

Month 12 Submission

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

	tirst middle las
C	inic Weight
We	eight date and time:/
	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	eight 1:kg
We	eight 2: kg
We	sight 3: kg
We	sight of gown: kg
	ital 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: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: initials:
6	Blood pressure (check only one): 1 Left arm 2 Right arm Staff initials: 1 Init
	6a Blood pressure 1:/ mm Hg Time:: OR Not done → Specify reason (use codelist below):
	6b Blood pressure 2: / mm Hg
	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



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

Month 12 Submission Visit 1

Center I	Nomber: runicipum i	Number: Par	first middle last		
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: day mon	: : : : : : : : : : : : : : : : : : :				
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: ————————————————————————————————————					

3 Insufficient time

4 Instrument failure

5 Not required



		Center Number:	Participant Number:	Participant's Initials: first middle last				
De	oubly Labeled V	Vater (DLW)						
1	Date and time of DLW d	losing:/	::::::	Staff initials:				
	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 00:00 to 23:59				
		PDb	/	year 00:00 to 23:59				
	Day 0 (Visit 1)	D0a	/	year 00:00 to 23:59				
		D0b	/	year 00:00 to 23:59				
	Day 7 (Visit 2)	D7a	/	year 00:00 to 23:59				
		D7b	/ _{month} /	year 00:00 to 23:59				
	Day 14 (Visit 4)	D14a	/	year 00:00 to 23:59				
		D14b	/ _{month} //	year 00:00 to 23:59				
5	5 Affix CRF page label(s) corresponding to this urine sample set:							
			Affix Test Sample Label Here	Affix Retest Sample				
			Label Here	Label Here				

3 Insufficient time

5 Not required

4 Instrument failure

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



CRF, page 164

	Center Nu	mber:	Participant Nu	mber: Participant's Initials:
Physical Examination				
Date of examination:/	_/	_		Staff initials:
OR Not done → Specify reason (use co				
		Assessments	;	
Body System	Normal	I Abnormal Not Done		If Abnormal or Not Done: Explain
General appearance:		□ _o →	₉₇ →	
2 Head, Ears, Eyes, Nose, Throat:	\square_1	□ _o →	□ ₉₇ →	
3 Neck:		□₀→	□ ₉₇ →	
4 Heart:		□₀→	□ ₉₇ →	
5 Lungs:		□₀→	₉₇ →	
6 Abdomen:		□₀→	₉₇ →	
7 Lymph nodes:		□₀→	□ ₉₇ →	
8 Extremities/Skin:		□₀→	□ ₉₇ →	
9 Neurological:		\square_{o} \rightarrow	□ ₉₇ →	
10 Musculoskeletal:		\square_{o} \rightarrow	□ ₉₇ →	
	Normal	Abnormal	Not Done*	
11 Genitourinary:		□₀→	₉₇ →	
12 Breast:		□ _o →	□ 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:	ramcipant's initials:	first middle last			
DXA Scan							
 Has the participant taken a calcium supplement today? □₀ No □₁ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. 							
Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? \[\bigcup_0 \text{No} \bigcup_1 \text{Yes} \]							
DXA Scan DXA Rescan OR \square_{96} NA							
Date of scan:/	Date of rescan:/						
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scan Check all tha					
☐ Whole body		☐ Whole body					
Forearm		Forearm					
Spine		☐ Spine					
☐ Hip		Hip					



	Center I	Number: Participant Numbe	er:	Participant's Ini	first middle last		
Da	ite completed:/ _{month} _/ _{year}	OR Not done → Specify reason	(use codelist below	·):			
R/	AND SF-36				_		
Ins	nstructions: 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:		ood 🔲 3 Go	od □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	e following items are about activitie 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 moving 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						
9	Walking more than a mile				\square_3		
10	Walking several blocks						
11	Walking one block				3		
12	Bathing or dressing yourself						
No	ot Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insufficient	time 4 Instrumer	nt failure 5 No	t required		

Participant's Initials: first middle last



Center Number: Participant Number	: Parti	icipant's Initials: _	first middle last
Rand SF-36 (continued)			
During the past 4 weeks, have you had any of the following prob			
with your work or other regular daily activities as a result of your physical health?		Yes	No
13 Cut down on the amount of time you spent on work or other	activities	1	
14 Accomplished less than you would like			
15 Were limited in the kind of work or other activities	[1	
16 Had difficulty performing the work or other activities (for example, it took extra effort)		_1	
During the past 4 weeks, have you had any of the following probyour work or other regular daily activities as a result of any emot			
problems (such as feeling depressed or anxious)		Yes	No
17 Cut down on the amount of time you spent on work or other ac	tivities	1	
18 Accomplished less than you would like		1	
19 Didn't do work or other activities as carefully as usual	[1	
20 During the past 4 weeks , to what extent has your physical heal problems interfered with your normal social activities with famil neighbors or groups?	th or emotional [1 Not at all 2 Slightly 3 Moderate 4 Quite a b 5 Extremely	ely it
21 How much bodily pain have you had during the past 4 weeks ?		None Very mild Moderate Severe Very seve	
22 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the hand housework)?		1 Not at all 2 A little bit 3 Moderate 4 Quite a b 5 Extremely	ely it

