

Month 24 Submission Month 23 Visit

	Center Number:	Participant Number:	Participant's Initio	first middle last		
Clinic Weight						
Weight date and time: —	/	: 0 to 23:59	Staff initials: ${}_{first}$	middle last		
	reason (use codelist below):		m si	illiddie idsi		
Clinic weight (if the two me	asurements 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					
Pregnancy Test						
Complete only for females. Does participant have reproductive potential? Only No In Yes If Yes: Date urine pregnancy test performed: In Negative In Negati						
Sample	day month	year 00:00 to 23:59	If Not Done,	Staff		
If a sample is not obtained, indicate with a Not Done.	Sample Co	omplete?	Reason (Use codelist below)	Initials		
Blood	□ ₀ No □ ₁ Yes			first middle last		
NOTE: Befor	Vaccine Administration e any vaccine is administered, review the and protocol for participant eligibi		If Not Done, Reason (Use codelist below)	Staff Initials		
Vaccine(s) given (check all that apply):	98 (/aqta (Merck) Other:] Adult2 Pediatric		first middle last		
Not Done Codelist: 1 Par	ticipant refused 2 Clinician unable to	obtain 3 Insufficient time	4 Instrument failure 5 Not i	required		



	Center Number: Participant Number: Participant's Initials: first middle last
C	nic Weight
	ght date and time: $\frac{1}{\log y} / \frac{1}{\log y} / \frac{1}{\log y} = \frac{1}{\log y} $ Staff initials: $\frac{1}{\log y} = \frac{1}{\log y} = \frac{1}$
Cli	ic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
W	ght 1: kg
We	ght 2: kg
W	ght 3: kg
We	ght of gown: kg
V	tal Signs
As	essment date and time:/
1	If waist measurement not done → Specify reason (use codelist below): Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time): 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: lirst middle last
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: first middle lost
6	Blood pressure (check only one): 1 Left arm 2 Right arm
	6a Blood pressure 1:/ mm Hg Time:: OR Not done →
	Specify reason (use codelist below): 6b Blood pressure 2:/ mm Hg Time:: systolic diastolic 00:00 to 23:59 Specify reason (use codelist below):
	6c Blood pressure 3:/ mm Hg
No	Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required



Center	Number: Participant	Number: Par	rticipant's Initials: first middle last			
12-Lead ECG						
Date and Time		Findings	Staff Initials			
	done → Specify reason (see codelist below): Abnormal, not clinically significant (specify): Abnormal, clinically significant (specify):					
Safety Labs Date and time of last meal:/	/ .					
Date and time of sample collection:/	onth year 00:00 to conth y					
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					
Pregnancy Test						
Complete only for females. Does participant have reproductive potential? □₀ No □₁ Yes → If Yes: Date urine pregnancy test performed: ————————————————————————————————————						
Not Done Codelist: 1 Participant refused 2 Clinic	cian unable to obtain 3 Insuf	ficient time 4 Instrument failu	ure 5 Not required			



		Center Number:	Participant Number:	Participant's Initials:
D	oubly Labeled W	Vater (DLW)		
1	Date and time of DLW do	osing:/ _{month} / _{year}	:: _	Staff initials:
	OR Not done → Specify	reason (use codelist below):		
2	DLW dose mixture ID an	d bottle number:	CA	
3	_	cture: grams		
4	Urine samples:			
	Collection	Sample	Date and Time	Collected
	Pre dosing (PD)	PDa	/	00:00 to 23:59
		PDb	/	00:00 to 23:59
	Day 0 (Visit 1)	DOa	/	00:00 to 23:59
		D0b	/	00:00 to 23:59
	Day 7 (Visit 2)	D7a	/	: 00:00 to 23:59
		D7b	/	: 00:00 to 23:59
	Day 14 (Visit 4)	D14a	/	: 00:00 to 23:59
		D14b	/	00:00 to 23:59
5	Affix CRF page label(s) o	corresponding to this urine sample	e set: Affix A	ffix
			Test Sample Retest	Sample el 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: ___ __

Physical Examination Date of examination:/	/			Staff initials: First middle last
OR Not done → Specify reason (use c				first middle last
Dada Castana		Assessments	•	If Above and an Net Beauty Foundation
Body System	Normal	Abnormal	Not Done	If Abnormal or Not Done: Explain
1 General appearance:		□₀→	₉₇ →	
2 Head, Ears, Eyes, Nose, Throat:		□₀→	₉₇ →	
3 Neck:		□ _o →	□ ₉₇ →	
4 Heart:		□₀→	₉₇ →	
5 Lungs:		□₀→	□ ₉₇ →	
6 Abdomen:		□₀→	₉₇ →	
7 Lymph nodes:		□₀→	₉₇ →	
8 Extremities/Skin:		□₀→	₉₇ →	
9 Neurological:		□₀→	₉₇ →	
10 Musculoskeletal:		□ _o →	₉₇ →	
	Normal	Abnormal	Not Done *	
11 Genitourinary:		□₀→	₉₇ →	
12 Breast:		□₀→		
Physician's Signature				
Investigator:	signatu	ure		Date:/

