	nments 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 One Yes	Day PAR interview?			
7	Were there any activities reported b	y the participant that yo	ou don't know how to classif	y? 	-



	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: first middle last

Participant Number:

Center Number: ____

<u>5</u>	Signs, symptoms and Adverse Events	a Aavei	Se EVELLS			1 12	
	Baseline 1 Baseline 2	Month 1	Month 3	Month 6 Month 9	Opagre form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline: Baseline 1	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
		o Z o Z o Z o Z o Z o Z o Z o Z o Z o Z	in Mild Moderate Severe	\(\text{\tint{\text{\tint{\text{\tint{\text{\tint{\text{\tint{\text{\tinte\tint{\text{\text{\text{\text{\tint{\text{\text{\tinte\tint{\text{\text{\text{\text{\text{\text{\text{\tinit}}\tint{\text{\text{\text{\text{\text{\text{\text{\tinithter{\text{\text{\texi}\text{\text{\text{\texi}\tint{\text{\text{\texi}\tint{\text{\texi}\tint{\text{\texi}\tint{\texitile\tint{\text{\texi}\texitilex{\tiint{\texitilex{\tiint{\texi\	\text{\tint{\text{\tint{\texi\text{\tet{\te	Still present and unchanged 2 Improving 3 Resolved 4 Resolved with sequelae 5 Death	Start Date: doy /// End Date:
		°Z , «se» , .	Mild Moderate Severe	None Doubtful Possibly Probably Stery likely	None 2 Intervention temporarily discontinued 3 Medical therapy required 1 Intervention permanently discontinued 1 Secontinued 2 Other (specify):	1. Still present and unchanged 2. Improving 3. Resolved 4. Resolved with sequelae 5. Death	Start Date: doy // End Date: /
		o Z o Z o Z o Z o Z o Z o Z o Z o Z o Z	in Mild Moderate Severe	\(\text{\tint{\text{\tint{\text{\tint{\text{\text{\tint{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tint{\text{\tint{\text{\tinte\tint{\text{\text{\text{\text{\tinit}}\text{\text{\text{\text{\text{\text{\text{\text{\text{\tert{\text{\text{\text{\text{\text{\text{\texi}\tint{\text{\text{\tinithter{\text{\text{\texi}\text{\text{\texict{\text{\texit{\text{\texi}\text{\text{\texi}\text{\texit{\texi}\text{\text{\texi}\tint{\text{\tinithter{\text{\texi}\texitilex{\texit{\texi	\text{\tint{\text{\tint{\text{\ticl{\tilit{\tert{\texi}\text{\text{\text{\text{\text{\tex{	Still present and unchanged 2 Improving 3 Resolved 4 Resolved with sequelae 5 Death	Start Date: doy //
		No □ Yes*	1 Mild 2 Moderate 3 Severe	, None, Doubsful, Possibly, Probably, Very likely	In None discontinued Medical therapy required discontinued discontinued discontinued discontinued discontinued De Other (specify):	1. Still present and unchanged 2. Improving 3. Resolved 4. Resolved with sequelae 5. Death	Start Date:
*If Ser	* If Serious is Yes, submit expedited SAE form.	d SAE form.	SAE Reporting Criteria:	Criteria: 1 Death 2 Life threatening	 Persistent or significant disability/incapacity Prolonged or required hospitalization 	pacity 5	Congenital anomaly or birth defect Other significant medical event

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



Concomitant Medications Log

		Center Number:	Participant Number:	Participant's Initials: first middle last
C	oncomitant Medica	ıtions Log		
Red	cord any medications taken af oplements, and herbal medica nd copies of this form with eac	fter start of baseline visit, including ations. Update form for each visit a ch submission starting with baselin Month 1 Month 3 Month	and mark corresponding addition ne:	
	Medication	Start Date or 🗹 if Pre-study	Stop Date or ☑ if Continuing	Indication
1	Study vitamin-mineral supplement	day month year	day month year	
2	Study calcium supplement	//day month year	//day month year	
3		or1 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	OR1 Continuing	
8		OR 1 Pre-study	or	
9		OR 1 Pre-study	or	
10	1	OR 1 Pre-study	OR	
11		OR 1 Pre-study	OR	
12		OR 1 Pre-study	day month year OR 1 Continuing	