CRF, page 167



	Center Number:	Part	icipant Numbe	er:	Parti	icipant's Initials	first middle last
RAND SF-36 (continued)							
These questions are about how weeks. For each question, please been feeling.	-	_		_	-	-	
How much of the time during the p	ast 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 nerv	ous person?			\square_3	4	5	6
25 Have you felt so down in the nothing could cheer you up				\square_3	4	5	
26 Have you felt calm and pea	ceful?			\square_3	4	5	6
27 Did you have a lot of energ	y?			\square_3	4	5	6
28 Have you felt downhearted	and blue?		\square_{2}	\square_3	4	5	6
29 Did you feel worn out?				\square_3	4	5	6
30 Have you been a happy pe	rson?		\square_{2}	\square_3	4	5	6
31. Did you feel tired?				\square_3	4	5	
32 During the past 4 weeks, how your physical health or emointerfered with your social or relatives, etc.)?	tional 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 fol	lowing statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little eas	sier than other pe	eople.			\square_3	4	5
34 I am healthy as anybody I i	know.				\square_3	4	5
35 I expect my health to get we	orse.				\square_3	4	
36 My health is excellent.					\square_3	4	5



		Center Number: Participant Number: Participant's Initials:
Do	ate 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 estatement 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:	 □₀ I get as much pleasure as I ever did from the things I enjoy □₁ I don't enjoy things as much as I used to □₂ I get very little pleasure from the things I used to enjoy □₃ I can't get any pleasure from the things I used to enjoy
5	Guilty feelings:	 □₀ I don't feel particularly guilty □₁ I feel guilty over many things I have done or should have done □₂ I feel quite guilty most of the time □₃ I feel guilty all of the time
6	Punishment feelings:	☐₀ I don't feel I am being punished ☐₁ I feel I may be punished ☐₂ I expect to be punished ☐₃ I feel I am being punished
7	Self-dislike:	 □₀ I feel the same about myself as ever □₁ I have lost confidence in myself □₂ I am disappointed in myself □₃ I dislike myself
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:



		Center Number:	Participant Number:	Participant's Initials: First middle last
BI	DI-II (continued)			
8	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	Suicidal thoughts 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, k	used to ttle 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 interest:		erest in other people or activitied d in other people or things that f my interest in other people or erested in anything	n before
13	Indecisiveness:	•	cult to make decisions than usuc ter difficulty in making decision	
14	Worthlessness:		yself as worthwhile and useful ess as compared to other peop	
15	Loss of energy:			



	Center Number: Participant Number:	Participant's Initials: _{first midd}	dle las
BDI-II (continued)			
16 Changes in sleeping pattern:	□₀ I have not experienced any change in my sleed □₁ I sleep somewhat more than usual □₂ I sleep somewhat less than usual □₃I sleep a lot more than usual □₄I sleep a lot less than usual □₅ I sleep most of the day □₅ I wake up 1-2 hours early and can't get back		
17 Irritability:	\square_0 I am no more irritable than usual \square_1 I am more irritable than usual \square_2 I am much more irritable than usual \square_3 I am irritable all of the time		
18 Changes in appetite:	□₀ I have not experienced any change in my applus 1 My appetite is somewhat less than usual 1 My appetite is somewhat greater than usual 1 My appetite is much less than before 1 My appetite is much greater than usual 1 I have no appetite at all 1 Crave food all of the time	petite	
19 Concentration difficulty:	☐ I can concentrate as well as ever ☐ I can't concentrate as well as usual ☐ It's hard to keep my mind on anything for very ☐ I find I can't concentrate on anything	r long	
20 Tiredness or fatigue:	\square_0 I am no more tired or fatigued than usual \square_1 I get more tired or fatigued more easily than usual \square_2 I am too tired or fatigued to do a lot of the thin \square_3 I am too tired or fatigued to do most of the thin \square_3 I am too tired or fatigued t	ngs I used to do	
21 Loss of interest in sex:	\square_0 I have not noticed any recent change in my in \square_1 I am less interested in sex than I used to be \square_2 I am much less interested in sex now \square_2 I have lost interest in sex completely	terest in sex	



		Center Number:	Participant N	Number:	Participant's Ir	nitials:
Date compl	eted:/ _{month} /	OR Not don	e → Specify re	ason (use codelist be	low):	
Profile	of Mood States					
Instruction	s: 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 Friend	ly				\square_3	4
2 Tense		\square_{o}		\square_{2}	\square_3	4
3 Angry	,					4
4 Worn	out					
5 Unhap	рру				\square_3	4
6 Clear-	headed	\square_{o}			\square_3	4
7 Lively						4
8 Confu	sed					
9 Sorry	for things done					4
10 Shaky	,				\square_3	
11 Listles	s					4
12 Peeve	d	\square_{o}		\square_{2}	\square_3	4
13 Consid	derate					4
14 Sad						4
15 Active						4
16 On ed	ge					
17 Groud	hy					4
18 Blue						
19 Energ	etic					
20 Panick	ху					
	2005 Maurice Lorr, Ph.D., Douglas M. Ma anda, NY 14120-0950. In Canada, 3770 V			license to Multi-Health System	ns Inc. All rights reserved.	In the U.S.A., P.O. Box
Not 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				\square_3	
23 Unworthy					4
24 Spiteful				\square_3	
25 Sympathetic					4
26 Uneasy			\square_{2}	\square_3	4
27 Restless				\square_3	4
28 Unable to concentrate	\square_{o}		\square_{2}	\square_3	
29 Fatigued				\square_3	4
30 Helpful	\square_{o}		\square_{2}	\square_3	4
31 Annoyed				\square_3	4
32 Discouraged	\square_{o}		\square_{2}	\square_3	4
33 Resentful				\square_3	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					
41 Anxious					4
42 Ready to fight					4
43 Good-natured	o			\square_3	4