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



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

		tirst middle last				
DXA Scan	DXA Scan					
 Has the participant taken a calcium supplement today? □ No □ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? □ No □ Yes 						
DXA Scan		DXA Rescan OR \square_{96} NA				
Date of scan:/						
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply				
☐ Whole body		☐ Whole body				
Forearm		Forearm				
Spine		Spine				
☐ Hip		☐ Hip				
Not Done Codelist: 1 Participant refused 20	Clinician unable to obtain	a 3 Insufficient time 4 Instrument failure 5 Not required				



	Cent	er Number: Participant Numb	er:	Participant's In	first middle last
Da	ite completed:/ _{month} / _{year}	_ OR Not done → Specify reason	(use codelist below	v):	
R	AND SF-36				
Ins		about your health. This information e answer every question by placing question, give the best answer you c	a check "X" in th		
1	In general, would you say your health is:	☐₁ Excellent ☐₂ Very ç	good 🔲 Go	ood □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 activit pical day. Does your health now lin so, how much?	- 0	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
3	Vigorous activities, such as run participating in strenuous sports	ning, lifting heavy objects,			
4	Moderate activities , such as movacuum cleaner, bowling, or playi			\square_2	\square_3
5	Lifting or carrying groceries				\square_3
6	Climbing several flights of stairs				\square_3
7	Climbing one flight of stairs				\square_3
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 Cli	nician unable to obtain 3 Insufficient	time 4 Instrume	nt failure 5 No	ot required



	Center Number:	Participant Number:	Participant's Init	first middle last
Rand SF-36 (continued)				
During the past 4 weeks, have y	-	-		
with your work or other regular physical health?	daily activities as d	a result of your	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 your work or other regular daily				
problems (such as feeling depresse		o. , ooo	Yes	No
17 Cut down on the amount of ti	i me you spent on wo	ork or other activities		
18 Accomplished less than you v	would like			
19 Didn't do work or other activi	ities as carefully as	usual		
20 During the past 4 weeks, to very problems interfered with your neighbors or groups?		. ,	☐, Not on the life of the lif	itly lerately e a bit
21 How much bodily pain have y	you had during the	past 4 weeks?	☐ ₁ None ☐ ₂ Very ☐ ₃ Mild ☐ ₄ Mod ☐ ₅ Seve ☐ ₆ Very	mild lerate
22 During the past 4 weeks, how interfere with your normal we and housework)?	•	ork outside the home	☐ ₁ Not a ☐ ₂ A littl ☐ ₃ Mod ☐ ₄ Quite ☐ ₅ Extre	le bit lerately e a bit



	Center Number: _	Part	icipant Numbe	er:	Part	icipant's Initials	first middle last
RAND SF-36 (continued)							
These questions are about how y weeks. For each question, please been feeling.		_		_		-	
How much of the time during the pas	t 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 nervou	s person?			\square_3	4	5	
25 Have you felt so down in the nothing could cheer you up?	dumps that			\square_3	4		6
26 Have you felt calm and peace	ful?		\square_{2}	\square_3	4	5	6
27 Did you have a lot of energy?				\square_3	4	5	
28 Have you felt downhearted a	nd blue?		\square_2	\square_3	4	5	6
29 Did you feel worn out?				\square_3	4	5	
30 Have you been a happy perso	on?		\square_{2}	\square_3	4	5	6
31. Did you feel tired?				\square_3	4	5	6
32 During the past 4 weeks, how n your physical health or emotion interfered with your social act	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)?	IVIIIe3 (like visiling	menas,			3	4	5
How true or false is each of the follow	wing statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easie	r than other p	eople.					5
34 I am healthy as anybody I kno	ow.				\square_3	4	5
35 I expect my health to get wors	se.				\square_3		
36 My health is excellent.							

Participant's Initials: first middle last



		Center Number: Participant Number: Participant's Initials: isst middle last
Do	ite completed:/ _{mor}	/OR Not done → Specify reason (use codelist below):
В	DI-II	
In	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:	\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 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
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
N	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:
В	DI-II (continued)			
	Self-criticalness:	\square_1 I am more critical of \square_2 I criticize myself for \square_2	ame myself more than usual myself than I used to be all of my faults verything bad that happens	
9	Suicidal thoughts or wishes:	☐₀ I don't have any tho ☐₁ I have thoughts of kil ☐₂ I would like to kill my ☐₃ I would kill myself if	lling myself but I would not co vself	arry them out
10	Crying:	\square_0 I don't cry any more \square_1 I cry more than I use \square_2 I cry over every little \square_3 I feel like crying, but	ed to thing	
11	Agitation:	\square_1 I feel more restless o \square_2 I am so restless or ag	I up or restless than usual r wound up than usual gitated that it's hard to stay st gitated that I have to keep mo	
12	Loss of interest:	, I am less interested i	st in other people or activities n other people or things than y interest in other people or t ested in anything	before
13	Indecisiveness:	•	to make decisions than usual difficulty in making decisions	
14	Worthlessness:		elf as worthwhile and useful c s as compared to other peopl	
15	Loss of energy:	o I have as much ener 1 I have less energy th 2 I don't have enough 1 don't have enough	an I used to have energy to do very much	