Concomitant Medications Log

	Center Number:	Participant Number:	Participant's Initials:
Concomitant Medica	itions Log		
Record any medications taken at supplements, and herbal medica Send copies of this form with eac	fter start of baseline visit, including tions. Update form for each visit c ch submission starting with baselir	and mark corresponding addition ne:	nal box.
Baseline 1 Baseline 2	Month 1 Month 3 Mont Start Date	h 6 Month 9 Month 12 Stop Date	Month 18 Month 24
Medication	or 🗹 if Pre-study	or 🗹 if Continuing	Indication
1	OR 1 Pre-study	or Continuing	
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 Continuing	
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 Number	ber:	_ Participant Number: _	Participant's Initials:
SAE Details:			Participant's Details:
SAE Term (Medical Diagnosis):		Date of birth:	//
SAE Onset Date:/		Gender: Male	Female
SAE Stop Date:/			
Serious Reporting Criteria: (check all that apply)		sality & Intensity: check 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	Intensity:	None Doubtful Possibly Probably Very likely Mild Moderate	☐ Still present and unchanged ☐ Improving ☐ Resolved ☐ Resolved with sequelae ☐ Death → If Death: Date of death: ☐ Manuary Andrew Andr
Action Taken with Study Intervention: (check all that approximately None ☐ None ☐ Intervention temporarily discontinued → Complete and ☐ Medical therapy required ☐ Intervention permanently discontinued → Complete ar ☐ Other (specify):	nd fax the Te	Permanent Discontinua	

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 #:	Cent	er Number		Participant Number:	Pari	ticipant's Initials: first middle last
		er romber		Turnelpulli Holliber.		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
				day month year	□ ₀ No □ ₁ Yes	day month year
				/ /	□ ₁ Tes	/ /
				day month year	Yes	day month year
				day month year	□ ₀ No	/
				Gay	Yes	aayo yea
				day month year	U₀ No U₁ Yes	day month year
				/	□ _o No	/
				day month year	Yes	day month year
				day month year	□ ₀ No □ ₁ Yes	day month year
Relevant Lab Tests:		1				
Test		Date		Value/Results	1	Normal Range
	/	/	vear			
	/	/	year			
	/	/	rear			
	/	/	ear			

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	ment given, hospital dates, etc.:		
Information Source:			
mornanon source.			
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:
Excessive Weight Los	s Episode		
excessive weight loss is defined as a B when the BMI level is first observed to discontinued from the CR intervention	be $< 18.5 \text{ kg/m}^2$, and ends when		- · · · · · · · · · · · · · · · · · · ·
A Identifying information			
1 Date of initial report:	/		
2 Name of person making th			
B BMI below 18.5 kg/m²			
3 Date of threshold value: _	/		
4 Height: c		Screening)	
5 Weight:	kg		
6 Calculated BMI:	kg/m²		
\square_1 Yes \rightarrow If Yes: Complete	ine level for up to one month.	bed? porarily discontinued: n from CR Intervention form	·
The CR intervention is only restart	ed if the BMI increases to 18.5 kg	g/m² or higher after one month	of treatment.
8 Date of follow-up value: _	/		
9 Weight:	kg		
10 Calculated BMI:	kg/m²		
Permanent Discontinuation			
If BMI is still < 18.5 kg/m2 after o	one month of increased calorie int	take, CR intervention is permane	ently discontinued.
$\square_0 \text{ No} \rightarrow \text{If No: Indicate th}$ $\square_1 \text{ BMI re}$	nently discontinued from the C he reason CR was not permane eturned to 18.5 kg/m² or higher or (specify): the Permanent Discontinuation ely.	ently discontinued (check only	
Note that a participant is p any point after the CR was Intervention form.	_		a BMI < 18.5 kg/m² occurs at Discontinuation from CR



Excessive Weight Loss Episode Report

	Center Number:	Participant Number:	Participant's Initials:	first middle last
Excessive Weight Loss E	pisode (continued)			
F Please provide a description of	this opicado includina	actions taken		
r rieuse provide a description of	inis episode incloding	utilolis lukeli.		
Study Manager's Signat	ture			
Signature:			Date:/	-