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



	Center Number:	Participai	nt Number:	Participant's	Initials:
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy	\square_{0}			\square_3	4
45 Desperate					4
46 Sluggish				\square_3	4
47 Rebellious					4
48 Helpless					4
49 Weary					4
50 Bewildered					4
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	\square_{0}		\square_{2}	\square_3	4
61 Terrified					4
62 Guilty					4
63 Vigorous				\square_3	4
64 Uncertain about things					
65 Bushed	o			\square_3	

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

Participant's Initials: first middle last

CRF, page 174



Center Number: Po	rticipant Number:		Participant's	s Initials:	rst middle last
Date completed: $\underline{\hspace{1cm}}_{day}$ / $\underline{\hspace{1cm}}_{month}$ / $\underline{\hspace{1cm}}_{year}$ OR Not done \rightarrow S	pecify reason (use code	list below):			
Perceived Stress Scale (PSS)					
Instructions: The questions in this scale ask you about your feelings indicate how often you felt or thought a certain way.	•			-	ease
	Never	Almost Never	Some- times	Fairly Often	Very Often
1 In the last month, how often have you felt that you unable to control the important things in your life?	vere				
2 In the last month, how often have you felt confident your ability to handle your personal problems?	about		\square_2	\square_3	
3 In the last month, how often have you felt that thing going your way?	s were				4
4 In the last month, how often have you felt difficulties piling up so high that you could not overcome them?					
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain	3 Insufficient time 4	Instrument f	ailure 5	Not requir	red



	Center Number: Participal	nt Number:	Partic	cipant's Initials	first middle last
Da	te completed:/ _{month} / _{year} OR Not done → Specify	reason (use code	list below):		
Pi	ttsburgh Sleep Quality Index (PSQI)				
Ins	tructions: The following questions relate to your usual sleep habits dur the most accurate reply for the majority of days and nights i	• .	•		
Du	ring the past month	•		·	
1	When have you usually gone to bed?:				
2	How long (in minutes) has it taken you to fall asleep each	h night?	minutes	5	
3	When have you usually gotten up in the morning?	: to 23:59			
4	How many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) hours				
5	During the past month, how often have you had trouble sleeping because you (check only one answer per question)	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week
	a Cannot get to sleep within 30 minutes	\square_{o}			\square_3
	b Wake up in the middle of the night or early morning	\Box_{o}			\square_3
	• Have to get up to use the bathroom	\square_{o}			\square_3
	d Cannot breathe comfortably	\square_{o}			\square_3
	e Cough or snore loudly				\square_3
	f Feel too cold	\square_{o}			\square_3
	g Feel too hot				\square_3
	h Have bad dreams	\square_{o}			\square_3
	i Have pain	\square_{o}			\square_3
	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. 1 Participant refused 2 Clinician unable to obtain 3 Ins	ufficient time 4	Instrument failure	5 Not re	quired

Participant's Initials: first middle last



	Center Number: Participan	t 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_{0}			3
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?	\square_{0}			



Month 12 Submission

Center	Number:	Partic	ipant Num	her•		Parti	cipant's Ir		SIT I
							cipaiii 3 ii	firs	t middle last
	ot done → Spec								
Derogatis Interview for Sexua	ıl Function	(DISF-S	R) (F) Fe	male Ve	rsion				
Instruction: Below you will find a brief set of questions that ask about different aspects of your while another inquires about the kinds of sexual sexual arousal and the quality of your organized relationship.	sexual experient I l experiences	ces. One that you	section by have. Ye	asks abo ou are a	out sexu Iso aske	al fant e d about t	asies or the natu	daydre re of you	ams, ur
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 how Some satisfaction scales range from "0 = could not make the scale of the sc	ency scales go always." In the much you enjo not be worse" to	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 refollow. Although it is brief, take your time with the describes your personal experience.									
If you have any questions, please ask the person	ı who gave you	the inve	ntory for	help.					
Section 1—Sexual Cognition/Fantasy									
During the past 30 days or since the last till you filled out this inventory, how often have you had thoughts, dreams, or fantasies about	7 e	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person					4				8
1.2 Erotic parts of a man's body (e.g., fa shoulders, legs)	се,			\square_3	4		6		8
1.3 Erotic or romantic situations				\square_3	4				8
1.4 Caressing, touching, undressing, of foreplay	r o				4				8
1.5 Sexual intercourse, oral sex, touch to orgasm	ing				4			7	8
Copyright © 1987 by Leonard R. Derogatis, PhD.									

Participant's Initials: first middle last

5 Not required

4 Instrument failure

3 Insufficient time

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



Center No	ımber:	Pa	rticipant N	umber: _		Par	ticipant's I	nitials:	st middle last
Derogatis Interview for Sexual	Functi	on (DIS	F-SR) (F)	Female \	ersion (c	ontinued)		
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone					4	5	6	7	8
2.2 Actively seek sexual satisfaction					4	5	6	7	8
2.3 Feel sexually aroused with a partner					4	5	6	7	8
	Never	Rarely	Sometimes	Usually	Always				
2.4 Have normal lubrication with masturbation					4				

Copyright © 1987 by Leonard R. Derogatis, PhD.

throughout sexual relations

2.5 Have normal lubrication

CRF, page 179



Center Nu	mber:	Po	articipant N	lumber:		Po	irticipant's	Initials:	rst middle last
Derogatis Interview for Sexual I	Functi	on (DIS	SF-SR) (F)	Female \	/ersion (d	ontinue	d)		
Section 3—Sexual Behavior/Experiences	;								
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	По				4	5			
3.2 Masturbation	По			\square_3	4	5	□ ₆		□ ₈
3.3 Casual kissing and petting	По				4	5			
3.4 Sexual foreplay	По			\square_3	4	5			8
3.5 Sexual intercourse, oral sex, etc.				\square_3	4	\square_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				4				
4.2 The intensity of your orgasm	o			\square_3	4				
4.3 The ability to have multiple orgasms (if typical for you)					4				
4.4 Feelings of closeness and togetherness with your partner	По			\square_3	4				
4.5 Your sense of control (timing) of your orgasm	По				4				
4.6 Feeling a sense of relaxation and well-being after orgasm				\square_3					

Copyright © 1987 by Leonard R. Derogatis, PhD.