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 more ☐ I sleep somewhat less ☐ I sleep 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 \square_1 I am more irritable tha \square_2 I am much more irritable \square_3 I am irritable all of the	n usual Ile 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 g ☐ I have no appetite at c ☐ I crave food all of the	nat greater than usual ess than before reater than usual all	;	
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 concentra	well as usual ind on anything for very long	3	
20 Tiredness or fatigue:	\square_2 I am too tired or fatigu	ratigued than usual gued more easily than usual ed to do a lot of the things ed to do most of the things	I used to do	
21 Loss of interest in sex:	☐₀ I have not noticed any ☐₁ I am less interested in s ☐₂ I am much less interest ☐₃ I have lost interest in se	ed in sex now	st in sex	



	Center Number:	Participant N	Number:	Participant's Ir	nitials:
Date completed:/ _{month} /	OR Not don	ne → Specify re	ason (use codelist be	low):	
Profile of Mood States					
Instructions: Please describe how you	feel right now by cl	hecking one box	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	
3 Angry				\square_3	4
4 Worn out	\square_{0}			\square_3	4
5 Unhappy					4
6 Clear-headed	\square_{o}			\square_3	4
7 Lively				\square_3	4
8 Confused				\square_3	4
9 Sorry for things done				\square_3	4
10 Shaky	\square_{o}			\square_3	4
11 Listless	□ _o			\square_3	4
12 Peeved	\square_{o}		\square_{2}	\square_3	4
13 Considerate					4
14 Sad	\Box_{o}			\square_3	4
15 Active	\square_{o}				4
16 On edge	\square_{o}		\square_2	\square_3	
17 Grouchy				\square_3	4
18 Blue	\square_{o}		\square_2	\square_3	
19 Energetic	\square_{o}				
20 Panicky				\square_3	4
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Not Done Codelist: 1 Participant refused	2 Clinician unable to	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N	ot required



	Center Number: _	Participa	nt Number:	Participant's	Initials: first middle last
Profile of Mood States	continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless					4
22 Relaxed					
23 Unworthy					4
24 Spiteful				\square_3	4
25 Sympathetic					4
26 Uneasy			\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					4
31 Annoyed				\square_3	4
32 Discouraged					4
33 Resentful					4
34 Nervous					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				\square_3	4

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

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Participant's Initials: first middle last



	Center Number: Po	rticipant Number:		Participant's	s Initials:	irst middle last
Date completed:/	OR Not done → Sp	pecify reason (use code	list below):			
Perceived Stress Scale (PSS)						
Instructions: The questions in this scale as indicate how often you felt of	, ,	•				lease
		Never	Almost Never	Some- times	Fairly Often	Very Often
In the last month, how often ha unable to control the important	-	vere			\square_3	4
2 In the last month, how often ha your ability to handle your pers	•	about $_{\Box_0}$		\square_2	\square_3	4
3 In the last month, how often ha going your way?	ve you felt that thing	s were				4
4 In the last month, how often ha piling up so high that you could	-				\square_3	
Not Done Codelist: 1 Participant refused 2	2 Clinician unable to obtain	3 Insufficient time 4	Instrument f	ailure 5	Not requi	red



		Center Number: P	articipant Number:	Pa	rticipant's Initials	first middle last
Da	te completed:/ _{month} /	OR Not done → S	opecify reason (use c	odelist below): _		
Pi	ttsburgh Sleep Quality I	ndex (PSQI)				
Ins	structions: The following questions re the most accurate reply fo	elate to your usual sleep hal or the majority of days and i		-		
Du	ring the past month					
1	When have you usually gone	to bed?:				
2	How long (in minutes) has it t	aken you to fall aslee	p each night? _	minut	es	
3	When have you usually gotte	n up in the morning?	: 00:00 to 23:59			
4	How many hours of actual slee (This may be different than the number of hour	. , .	nours			
5	During the past month, how a sleeping because you (check	•	the bds	it once	Once or twice a week	3 or more times a week
	a Cannot get to sleep within	30 minutes				\square_3
	b Wake up in the middle of t	he night or early mor	ning			\square_3
	• Have to get up to use the k	oathroom				$\square_{_3}$
	d Cannot breathe comfortab	ly				\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 de you have had trouble sleep reason(s):		often			\square_3
6	During the past month, how a medicine (prescribed or "over the cou		? □₀			\square_3
	89,with permission from Elsevier Science. bt Done Codelist: 1 Participant refused	2 Clinician unable to obtain	3 Insufficient time	4 Instrument fail	ure 5 Not re	quired



	Center Number:	Participant	Number:	Parti	cipant's Initials:	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (c	ontinued)				
			Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how often have you ha staying awake while driving, eating meals, or e 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 probl been for you to keep up enthusiasm to get th					3
			Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate quality overall?	your sleep				