Depression Episode Report

Depression Episode Depression is defined as a BDI score ≥ 20. This report is completed for each episode of depression. Reporting starts when BDI is ≥ 20, and ends when the episode either resolves or the participant is permanently discontinued from the CR interver A Identifying information 1 Date of initial report:	s Initials:	ddle last
BDI is ≥ 20, and ends when the episode either resolves or the participant is permanently discontinued from the CR interver A Identifying information 1 Date of initial report: —		
1 Date of initial report:		
2 Name of person making this report: B Initial Elevation in BDI Score ≥ 20 3 Date of initial elevation:/		
B Initial Elevation in BDI Score ≥ 20 3 Date of initial elevation:/		
3 Date of initial elevation:/		
C Repeat BDI Score		
The questionnaire is repeated in one week .		
5 Date of follow-up questionnaire:/		
6 BDI score:		
D Temporary Discontinuation		
If the repeat score is ≥ 20, the CR intervention is temporarily discontinued and a participant is advised to seek medical study.	help outside of	f the
7 Was the participant temporarily discontinued from the CR intervention?		
\square_0 No \rightarrow If No: Indicate the reason CR was not temporarily discontinued (check only one):		
□ ₁ BDI score returned to < 20 → If the BDI score returned to < 20, then stop here; the exercise resolved.	isode has	
Sign the form on the last page and store in participant	s binder.	
☐ Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety immediately.	ourveillance	
E Follow-up BDI Score		
The questionnaire is repeated in one month .		
8 Date of follow-up questionnaire:/		
9 BDI score:		



Depression Episode Report

		Center Number:	Participant Number:	Participant's Initials:
D	epression Episode (conf	inued)		
		ntinued. tly discontinued from the CR was not permanently returned below 20 alth professional indicated pecify): Permanent Discontinua	e CR intervention? v discontinued (check only one): it is safe to resume ution from CR Intervention form an	nd fax to Safety Surveillance
ро	oie that a participant is permand oint after the CR was restarted. I itervention form.	-		-
G	Please provide a description of	f this episode, including	ng actions taken:	
Si	tudy Manager's Signa	ture		
Się	gnature:		Date:	day month year



Eating Disorder Episode Report

		Center Number:	Participant Number: Part	ticipant's Initials: first middle last				
Eat	ing Disorder Episode							
Accep and/c	otability Morph (BAM) and Interview for	r the Diagnosis of Eating Di	nent of Eating Disorder Symptoms (MAEDS) isorders—Fourth Version (IDED-IV). Reporting the episode either resolves or the participant	starts when MAEDS				
A Id	lentifying information							
1	Date of initial report:/	/						
	2 Name of person making this report:ease complete Section B and/or C according to whether the episode was defined in terms of the MAEDS or the							
BAM B Di	I, or both.	•	the episode was defined in terms of core of 70 or higher on any subscale of the					
	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 or 9	(c) shows confirming acceptability of the Was an alert issued for the current Was an alert issued for the ideal Was there confirming acceptability Blow-up with IDED-IV The diagnostic criteria for anorexia nervo	e extreme body size shown nt body size scale? body size scale? ty of the extreme body si osa, bulimia nervosa, or bing	body size, (b) scores a t-score lower than 30 in the acceptability phase of the measure is	administered the IDED-IV. → If Yes: t-score: → If Yes: t-score:				
	of its diagnostic criteria. A sub threshold of the symptoms for bulimia nervosa and anore:	=	as an IDED-IV rating of "3" or more on at lec	ast 5 of the 8 combined				
1	Anorexia nervosa		theck all that apply)?					



Eating Disorder Episode Report

		Center Number:	Participant Number:	Participant's Initials:
Ea	ıting Disorder Episod	e (continued)		
E	advised to seek medical help outside 13 Was the participant permane □₀ No → If No: Indicate wh □₁ Did not to	e of the study. ently discontinued from the y CR was not permanently meet diagnostic criteria for the specify): the Permanent Discontinuation	discontinued (check only one):	, ,
F	Please provide a description (of this episode including	j actions taken:	
St	udy Manager's Sign	ature		
Sig	nature:		Date:	/



Elevated Potassium Episode Report

		Center Number:	Participant Number:	Participant's Initials: middle last
E	levated Potassium Episo	de		
rep	perkalemia is defined as an initial potassiun port is completed for each episode of hypen nen the episode either resolves or the partic	rkalemia. Reporting star	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 repo			
В	Initial Elevation in Potassium Lev	el		
	3 Date of initial elevation:/_			
	4 Potassium level: mEd	q/L		
C	Follow-up Repeat Potassium Leve If the initial potassium level is between 5.x 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
D	Temporary Discontinuation If the follow-up test is > 5.5 mEq/L, the C to seek medical help outside of the study.	R intervention is tempore	•	ervention and the participant is advised
	7 Was the participant temporarily d □ ₀ No → If No: Indicate the reas			one):
			ower → If potassium returned to	o 5.5 mEq/L or lower, then the Stop here, sign the form on the last
				· ·
		mporary Discontinuat ntinue to Section E bel		and fax to Safety Surveillance
E	Follow-up Potassium Level The CR intervention will only be restarted 8 Date of follow-up test:/		ecreases to ≤ 5.0 mEq/L within on	ne month of treatment.