Ce	enter Number:		Participant	Number:		P	articipant's	s Initials:	irst middle last
Derogatis Interview for Sex	ual Fund	tion (DISF-SR) (F) Female	Version	(continue	ed)		
Section 5—Drive and Relationship									
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice what would be your ideal frequency of sexual intercourse				3	4	5		7	
	Not at	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how interested have you been in sex	?				4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				3	4				
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better

Copyright © 1987 by Leonard R. Derogatis, PhD.

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

of your sexual functioning?



	Center Number	:	Partici	pant Numl	ber:		_ Parti	cipant's Ir	nitials:	t middle last
Date completed: —_day /—_month /—_year —	OR Not done	→ Spec	ify reaso	on (use co	delist bel	ow):				
Derogatis Interview for Se	exual Fun	nction	(DISF-S	R) (M) N	lale Ver	sion				
Instruction: Below you will find a brief so sections that ask about different aspects o while another inquires about the kinds of sexual arousal and the quality of your orelationship.	f your sexual e sexual expe	experien riences	ces. One	section of have. Yo	asks abo ou are a	out sexu Iso aske	al fant e d about t	asies or the natu	daydre re of you	ams, ur
On some questions you are asked to ractivities asked about in that section. Some frequency scales range from "0 = never" to a satisfaction scale. This type of scale te Some satisfaction scales range from "0 = 6"0 = not at all satisfied," to "4 = extremely In every section of the inventory the scales.	e frequency so to "4 = always ells how much y could not be w y satisfied." cales required	ales go f s." In the you enjo yorse" to for that	from "O case of yed, or "8 = co	= not at o other quo were sati uld not b are printe	all" to "Sestions, sied by e better.	8 = four you will the sexu " Other pove the	or more be asked al activit satisfacti question	times a d to resp y being on scale	day." Of ond in to asked a s go froi vill be ea	ther erms bout. m
follow. Although it is brief, take your time describes your personal experience.		tory. Fo ı	r each i	tem, ple	ase cho	eck the	scale n	umber	that be	st
If you have any questions, please ask the	person who g	ave you	the inve	ntory for	help.					
Section 1—Sexual Cognition/Fan	tasy									
During the past 30 days or since the l you filled out this inventory, how ofte you had thoughts, dreams, or fantasi	en have	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
1.1 A sexually attractive person										
		0			\square_3	4	5		7	8
1.2 Erotic parts of a woman's booface, genitals, legs)	dy (e.g.,	□ ₀			\square_3	4				8
-	dy (e.g.,				\square_3	4		□ ₆		
face, genitals, legs)								□ ₆ □ ₆	\Box_7 \Box_7	

5 Not required

4 Instrument failure

3 Insufficient time

Copyright © 1987 by Leonard R. Derogatis, PhD.

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



Cer	nter Number:	Part	ricipant Nu	mber:		Part	icipant's l	nitials:	st middle last
Derogatis Interview for Sexu	Jal Functio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal									
During the past 30 days or since the last you filled out this inventory, how often d you have the following experiences?	l 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
2.1 A full erection upon awakening				\square_3	4	5	6	7	8
2.2 A full erection during a sexual fantasy or daydream				\square_3	4	5	6		8
2.3 A full erection while looking at a sexually arousing person, movie picture					4	5	6	7	8

Copyright © 1987 by Leonard R. Derogatis, PhD.

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

Participant's Initials: first middle last



Center Nu	mber:	Pai	ticipant Nu	mber:		Pa	rticipant's	Initials:	rst 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					4	5	6		8
3.2 Masturbation				\square_3	4	5	6		8
3.3 Casual kissing and petting					4	5	6		8
3.4 Sexual foreplay				\square_3	4	5	6		8
3.5 Sexual intercourse, oral sex, etc.				3	4	5			8
Section 4—Orgasm	•	•			•				
During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm				3	4				
4.2 The intensity of your orgasm				\square_3	4				
4.3 The length or duration of your orgasm					4				
4.4 The amount of seminal liquid that you ejaculate									
4.5 Your sense of control (timing) of your orgasm					4				
4.6 Feeling a sense of relaxation and well-being after orgasm									

Copyright © 1987 by Leonard R. Derogatis, PhD.



Cer	ter Number:		Participant	Number: _		P	articipant's	s Initials:	irst middle last
Derogatis Interview for Sexu	al Fund	ction (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_4	5	□ ₆	7	8
	Not at all	Slightly	Moderately	Highly	Extremely				
5.2 During this period, how intereste have you been in sex?	d			\square_3	\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?					4	5			8

Copyright © 1987 by Leonard R. Derogatis, PhD.