	Center Number	:	Partici	pant Num	ber:		Parti	cipant's In	nitials:	t middle las	
Date completed:/	OR Not done	→ Spec	ify reasc	on (use co	delist bel	ow):					
Derogatis Interview for Sex	kual Fun	ction	(DISF-S	R) (F) Fe	male Ve	rsion					
Instruction: Below you will find a brief set sections that ask about different aspects of y while another inquires about the kinds of se sexual arousal and the quality of your or relationship.	your sexual e exual expe	experien riences	ces. One	section of have. You	asks abo ou are a	out sexu Iso aske	al fante d about 1	isies or the natu	daydre	ams, Jr	
activities asked about in that section. Some frequency scales range from "0 = never" to of a satisfaction scale. This type of scale tells Some satisfaction scales range from "0 = co	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 pe	erson who g	ave you	the inve	ntory for	help.						
Section 1—Sexual Cognition/Fanto	ısy										
During the past 30 days or since the la you filled out this inventory, how often you had thoughts, dreams, or fantasies	have	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day	
1.1 A sexually attractive person						4	5				
1.2 Erotic parts of a man's body (e. shoulders, legs)	g., face,					4	5	6			
1.3 Erotic or romantic situations					\square_3	4					
1.4 Caressing, touching, undressing foreplay	g, or					4	5				
1.5 Sexual intercourse, oral sex, to to orgasm	ouching					4	5	6		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 1	lumber:	Po	ırticipant N	umber: _		Par	rticipant's I	nitials:	st middle lasi
Derogatis Interview for Sexual	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					4	5	6		8
2.2 Actively seek sexual satisfaction				3	4		6	7	8
2.3 Feel sexually aroused with a partner					4		6	7	8
	Never	Rarely	Sometimes	Usually	Always				
2.4 Have normal lubrication with masturbation					4				
	1	1	1	1	1				

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throughout sexual relations

2.5 Have normal lubrication



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	l 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			8
3.2 Masturbation	По			3	4	5	□ ₆		□ ₈
3.3 Casual kissing and petting					4	5			
3.4 Sexual foreplay				\square_3	4		□ ₆		□ ₈
3.5 Sexual intercourse, oral sex, etc.					4	₅	□ ₆		
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 ability to have multiple orgasms (if typical for you)	o			\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	4				

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

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

Section 5—Drive and Relationship

-									
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?					4	5			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?					4				
	Could not be worse	Very poor	Poor	Somewhat inadequate		Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?					4	5	6	7	8

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Month 24 Submission V:_:_ 1

								VI	SIT I
Center Numb	oer:	Partici	ipant Num	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed:/ OR Not do	ne → Spec	ify reaso	on (use co	delist be	low):				
Derogatis Interview for Sexual Fu	ınction	(DISF-S	R) (M) N	Nale Ver	sion				
Instruction: Below you will find a brief set of question sections that ask about different aspects of your sexual while another inquires about the kinds of sexual expressexual arousal and the quality of your orgasm. The relationship.	ıl experien eriences	ices. One that you	section have. Y	asks abo ou are a	out sexu Iso aske	al fant d about t	asies or the natu	daydre re of you	ams, ur
On some questions you are asked to respond in the 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 v	= not at other qu were sati	all" to " estions, sfied by	8 = four you will the sexu	or more be asked al activit	times a I to resp y being	day." Of ond in to asked a	ther erms bout.
In every section of the inventory the scales require follow. Although it is brief, take your time with the invedescribes 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	5	6		8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)				\square_3	□ 4		6		8
1.3 Erotic or romantic situations				\square_3	4	5	6		8
1.4 Caressing, touching, undressing, or foreplay				\square_3	4	₅	6		8
1.5 Sexual intercourse, oral sex, touching to orgasm					4	5	6		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:	Participant Number:	Participant's Initials:	first middle last
Derogatis Interview for S	exual Function (DISF-SR) (M) Male Version (continu	ed)	

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 all than 1 week per day per per per more you filled out this inventory, how often did per per month week week day month day you have the following experiences? 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



Center Num	ber:	Par	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					4				8
3.2 Masturbation	По			\square_3	4	5	6		8
3.3 Casual kissing and petting	□ _o			\square_3	4	5	6		8
3.4 Sexual foreplay	o			\square_3	4	5			8
3.5 Sexual intercourse, oral sex, etc.					4	5			8
Section 4—Orgasm									
During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm	o				4				
4.2 The intensity of your orgasm	o			\square_3	4				
4.3 The length or duration of your orgasm	О			\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	□ _o				4				
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3					

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Center	r Number: Participant Number: Participant's Initials:								
Derogatis Interview for Sexua	ıl Fund	tion (DISF-SR) (M) Male \	/ersion (d	ontinue	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	_ ₇	8
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex?				\square_3	□ ₄				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				\square_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	5			8

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Center Number:	Center Number: Participant Number: Participant's Initials:										
Date completed:/ OR Not done											
Food Cravings Questionnaire—State (FCQ-	-S)										
Below is a list of comments made by people about their eating he how much you agree with the comment right now, at this very while others refer to one or more specific foods. Please respond	moment.	Notice that	some quest	tions refer t							
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree					
1 I have an intense desire to eat [one or more specific foods].					4						
2 I'm craving [one or more specific foods].			\square_{2}	\square_3	\square_{4}	5					
3 I have an urge for [one or more specific foods]				\square_3	4	5					
4 Eating [one or more specific foods] would make seem just perfect.	things			\square_3		5					
5 If I were to eat what I am craving, I am sure my would improve.	mood			\square_3	4	5					
6 Eating [one or more specific foods] would feel wonderful.			\square_{2}	\square_3	\square_{4}	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 gand irritable.	jrouchy			\square_3	\square_{4}						
9 I would feel more alert if I could satisfy my cravi	ng.			\square_3	\square_{4}	5					
10 If I had [one or more specific foods], I could not eating it.	stop		\square_{2}	\square_3	\square_{4}	5					
11 My desire to eat [one or more specific foods] seems overpowering.				\square_3	4	5					
12 I know I'm going to keep on thinking about [one more specific foods] until I actually have it.	or		\square_{2}	\square_3		5					
13 I am hungry.				\square_3		5					
14 If I ate right now, my stomach wouldn't feel as e	mpty.										
15 I feel weak because of not eating.					4	5					
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	tain 3 Insu	fficient time	4 Instrume	ent failure	5 Not req	uired					