Elevated Potassium Episode Report

	Center Number:	Participant Number:	Participant's Initials:
Elevated Potassium	Episode (continued)		
F Permanent Discontinuation	o n ed above 5.0 mEq/L after one mon	th of transment the CR intervention	is sormanantly discontinued
10 Was the participant pern	manently discontinued from the	CR intervention?	т із регінапенну аізсоннічеа.
, Poto	e why CR was not permanently assium returned to 5.0 mEq/L or lother (specify): Lete the Permanent Discontinuat	ower	
	lete the Permanent Discontinuat diately.	ion from CR Intervention form o	and fax to Safety Surveillance
Note that a participant is pendigher occurs at any point at from CR Intervention form.	-	-	otassium level of 5.5 mEq/L or Permanent Discontinuation
G Please provide a descript	tion of this episode including	g actions taken:	
Study Manager's Si	gnature:		
Signature:		Date:	/



Anemia Episode Report

	Center Number: _	Participant Number:	Participant's Initials:
nemia Episode	.		
confirmatory value satisfyir	•	crit level below the lower limit of normal (LLN) for s when the initial value is observed, and ends w CR intervention.	•
Identifying Informa	ition		
1 Date of initial repo	ort:/		
	naking this report:		
ormal.	on B according to whether the Lower Limit of Normal:	hemoglobin and/or hematocrit was be	low the lower limit
3 Date of lab test: _	day month year		
	Value	Lower Limit of Normal (LLN)	Below LLN?
4 Hemoglobin:			O No 1 Yes
5 Hematocrit:			□ ₀ No □ ₁ Yes
6 RBC:			No 1 Yes
7 Iron level:			□ □ No □ 1 Yes
	s repeated in two weeks. The iron lev	vel is also repeated.	
11 Date of repeat lab		-	
	Value	Lower Limit of Normal (LLN)	Below LLN?
12 Hemoglobin:			O No 1 Yes
13 Hematocrit:			□ ₀ No □ ₁ Yes
			No 1 Yes
14 RBC: 15 Iron level:			



Anemia Episode Report

		Center Number:	Participant Number:	Participant's Initials: ${\text{first middle last}}$
A	nemia Episode (continued)		
E	$\square_0 \ \text{No} \rightarrow \text{If No: Ind}$	advised to seek medical help outside licate the reason why not:	•	
			episode ha sign the for store in the	cceptable values, then the services resolved. Stop here, rm on the last page, and participant's binder.
		₉₈ Other (specify): ite on which patient was advised:		
F	If the hematology and iron the treatment was initiated	n levels do not return to acceptable valu	ies, the hematology panel and iron levels o	are repeated one month after
		Value	Lower Limit of Normal (LLN)	Below LLN?
	18 Hemoglobin:	<u> </u>		□₀ No □₁ Yes
	19 Hematocrit:	<u> </u>		\square_0 No \square_1 Yes
	20 RBC:			\square_0 No \square_1 Yes
	21 Iron level:			□ ₀ No □ 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	R intervention? mporarily discontinued (check only one) rned to acceptable values → If the hemo return to a episode ho the form o forward to	oglobin and iron levels acceptable levels, the as resolved. Stop here, sign in the last page, and the coordinating center
		98 Other (specify):	with the ne	ext batch of data forms.
	Yes → If Yes: Co	omplete the Temporary Discontinuation	on from CR Intervention form and fax	to Safety Surveillance
	Со	ontinue to Section H, next page.		