	Center Number:	Participant	Number:		Participa	nt's Initials:	
Da	te completed:/OR Not done						first middle last
	ood Cravings Questionnaire—State (FCQ-						
hov	ow is a list of comments made by people about their eating how much you agree with the comment right now, at this very ile others refer to one or more specific foods. Please respond t	moment.	Notice that	some quest	ions 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	4	5
3	I have an urge for [one or more specific foods]					4	
4	Eating [one or more specific foods] would make seem just perfect.	things				4	
5	If I were to eat what I am craving, I am sure my would improve.	mood			\square_3	4	
6	Eating [one or more specific foods] would feel wonderful.					4	
7	If I ate something, I wouldn't feel so sluggish and lethargic.					4	
8	Satisfying my craving would make me feel less gand irritable.	rouchy				4	
9	I would feel more alert if I could satisfy my cravi	ng.			\square_3	4	5
10	If I had [one or more specific foods], I could not eating it.	stop			\square_3	4	5
11	My desire to eat [one or more specific foods] seems overpowering.					4	
12	I know I'm going to keep on thinking about [one more specific foods] until I actually have it.	or				4	
13	I am hungry.						
14	If I ate right now, my stomach wouldn't feel as e	mpty.			\square_3	4	5
15	I feel weak because of not eating.					П.	П

4 Instrument failure

2 Clinician unable to obtain

3 Insufficient time

Not Done Codelist: 1 Participant refused



Center Nu	ımber: Po	ırticipant Number:		Participant's I	nitials:
Date completed:/	OR Not done → S _I	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 co Over the past month, how often		Rarely			Always/Almost
have you experienced a craving for	Never	(once or twice)	Sometimes	Often	Every Day
1 Cake			\square_3	4	
2 Pizza			\square_3	4	5
3 Fried chicken			\square_3	4	
4 Gravy			\square_3	4	
5 Sandwich bread			\square_3	4	
6 Sausage			\square_3	4	5
7 French fries			\square_3	4	
8 Cinnamon rolls			\square_3	4	
9 Rice			\square_3	4	
10 Hot dog			\square_3	4	
11 Hamburger			\square_3	4	
12 Biscuits			\square_3	4	
13 Ice cream				4	
14 Pasta					
15 Fried fish				4	
16 Cookies				4	
17 Chocolate				4	
18 Pancakes or waffles					
19 Corn bread				4	
20 Chips					5
21 Rolls					
22 Cereal					
23 Donuts					
24 Candy					
25 Brownies				4	
26 Bacon					
27 Steak				4	
28 Baked potato					
Not Done Codelist: 1 Participant refused 2 Clinician	n unable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	lot required



		Center Number:	Participant Number:	Participant's I	nitials:
Date o	completed:/ _{month} /	OR Not done =	→ Specify reason (use codelist below):		
Eati	ng Inventory				
1	When I smell a sizzling st 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	nree times a day.		o False
4	When I have eaten my que not eating anymore.	uota of calories, I am	usually good about		□₀ False
5	Dieting is so hard for me	because I just get to	o hungry.	, True	o False
6	I deliberately take small h	nelpings as a means	of controlling my weight.		o False
7	Sometimes things just tast I am no longer hungry.	te so good that I kee	p on eating even when	, True	o False
8	Since I am often hungry, expert would tell me that something more to eat.			, True	o False
9	When I feel anxious, I find	d myself eating.		, 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		□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.		o False
14	I have a pretty good idea	of the number of ca	llories in common food.	, True	o False
15	Sometimes when I start e	ating, I just can't see	m 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 to eating then.	y, I get hungry beca	use I have gotten used	, True	□₀ False
18	While on a diet, if I eat fo for a period of time to mo		ed, I consciously eat less	1 True	□₀ False
Not D	Iono Codoliste 1 Participant referred	2 Clinician unable to the	ain 3 Insufficient time 4 Instrument	failure E N	lot required



		Center Number:	Participant Number:	Participant's Ir	first middle last
Eat	ing Inventory (continued)				
19	Being with someone who is	eating often makes	s me hungry to eat also.	, True	□₀ False
20	When I feel blue, I often over	ereat.		, True	o False
21	I enjoy eating too much to s my weight.	spoil it by counting o	calories or watching	, True	o False
22	When I see a real delicacy, right away.	I often get so hungi	ry that I have to eat	, True	o False
23	I often stop eating when I a limiting the amount I eat.	ım not really full as	a conscious means of	, True	o False
24	I get so hungry that my stor	mach often seems li	ke a bottomless pit.	, True	o False
25	My weight has hardly chan	ged at all in the last	ten years.	, True	o False
26	I am always hungry so it is the food on my plate.	hard for me to stop	eating before I finish	, True	o False
27	When I feel lonely, I console	e myself by eating.		, True	□₀ False
28	I consciously hold back at n	neals in order not to	gain weight.	, True	☐₀ False
29	I sometimes get very hungr	y late in the evening	g or at night.	1 True	□₀ False
30	I eat anything I want, any ti	me I want.		, True	o False
31	Without even thinking abou	t it, I take a long tin	ne to eat.	1 True	□₀ False
32	I count calories as a conscio	ous means of contro	lling my weight.	1 True	□₀ False
33	I do not eat some foods bed	cause they make me	e fat.	1 True	□₀ False
34	I am always hungry enougl	n to eat at any time.		1 True	□₀ False
35	I pay a great deal of attenti	ion to changes in m	y figure.	, True	□₀ False
36	While on a diet, if I eat a fo eat other high calorie foods		ed, I often splurge and	, True	□₀ False

CRF, page 189

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?	\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?	☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult
42	How conscious are you of what you are eating?	\square_1 Not at all \square_2 Slightly \square_3 Moderately \square_4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	☐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."	☐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"

Participant's Initials: first middle last



5 I can resist eating when I am watching TV.

6 I can resist eating when I am depressed

I can resist eating when there are many different kinds of food available.