		Center Number:	Par	ticipant Number:		Participant's	Initials:
Da	te completed:/ _{month} / _{yea}						
	ood Craving Inventory (FCI						
	each of the foods listed below, please o		riate box.				
No	te: A craving is defined as an intense de		a particula	i i	ype that is diffi	cult to resist.	Al/Al
	Over the past month, how ofte have you experienced a craving f		Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1	Cake					4	
2	Pizza				\square_3		
3	Fried chicken				\square_3	4	
4	Gravy				\square_3	4	
5	Sandwich bread					4	
6	Sausage				\square_3		
7	French fries						
8	Cinnamon rolls				\square_3	4	
9	Rice						
10	Hot dog						
11	Hamburger						
12	Biscuits						
13	Ice cream						
14	Pasta						
15	Fried fish						
16	Cookies						
17	Chocolate						
18	Pancakes or waffles						
19	Corn bread						
20	Chips						
21	Rolls						
22	Cereal						
23	Donuts						
24	Candy						
25	Brownies						
26	Bacon						
27	Steak						
28	Baked potato						
No	ot Done Codelist: 1 Participant refused 2	2 Clinician unable	to obtain	3 Insufficient tim	e 4 Instrumen	t failure 5 N	Not required
						Participant's	nitials: first_middle_last

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		Center Number:	Participant Number:		Participant's I	nitials: middle last
Date c	ompleted:/ _{month}					
Eati	ng Inventory					
1	When I smell a sizzling ste difficult to keep from eating			it very	լ True	o False
2	I usually eat too much at s	ocial occasions, like	parties and picnic	s.		o False
3	I am usually so hungry the	it I eat more than th	ree times a day.		, True	o False
4	When I have eaten my que not eating anymore.	ota of calories, I am	usually good abo	ut	, True	o False
5	Dieting is so hard for me b	ecause I just get too	hungry.		1 True	o False
6	I deliberately take small he	elpings as a means	of controlling my w	veight.	, True	o False
7	Sometimes things just taste I am no longer hungry.	so good that I kee	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.			ı, an		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 o more than once.	ınd down, I have go	one on reducing die	ets	₁ True	o 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	00.		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 see	m to stop.		1 True	o False
16	It is not difficult for me to le	eave something on	my plate.			o False
17	At certain times of the day to eating then.	, I get hungry becau	use I have gotten u	sed	, True	o False
18	While on a diet, if I eat foo for a period of time to mak		d, I consciously ea	t less		□₀ False
Not D	one Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time	4 Instrument	failure 5 N	ot required



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

calerie Phase 2

Month 24 Submission Visit 1

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



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

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

I a	I am confident that:			e nt at a st the de		Very confident that you can resist the desire to eat					
		0	1	2	3	4	5	6	7	8	9
1	I can resist eating when I am anxious (nervous).				\square_3	4	5			8	9
2	I can control my eating on the weekends.				\square_3	4		6		8	9
3	I can resist eating even when I have to say "no" to others.					4	5			8	9
4	I can resist eating when I feel physically run down.	o			\square_3		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.					4			7	8	9
8	I can resist eating even when I feel it is impolite to refuse a second helping.	o			\square_3	4				8	9
9	I can resist eating even when I have a headache.									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	k



	Center Number: _		Particip	ant Nur	nber:			Particip	ant's Init	ials:	middle last	
Weight Efficacy Lifestyle Q	uestionnai	ire (w	/EL) (co	ntinue	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 re	ading.				\square_3	4	5	6		8	9	
11 can resist eating when I am a (or irritable).	ngry						5	6		8	9	
12 I can resist eating even when I a party.	am at	o			\square_3	4	5	6		8	9	
13 I can resist eating even when of pressuring me to eat.	thers are							6		8	9	
14 I can resist eating when I am in	pain.	\Box_{0}			\square_3		5	6		8	9	
15 I can resist eating just before go bed.	oing to					4		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-ca are available.	lorie foods	□ _o				4		6		8	9	
18 I can resist eating even when I to others will be upset if I don't ec		o			\square_3	4		6		8	9	
19 I can resist eating when I feel uncomfortable.		□ _o								8	9	
20 I can resist eating when I am ho	арру.						5	6		8	9	