Anemia Episode Report

		Center Number:	Participant Number:	Participant's Initials:					
Δ	nemia Episode (coi	ntinued)							
	-								
Н	Two Month Follow-up V								
	• •	is worsening after the CR interventi	on was temporarily discontinued for one mo	onth, the intervention					
	is permanently discontinued.								
	23 Date of two month follo	ow-up lab test:/ _{day} //	year year						
Г									
		Value	Lower Limit of Normal (LLN)	Below LLN?					
	24 Hemoglobin:			□ No □ Yes					
	25 Hematocrit:			□ No □ Yes					
	26 RBC:			No 1 Yes					
	27 Iron level:			□ ₀ No □ ₁ Yes					
I	Permanent Discontinua	tion							
	28 Was the participant per	rmanently discontinued from the	e CR intervention?						
			permanently discontinued (check only one	e):					
		emoglobin panel and iron levels re							
			entinuation from CR Intervention form a	nd fax to Safety					
	Surve	eillance immediately.							
J	Please provide a descri	ption of this episode includi	ng actions taken:						
Si	tudy Manager's S	ignature:							
		-	Deta: /	/					
သုပ္	gnature:		Date:/_						



Ventricular Ischemia Episode Report

	Center Number:	Participant Number:	Participant's Initials: First middle last
٧	Ventricular Ischemia Episode		
wł	This report is completed if an episode of ventricular ischemia occur when it is first observed, and ends when the episode either resolve CR intervention.		
A	A Identifying information		
	1 Date of initial report://		
	2 Name of person making this report:		
В	B Date when the ventricular ischemia was observed		
	3 Date:/		
C	C Temporary Discontinuation		
	The CR intervention is temporarily discontinued and a stress in	naaina study is recommended within two	o weeks.
	4 Was CR temporarily discontinued and a stress imagi	= = :	
	□ ₀ No → If No: Indicate the reason CR was not tem		
		uation from CR Intervention form ar	nd fax to Safety Surveillance
	immediately. Continue to Section D		ia iantio caron, con comanico
D	D Stress Imaging Study		
	If a stress imaging study confirms presence of ventricular ische	mia, the CR intervention will be perman	nently 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 isch	nemia?	
	□ _o No		
E	E Permanent Discontinuation		
	7 Was the participant permanently discontinued from	the CR intervention?	
	No → If No: Indicate the reason CR was not per	manently discontinued:	
	, The study did not confirm the prese	ence of ventricular ischemia.	
		Jation from CR Intervention form an	d fax to Safety Surveillance
	immediately.		



Ventricular Ischemia Episode Report

	Center Number:	Participant Number:	Participant's Initials:	middle la:
Ventricular Ischer	mia Episode (continued)			
- N				
F Please provide details	s of ECG findings including acti	ons taken:		
Study Manager's	: Signaturo:			
Sludy Manager's	s signature:			
Signature:		Date:	/	
			,	



Temporary Discontinuation from CR Intervention

Check one: Initial	Follow-up		•
Center Number:	Participant Number:	Participant's Initials:	

Te	Temporary Discontinuation						
	No	te: Compl	ete one fo	rm per re	eason for discontinuati	ion.	
1							
2							
	Persistent potassium level > 5.5	, .		ıt any point	during study, confirmed by re	epeat testing a	t 1 week
	\square_2 Persistent potassium level ≥ 6 .						
	if second level is above 5.5 n						
	Ventricular ischemia observed		se (stress ima	ge perform	ed in 2 weeks)		
	Decrease in BMI to <18.5 at						
	Other (includes any other disease)			es temporar	v discontinuation from interve	ention such as r	recovery from trauma
	surgery, or severe infections) (s				y alsocimination from line, re	inion socii do i	ceovery from fractina,
Pa	rticipant's Details:	,, <u></u>					
	•			⊔a:	g ht: cm		
	te of birth://	year					
Ge	nder: Male Female				ght: kg		
				ВМІ	(if applicable):		
Rel	evant Medical History:						
Rel	evant Concomitant Medication (do not list me	edication adn	ninistered to	o treat this event):		
	Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
					day month year	. O No	day month year
					,,,	Yes	,,,
					day month year	No No	/
					, ,	\square_1 les \square_0 No	, ,
					day month year	Yes	day month year
Rel	evant Lab Tests:						
	Test		Date		Value/Results	ı	Normal Range
		/	/	year			
		/	/	year			
		/	/	year			
		/	/	year			



Temporary Discontinuation from CR Intervention

Participant's Initials: _

		first middle las
Temporary D	scontinuation (continued)	
Please describe any o	dditional action taken (e.g., observation or seek medical attention outside study):	
Intervention	Resumption	
Was intervention res	med? If No: Fill out Permanent Discontinuation from CR Intervention form	
	If Yes: Date intervention was resumed:/	
Investigator'	Signature	
Investigator:	signature Date:/	
	aignuture , , , ,	