8 I can resist eating even when I feel it is impolite to refuse a second helping.

I can resist eating even when I have a

Not Done Codelist: 1 Participant refused

Month 12 Submission

	dioiio									Vis	sit 1
	Cen	ter Number:	Partici	pant Nur	mber:			Particip	ant's Init	ials:	middle last
D	ate completed:/ _{month} / _{year} _	OR Not done	→ Speci	fy reaso	on (use	codelist	below):				
V	Veight Efficacy Lifestyle Que	estionnaire	(WEL)								
of to	nis form describes some typical eating situation own. The following are a number of situation of ating situations which you find the hardest to Read each situation listed below and decide the difficult situations. In other words, preter 9 (very confident), choose ONE number that each each Check this number for each item.	s relating to eating manage. de how confident (nd that you are in t reflects how conf	pattern or certain the eatin	s and a n) you c ng situat	ttitudes are that tion righ	. This fo you wint now.	orm wil ill be al On a s	l help y ble to r cale fro	vou to id	lentify the ting in e	ach lent)
L	um confident that:		confide can resi			eat	yo		Very co		
1	um confident that:					eat 4	уо 5		_		
1		you	can resi	st the d		4	-	6	esist the	desire	to eat
1	I can resist eating when I am anxi	o ious	can resi	st the d		4	5	6	esist the	desire	to eat
1	I can resist eating when I am anxi (nervous). I can control my eating on the we	o ious ekends.	can resi	st the d	3	4	5	6	esist the	desire	to eat

Participant's Initials: first middle last

5 Not required

4 Instrument failure

CRF, page 191

3 Insufficient time

2 Clinician unable to obtain

(or down).

headache.



	Center Number:		Particip	ant Nun	nber:			Particip	ant's Init	ials:	middle last	
Weight Efficacy Lifestyle Qu	uestionnai	re (w	EL) (co	ntinuec	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		6		8	9	
11 can resist eating when I am a (or irritable).	ngry					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 of pressuring me to eat.	hers are					4		6		8	9	
14 I can resist eating when I am in	pain.	\Box_{o}			$\square_{_3}$	4	5	6		8	9	
15 I can resist eating just before go bed.	oing to					4	5	6		8	9	
16 I can resist eating when I have experienced failure.						4	5	6		8	9	
17 I can resist eating when high-ca are available.	lorie foods					4	5			8	9	
18 I can resist eating even when I to others will be upset if I don't ea		□ _o				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 ha	ірру.					4		6			9	



	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	middle last
Date completed:/	OR Not done →	Specify	reason	(use code	elist belov	/):			
Multiaxial Assessment of	Eating Disorder	Sym	otom	S (MAE	DS)				
Instructions: Using the scale shown, plea	se rate the following items o	on a sca	e from 1	to 7. Ple	ase ansv	ver as tru	uthfully	as possi	ble.
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	e weight.				\square_3	\square_4	5	6	
2 My sleep isn't as good as it u	used to be.				\square_3	\square_{4}			
3 I avoid eating for as long as	I can.				\square_3		5		
4 Certain foods are "forbidden	" for me to eat.				\square_3	\square_4			
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	nit.				\square_{3}	4	5	6	
7 I can feel that being fat is ter	rible.				\square_3	4	5		
8 I avoid greasy foods.						4	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.						4	5		
12 My eating is normal.							5		
13 I can't seem to concentrate la	itely.				\square_3	4	5		
14 I try to diet by fasting.						4	5		
15 I vomit to control my weight.					\square_3	4	5	6	
16 Lately nothing seems enjoyal	ole anymore.				\square_3	\square_4		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.					4	5		
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.					5	6	
21 When I feel bloated, I must do s 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		5	6	7
25 I would be very upset if I gair	ned 2 pounds.			\square_3	4	5	6	7
26 I crave sweets and carbohydr	ates.			\square_3	4			7
27 I lose control when I eat.					4	5	6	7
28 Being fat would be terrible.				\square_3	4		6	
29 I have thought seriously abou	t suicide lately.			\square_3	4	5	6	
30 I don't have any energy anymo	ore.			\square_3	4	5	6	
31 I eat small portions to control	my weight.				4	5	6	7
32 I eat 3 meals a day.				\square_3	4	5		7
33 Lately I have been easily irrito	ated.			\square_3	4	5	6	7
34 Some foods should be totally	avoided.			\square_3	4			7
35 I use laxatives to control my v	veight.				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.						5		

Participant's Initials: first middle last



	Center Number:	Participant No	umber:		Pai	rticipant's	Initials: _	rst middle last
Multiaxial Assessment of E	ating Disorder	Sympto	ms (MAEDS) (continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.	•			\square_3	4	5	6	
40 I am obsessed with becoming a	overweight.			\square_3	4	5		
41 I don't eat fried foods.				\square_3	4	5		
42 I skip meals.				\square_3	4	5	6	
43 Fat people are unhappy.				\square_3	4	5		
44 People are too concerned with	the way I eat.			\square_3	\square_{4}	5	6	
45 I feel good when I skip meals.				\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		
49 I eat until I am completely stuff	^S ed.			\square_3	4	5		
50 I hate to eat.				\square_3	\square_{4}	5		
51 I feel guilty about a lot of thing	s 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 ev	en if I am hungry.			\square_{3}	4	5	6	
54 I eat even when I am not hung	ry.			\square_{3}		5	6	7
55 Fat people are disgusting.					4	5	6	
56 I wouldn't mind gaining a few	pounds.					5		



	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	elow):			
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?				4	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)?			\square_3	4	5	
5	Have you worried about your flesh not being firm enough?				4	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	
8	Have you avoided running because your flesh might wobble?			\square_3	\square_{4}	5	6
9	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
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		5	
13	Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?			\square_3	4		
14	Has being naked, such as when taking a bath, made you feel fat?			\square_3		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
N	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuff	ficient time	4 Instru	ıment failu	re 5 N	lot require	ed .