Participant's Initials: first middle last



	Center Number:	Participa	cipant Number: Participant's Initials:						t 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	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		7
2 My sleep isn't as good as it u	sed to be.				\square_{3}		5	6	
3 I avoid eating for as long as I	can.				3		5	6	
4 Certain foods are "forbidden"	" for me to eat.				$\square_{_{3}}$	\square_{4}	5	6	
5 I can't keep certain foods in my binge on them.	house because I will				3	4	5	6	
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}	4	5	6	
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		
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.				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		5	6	
16 Lately nothing seems enjoyab	le anymore.				$\square_{_{3}}$	\square_{4}	5		
17 Laxatives help keep you slim.					\square_3		5		
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			
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 In:	sufficient	time 4	Instrume	nt failure	5 No	t require	ed



	Center Number:	Participant N	Participant's Initials: middle last								
Aultiaxial 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.					5	6				
21 When I feel bloated, I must do of that feeling.	something to rid myse	If			4	5	6				
22 I overeat too frequently.				\square_3	4	5					
23 It's okay to be overweight.					4	5					
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.				4	5		7			
26 I crave sweets and carbohyde	rates.			\square_3	4	5	6				
27 I lose control when I eat.				\square_3	4	5		7			
28 Being fat would be terrible.				\square_3	4	5	6				
29 I have thought seriously abou	ut suicide lately.			3	4	5					
30 I don't have any energy anymo	ore.			3	4	5	6	7			
31 I eat small portions to control	my weight.			\square_3	4	5		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		6				
35 I use laxatives to control my	weight.				4	5	6	7			
36 I am terrified by the thought	of being overweight.			\square_3	4	5					
37 Purging is a good way to lose	e weight.			\square_3	4	5		7			
38 I avoid fatty foods.											



Center Number:	Participant I	Participant Number: Participant's Initials:										
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)												
	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always					
39 Recently I have felt pretty blue.					5							
40 I am obsessed with becoming overweight.					5	6						
41 I don't eat fried foods.					5							
42 I skip meals.			\square_3		5							
43 Fat people are unhappy.					5							
44 People are too concerned with the way I eat.			\square_3		5							
45 I feel good when I skip meals.					5							
46 I avoid foods with sugar.			\square_3		5	6						
47 I hate it when I feel fat.					5							
48 I am too fat.			\square_3		5							
49 I eat until I am completely stuffed.				4	5							
50 I hate to eat.			\square_3	4	5	6						
51 I feel guilty about a lot of things these days.				4	5							
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 hung	ry.		3	4	5							
54 I eat even when I am not hungry.			\square_3		5	6						
55 Fat people are disgusting.				4	5							
56 I wouldn't mind gaining a few pounds.					5		7					



	Center Number: Participant I	Number: _		Par	ticipant's I	nitials:	t middle last
Da	te completed:/OR Not done → Specify re	ason (use	codelist b				
В	ody Shape Questionnaire (BSQ)						
	e 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?			\square_3		5	
2	Have you been so worried about your shape that you have been feeling that you ought to diet?			\square_3	4	5	
3	Have you thought that your thighs, hips, or bottom are too large for the rest of you?			\square_3		5	6
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
6	Has feeling full (e.g., after eating a large meal) made you feel fat?			\square_3	4	5	6
7	Have you felt so bad about your shape that you have cried?			\square_3	4	5	6
8	Have you avoided running because your flesh might wobble?			\square_3	4	5	6
9	Has being with thin women/men made you feel self-conscious about your shape?			\square_3	4	5	
10	Have you worried about your thighs spreading out when sitting down?			\square_3	4	5	6
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?			\square_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)?				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	4	5	
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	icient time	4 Instru	ument failu	re 5 N	lot require	ed



	Center Number:	Participant N	umber: _		Par	ticipant's	Initials: _	rst middle last
Body Shape Questionnai	re (BSQ) (continued)							
Over the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes or you feel fat?	other high calorie foo	d made			\square_3	4	5	
18 Have you not gone out on so because you have felt bad a		ties)			\square_3	4	5	6
19 Have you felt excessively lar	ge and rounded?				\square_3	4	5	6
20 Have you felt ashamed of yo	our body?				\square_3	4	5	6
21 Has worry about your shape	e made you diet?				\square_3	4	5	6
22 Have you felt happiest about stomach has been empty?	t your shape when yo	ur			\square_3	4	5	6
23 Have you thought that you a because you lack self-control					\square_{3}	4	5	6
24 Have you worried about oth flesh around your waist or st		of			\square_3		5	6
25 Have you felt that it is not faithinner than you?	ir that other women/n	nen are	□,		\square_3	4	5	
26 Have you vomited in order to	o feel thinner?				\square_3	4	5	6
27 When in company, have you much room (e.g., sitting on a sofa c		up too			\square_3	4	5	
28 Have you worried about you	ur flesh being dimply?				\square_3	4	5	6
29 Has seeing your reflection (e. you feel bad about your sha) made			\square_3	4	5	
30 Have you pinched areas of y fat is there?	our body to see how	much			\square_3	4	5	
31 Have you avoided situations your body (e.g., communal changin		see			\square_{3}	4	5	
32 Have you taken laxatives in	order to feel thinner?				\square_3		5	6
33 Have you been particularly s shape when in the company	self-conscious about yo of other people?	our			\square_3	4	5	
34 Has worry about your shape to exercise?	e made you feel you o	ught					5	6



		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 D	ynometer handle positior	n:				
2 D	ominant hand (check only	one):1 Left	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	\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 failu	re 5 Not required	