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



Permanent Discontinuation from CR Intervention

		Center Number:	Participant Number:	Participant's Initials: first middle last
P	ermanent Discontinuatio	on		
1	Date of permanent discontinuation:	day month	year	
2	Reason(s) for discontinuation (check of present potassium level > 5.0 mEq. 1 Persistent potassium level ≥ 5.5 mEq. 2 Persistent anemia (anemia still not in present potassium level ≥ 5.5 mEq. 3 Persistent anemia (anemia still not in present potassium level ≥ 5.5 mEq. 4 Ventricular ischemia confirmed by state of present potassium level ≥ 5.5 mEq. 5 Decrease in BMD at the hip or spine present potassium level ≥ 5.5 mEq. 6 Decrease in BMD at the hip or spine present potassium level 1.5 personal reasons (specify): 1 Personal reasons (specify):	I/L resistant to one more /L after CR was tempo improving or worsening tress image e of 5% or greater from the of 10% or greater from the of 10% or greater from the of increase calorie intervention restarted free depression) ion (BDI still > 20) after imporary discontinuation for more than one years of the or worse from the or worse in the or worse	orarily discontinued and restarted one month after temporary discontinued and restarted on baseline at any time during first 12 pm baseline at any time during mont of less than -2.5 at any time during os a or binge eating or experiencing intake or temporary discontinuation or CR intervention restarted or mode on of CR intervention	2 months of CR ths 12–24 of CR study a sub-threshold eating disorder) of CR intervention OR persistent
	rticipant's Details:			
	ate of birth:/	-	Height: kg BMI (if applicable):	_
Re	levant Medical History:			



Permanent Discontinuation from CR Intervention

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

tirst middle last							
Permanent Discontinuation (continued)							
Relevant Concomitant Medication (do not list medication administered to treat this event):							
Medication	Dose & Unit Frequency Route			Start Date	Continued	Stop Date	
				/	□ ₀ No	/	
					□ ₀ No □ ₁ Yes		
				/	□ ₀ No □ ₁ Yes	/	
Relevant Lab Tests:							
Test Date Value/Results Normal Range							
	/	/	year				
	/	/	year				
	/	month)	year				
/							
Please describe any additional action taken (e.g., observation or seek medical attention outside study):							
Investigator's Signat	Ure						
Investigator:		. ,		Dat	e:/	month year	
signature day month year							



_____1 Yes

2 Study Completion/ Early Discontinuation of Study Evaluation

		Center Number:	Participant Number:	Participant's Initials:
C	ompletion/Early Dis	continuation		
1	Date of study completion or ec	ırly discontinuation of study	day month year	_
2	Did the participant complete th	e study through Month 24?		
		contact:/ _{month} /_		
	Indicate the	orimary reason for discontin	nuation (check only one):	
		event → Complete Signs, Syr	mptoms and Adverse Events Log	g
		 If serious adverse 	event, complete Serious Adver	se Event (SAE) form
	□ ₄ Death →	Date of death:/	/	
		• Complete Signs, Sympto	ms and Adverse Events Log	
		Complete Serious Advers	se Events form	
		• Report cause of death as	s a Serious Adverse Event	
	on Other (sr	pecify):		

Phase 2	
erie	
Sa	

calerie	Phase 2	64			Completed by Calerie staff: Baseline 1 6 Month Baseline 2 12 Month	lerie staff: 6 Months 12 Months 24 Months
			Center Number:	: Participant Number:		Participant's Initials: first middle last
Daily Home Weight Log	eight Log					
Were you issued a new scale? $\square_{ m o}$ $ m No$ Please complete this log in either blue or		□ ₁ Yes → If Yes: Date first used: black ink.	month day ' year	Serial no.:	1	
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:
			,		,	` L
Ime:	II me:	IIMe:	IIMe:	IIMe:	IIMe:	IIMe:
Weight: 	Weight:	Weight:	Weight:	Weight:	Weight: lb	Weight:
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 month	month / day / year	month day / year	month day / year	month day ' year	month day / year	month day / year
Time: 1 AM 2 PM	Time:	Time: 1 AM 2 PM	Time: 1 AM 2 PM	Time: 1 AM 2 PM	Time: 1 AM 2 PM	Time:
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:
						Check scale memory

Send Completed Logs to DCRI Only If Completed During DLW Periods



Protocol Deviation

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