Center Number: Participant N	lumber: _		Pai	rticipant's	Initials: _	rst middle last
Body Shape Questionnaire (BSQ) (continued)						
Over the Past Four Weeks	Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?				4	5	6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?			\square_3	4	5	
19 Have you felt excessively large and rounded?			\square_3	4	5	6
20 Have you felt ashamed of your body?				4	5	6
21 Has worry about your shape made you diet?			$\square_{_3}$		5	6
22 Have you felt happiest about your shape when your stomach has been empty?					5	6
23 Have you thought that you are the shape you are because you lack self-control?			\square_3		5	
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?			\square_3	4	5	6
25 Have you felt that it is not fair that other women/men are thinner than you?			\square_3		5	6
26 Have you vomited in order to feel thinner?			\square_3	4	5	6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?			\square_3		5	
28 Have you worried about your flesh being dimply?			\square_3	4	5	6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?			$\square_{_3}$		5	6
30 Have you pinched areas of your body to see how much fat is there?			\square_{3}	4	5	6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?			\square_3	4	5	
32 Have you taken laxatives in order to feel thinner?				4	5	6
33 Have you been particularly self-conscious about your shape when in the company of other people?				4	5	
34 Has worry about your shape made you feel you ought to exercise?			\square_3			



CRF, page 198

		Center Number	: Participant Num	ber: Part	first middle last			
Har	ndgrip Strength							
Date (and time of assessment:	/	: : ear 00:00 to 23:59	Staff i	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	andgrip 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	one 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):	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



Month 12 Submission

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

Clinic Weight	tirst middle last
Weight date and time:/	Staff initials:
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

calerie

Month 12 Submission Visit 2

Participant's Initials: first middle last

Participant Number:

	enter Number:
•	

ט ח		1 (5)	721		Seven-Day ruysical Activity Necall (PAK)	(FAK)											
Tode	Today's date:	ë :			Day	Day (check only one):	Mon Tue] Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Spedify reason (use codelist below):	Thurs] Fri	at Sun	OR Not	done →	Specify re	eason (use	codelist bela	
_	Were yo	ou empl	oyed in t	e last se	an days?		°Z °C	$\square_0 \ \text{No} \rightarrow \text{Skip to question 3} \qquad \square_1 \ \text{Yes}$	stion 3	7es				Interv	Interviewer initials:	ials:	first middle last
4	If Yes: W	Vhich do	yys (check	If Yes: Which days (check all that apply)?	۲.		Mon	Tues Wed	ш	Thurs	i.E	Sat	Sun				
m	Which d	lays do	you cons	sider your v	veekend, or no	Which days do you consider your weekend, or non-work, days?	Mon	☐ Tues	Med	Thurs	Fri	Sat	Sun				
Dav	Day of				Sleek	Sleep Time	Work Time	Time	Morr	Morning (in minutes)	nutes)	Afteri	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
	Week		Date		ln Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	.boM	Hard	Very Hard
7		,		_	00:00 to 23:59	00:00 to 23:59											
(yester- day)		/	month month	year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
		`			00.00	00:00 00:50											
•		-/ day		year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
Ŋ		-/ day	month	year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
					00:00 to 23:59	00:00 to 23:59											
4		-/ day		year	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 to 23:59	00:00 to 23:59	00:00 to 23:59										
4				year	00:00 to 23:59	00:00 to 23:59											
1 (1 week ago)		day /	/	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



		Center Number:	Participant Number:	Participant's Initials:	first 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)?	er the past three mont	ths, was last week's physical a	ctivity more, less,	
In	terviewer: Please answer questions b	elow and note any co	mments on interview.		
5	Were there any problems with the Se	ven-Day PAR interview	v?		
6	Do you think this was a valid Seven-Do No	ay PAR interview?			
7	Were there any activities reported by One No	the participant that yo	ou don't know how to classify?		



		Center Number:	Partic	ipant Number: Partici	pant's Initials:
	ay Food Record lete below OR Not done → Spec	ify reason (use Codelist b	pelow): _	Staff ini	tials: First middle last
				Replacement Value	
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	Date of Record	Record Quality (check only one)
1	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	8	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
2	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	9	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
3	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	10	/	Reliable D2 Unreliable D3 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	one 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 ☐ NA
	HR when ischemic ECG changes occurred:bpm OR
6	Did frequent ventricular ectopy occur (e.g., ≥ 7 PVCs/min, bi/tri-geminy, NSVT [≥ 3 beats])? □₀ No □₁ Yes → If Yes: When did it occur (check all that apply)? □ During exercise □ During recovery
7	Peak 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



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

Month 12 Submission

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

Co	re Temp	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	
fii	rst middle last	Stop Date:	Stop Time	
		/	00:00 to 23:59	
Inp	oatient A	Admission and Discharge		
1	Inpatient adr	mission date and time:/ _{month}	: : :	
2	Inpatient disc	charge date and time:/		