			Center Number:	Participant Number:	Particip	first middle last
Is	sometric/Isokine	tic Kne	e Extension and	l Flexion		
	ate and time of assessment				Staff ini	rials:
_		1.1 0				
1	Recent injury or pain—riç					
2	Recent injury or pain—le					
3	Specify machine used (P	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:	Participant's Initials:	first middle last
Clinic Weight				
	/ _{month} / _{year} ify reason (use codelist below):		Staff initials:	- last
Clinic weight (if the two	measurements are more than 0.1 kg	apart, measure weight a third time):		
Weight 1:	kg			
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			

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

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Toda	Today's date:		-—— Dαy	Day (check only one):	Mon Tue	Mon Tues Wed Thurs Fri Sat Sun OR Not done → Speafy reason (use codelist below):	Thurs	Fri S	at Sur	OR NO	done →	Specify re	eason (use	codelist bel	ow):
_	Were yo	yed in the last sev	ın days?		°Z °C	$\square_0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	estion 3	Ty Yes				Interv	Interviewer initials:		first middle last
4	f Yes: W	If Yes: Which days (check all that apply)?	0.		Mon	Tues	Wed	Thurs	Fri	Sat	Sun				
6	Which d	Which days do you consider your weekend, or non-work, de	reekend, or n	on-work, days?		Tues	Med	Thurs	Fi.	Sat	Sun		I		
λ	Day of	1	Sleek	Sleep Time	Work Time	Time	Mor	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
✓	·	//-	00:00 to 23:59	00:00 to 23:59	 	 									
day)		day month year	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									
9		//	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									
Ŋ	•	//-		00:00 to 23:59											
		day month year			00:00 to 23:59	00:00 to 23:59									
4			00:00 to 23:59	00:00 to 23:59											
		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
m	•	doy / month wear	00:00 to 23:59	00:00 to 23:59											
			00:00 to 23:59	00:00 to 23:59											
7	-	day month yeer	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00									
			00:00 to 23:59	00:00 to 23:59											
_	•		00:00 to 23:59	00:00 to 23:59	 	 									
go)		day month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
1															

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:
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? One No Tyes
7	Were there any activities reported by the participant that you don't know how to classify? One Tyes



		Center Number:	Partic	ipant Number: Partici	pant's Initials:
	ay Food Record olete below OR Not done → Spec	ify reason (use Codelist b	pelow): _	Staff ini	tials: 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	/	n Reliable number to the large state of the large s	8	/	Reliable Unreliable Missing
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
3	/	n Reliable number unreliable number unreliable number unreliable	10	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
4	/	n Reliable number unreliable number unreliable number unreliable	11	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
5	/	n Reliable number unreliable number and sing	12	/	Reliable Unreliable 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	5 Not required



	Center Number: Participant Number: Participant's Initials:
V	O ₂ Max
1	Date and time of test:/
	OR Not done → Specify reason (use codelist below):
2	At what time was the participant's last meal/snack eaten?::
3	Rest ECG: Rhythm (check only one):
4	Heart rate (HR) data: Resting heart rate: bpm Age-predicted heart rate: bpm Heart rate (max): bpm
5	Reason(s) for termination of testing (check all that apply): ☐ Symptom limited (dyspnea, fatigue) ☐ Angina/ischemia → Complete all that apply: HR when true cardiac angina occurred: bpm OR ☐ ₉₆ NA
	HR when ischemic ECG changes occurred: bpm OR
6	Did frequent ventricular ectopy occur (e.g., \geq 7 PVCs/min, bi/tri-geminy, NSVT [\geq 3 beats])? \square_0 No \square_1 Yes \rightarrow If Yes: When did it occur (check all that apply)? \square During exercise \square During recovery
7	Peak VO ₂ : mL/kg/min L/min
8	Did the participant meet at least 2 of the 3 VO $_2$ max criteria (see box,right)? \square_0 No \square_1 Yes \rightarrow If Yes: VO $_2$ max: mL/kg/min L/min
9	Exercise time: : : : seconds
10	Blood pressure at VO ₂ peak/VO ₂ max:/ mm Hg
11	Borg RPE score at VO ₂ peak/VO ₂ max: (6-20)
12	Peak RER:
13	VE at VO ₂ peak/VO ₂ max: L/min
14	VE/VO ₂ at VO ₂ peak/VO ₂ max L/min

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

5 Not required



Date and time sam	ple collection started:/	month year 00:	: 00 to 23:59	
lf a sample is not ob	Sample stained, indicate with a Not Done.	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
	Blood	□ ₀ No □ ₁ Yes		first middle last
Core Tempe	rature			
Staff Initials	Provide Date Sample Collection/P		Time of Sample ollection/Procedure	If Not Done, Reason (Use codelist below)
	Start Date:		Start Time::	
first middle last	Stop Date:	year	Stop Time:00:00 to 23:59	
npatient A	dmission and Discha	ırge		
	ssion date and time:/_			
Inpatient disch	arge date and time:/_		.:	



		Center Num	ber: Pa	rticipant Numbe	r:	Participant's Initial	first middle last
D	elayed-type Hypers	ensitivity (DI	гн)				
1	Was the DTH worksheet complete \square_0 No \square_1 Yes \rightarrow If Yes: Were any Exception		? $\square_0 \ \text{No} \to \text{Pro}$ $\square_1 \ \text{Yes} \to \text{STO}$				
2	Date of injection:/	/	OR Not done →	Specify reason	(use codelist below):		
3	Injection by (initials):	-					
4	Arm injected: \square_1 Right \square_2	Left					
5	DTH results: Note: For each reaction, meass because the induration in diameter and then the di average diameter is equ A = Largest diameter B = Second diameter per	nay not be in the s iameter perpendic al to or greater the	hape of a circle. ular to it. Do not	If the indurati	on is an oval sha	pe, first measure	he long
		24	Hour (@ Visit 4)	Visit 4) 48 Hour (@ Visit 5)			
	Antigen	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:
	1 Normal saline	mm	mm		mm	mm	
	2 Tetanus toxoid (TT) (check only one):	mm	mm		mm	mm	
	3 Candida (check only one):	mm	mm	first middle last	mm	mm	first middle last
	4 Trichophyton (check only one):	mm	mm		mm	mm	

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



Clinic Weight				
Weight date and time: _ OR Not done → Specify	reason (use codelist below):	: 000 to 23:59	Staff init	ials: first middle last
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	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	atecholamines	□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 Done Reason (Use codelist be	Staff Initials
	Start Date:	Start Time:		
mL	day month year	00:00 to 23:59		first middle last
	Stop Date:	Stop Time:		

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

Stop Date:



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

Sex Hormone						tirst middle last
If Not Done → Specify reason (use code	list below)	:				
Contraception method (females only):			: → Specify: Record on Cor (e.g., barrier, IUD):	ncomitant	Medica	
Day 1		Date	Time	If Not I Reas (use cod	on ´	Staff Initials
Day 1 of menses (females only)						
Date and time of last meal (males only	r)	/	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	only)					
Day 2		Date	Time	If Not I Reas (use cod	ion	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	f Initials
Resting Metabolic Rate (RMR)—Visit 4		/			first	middle last
Cart ID	l	-003 (623-002)		PBRC-010	•	
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	ime 4 Instrument	failure	5 Not re	equired

Month 24 Submission

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

?				2221	(NIC)											
, 60	oday's date:	200			Day (check only one):		Mon Tues Wed Thurs Tri Sat Sun OR Not done → Specify reason (use codelist below):	Thurs	Fri S	at Sun	OR Not	done →	Specify re	eason (use	codelist beld	
_	Were yo	u employ	e last se	en days?		o N O	$\square_{0} \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	stion 3	Yes				Interv	Interviewer initials:	ials:	first middle last
61	If Yes: W	/hich day	If Yes: Which days (check all that apply)?	<u>c.</u>		Mon	Tues Wed Thurs	Med	Thurs	Fi	Sat	Sun				
_	Which d	ays do ya	Which days do you consider your weekend, or non-work, days?	weekend, or n	on-work, days'	Mon	Tues	Med	Thurs	Ē.	Sat	Sun				
	Jo you			Sleek	Sleep Time	Work Time	Time	Morr	Morning (in minutes)	nutes)	Aften	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
ster-	· ·			00:00 to 23:59	00:00 to 23:59	 	 									
ay)		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	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											
	•	/	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											
		day	month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
_	<u>'</u>				00:00 to 23:59											
week go)		day	month year	00:00 to 23:59	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



		Center Number:	Participant Number:	Participant's Initials:	· last
S	even-Day Physical Activ	vity Recall (PAR) (c	ontinued)		
4	Compared to your physical activity or about the same (check only one)? More Less About the same	over the past three month	ns, was last week's physical	activity more, less,	
In	terviewer: Please answer questions	below and note any com	nments on interview.		
5	Were there any problems with the S \square_0 No \square_1 Yes	Seven-Day PAR interview	?		
6	Do you think this was a valid Seven one No one Tes	-Day PAR interview?			
7	Were there any activities reported by No	by the participant that you	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

Phase 2	
erie	
la	

calerie	Te Phase 2	ď			Completed by Calerie staff: Baseline 1 6 Month Baseline 2 12 Month	erie staff: 6 Months 18 Months 12 Months 24 Months
			Center Number:	: Participant Number:		Participant's Initials: first middle last
Daily Home Weight Log Were you issued a new scale? $\square_0 \mathbb{N}_0$	5	☐, Yes → If Yes: Date first used: black ink	: month / day / wear	Serial no.:		
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:
month/_day/year	month day vear	month day year	month day / year —	month day / year	month day / year	month day / year
Time:	Time:	Time: 1 AM 2 PM	Time:	Time:	Time:	Time:
Weight: 	Weight:	Weight:	Weight:	Weight:	Weight:	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 / year	month day year	month day year	month day / year	month day year	month / day / year
Time: 1 AM 2 PM 0.0000 11:59	Time: 1, AM 2 PM	Time:	Time:	Time:	Time:	Time: 1 AM 2 PM 00000 PM 00000 PM
Weight: 	Weight: 	Weight: 	Weight: lb	Weight: 	Weight: 	Weight:

Send Completed Logs to DCRI Only If Completed During DLW Periods