3 Insufficient time

4 Instrument failure

5 Not required



D	elayed-type Hypers	ensitivity (D1	гн)				
1	Was the DTH worksheet comp □ ₀ No □ ₁ Yes → If Yes: Were any Ex		$\begin{array}{c} P : $				
2	Date of injection:/	/	OR Not done →	Specify reasor	(use codelist below):		
3	Injection by (initials):	.					
4	Arm injected: \square_1 Right \square_2						
5	DTH results: Note: For each reaction, meast because the induration rediameter and then the decayerage diameter is equal A = Largest diameter B = Second diameter pe	nay not be in the s iameter perpendic al to or greater th	hape of a circle. ular to it. Do not	If the indurati	on is an oval sha	pe, first measure	the long
	Antigen	24 Hour (@ Visit 4)			48 Hour (@ Visit 5)		
	Ailigeil	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:
	1 Normal saline	mm	mm		mm	mm	
	2 Tetanus toxoid (∏) (check only one): □₁ Tetanus toxoid (Sanofi- Pasteur) □₂8 Other: Lot #:	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	

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

Lot #: ____



	Center Number:	Participant Number: _	Particip	pant's Initials: first middle last		
Clinic Weight						
Weight date and time: _	/	: : 0 to 23:59	Staff ini	tials:		
	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	day /	00:00 to 23:59				
Date and time sample co	ollection started:/	year	59			
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Са	techolamines	□₀ No □₁ Yes		first middle last		
	Blood	□ ₀ No □ ₁ Yes		first middle last		
Oral glucos	e tolerance test (OGTT)	□₀ No □₁ Yes		first middle last		
If a sample is not obtained,	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.	/	00:00 to 23:59				
mL	Stop Date:	Stop Time:		first middle last		
	/	00:00 to 23:59				

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

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



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

If Not Done → Specify reason (use code	,				
Contraception method (females only):		None OR Check all that appl	-		
		Oral contraceptiv	re → Specify:		
		Other - Specify	Record on Co (e.g., barrier, IUD):	ncomitant Medico	
		Onler * Specify	(e.g., burner, rob).	If Not Done,	Staff
Day 1		Date	Time	Reason (use codelist)	Initials
Day 1 of menses (females only)					
Date and time of last meal (males only	r)	/	. : : : : : : : : : : : : : : : : : : :		
Hormone level blood draw 1 (males o	nly)	/			first middle last
Hormone level blood draw 2 (females of Progesterone level	o nly)				
Day 2		Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Date and time of last meal					
Hormone level blood draw 3 (females of Progesterane level	o nly)				
Metabolic Rate					
Sample		Date of Collection	If Not Done, R		f Initials
Resting Metabolic Rate (RMR)—Visit 4		ay month year		first	middle last
Cart ID			01 (623-003)	PBRC-016 (623- PBRC-017 (623-	•

Month 12 Submission

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

Se	ven-L	Say P	hysic	al Acti	Seven-Day Physical Activity Recall (PAR)	II (PAR)											
Tod	Today's date:	e:	_/honth	/	Day	Day (check only one):	Mon Tues Wed Thurs	wed	Thurs		at Sun	OR No	done →	Specify re	Fri Sat Sun OR Not done — Specify reason (use codelist below):	codelist bel):
-	Were yo	oldmə u	yed in th	Were you employed in the last seven days?	ren days?		°Z C	No → Skip to question 3	estion 3	Ty Yes				Interv	Interviewer initials:		first middle last
N	If Yes: W	/hich day	ys (check	If Yes: Which days (check all that apply)?	ر)خ		Mon	Tues Wed	Ш	Thurs	i.E	Sat	Sun				
ო	Which d	ays do y	on cons	ider your	weekend, or n	Which days do you consider your weekend, or non-work, days?	Mon	Tues	Wed	Thurs	Fi	Sat	Sun				
Dav					Sleek	Sleep Time	Work Time	Time	Mori	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
7			`		00:00 to 23:59	00:00 to 23:59											
(yester- day)		/ dαy	month	year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			`			: 00.00											
•		/	month	year	00:00 to 23:37	00:00 to 23:37	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	00:00 to 23:59	00:00 to 23:59									
			`			00:00 to 23:59											
4		/dαy		year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
m		/	/	year		00:00 to 23:59 00:00 to 23:59	. :	00:00 to 23:59									
64		—/———	/	year			: :	00:00 to 23:59									
1 (1 week ago)		/	_/month	year		: : : : : : : : : : : : : : : : : : :	. :	: 00:00 to 23:59									

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

3 Insufficient time



	Center Number: Participant Number: Farticipant'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	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? No Yes



CRF, page 210

	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	
cal	

caler	TIO Phase	7			Completed by Calerie staff: Baseline 1 6 Month Baseline 2 12 Month	srie staff: 6 Months 18 Months 12 Months 24 Months 12 Months 13 Months 14 Months 15 Mont
			Center Number:	: Participant Number:		Participant's Initials: first middle lost
Daily Home Weight Log						
Were you issued a new scale? $\square_0 \text{No}$ Please complete this log in either blue or		□ 1 Yes → If Yes: Date first used: black ink.	· month day / year	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:	Date:	Date:
		` L	i			
lime:	lime:	lime:	Time:	lime:	lime:	Lime:
Weight: 	Weight: lb	Weight: lb	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:
-		, com	- Control			Date:
Month / day / wear	Month day / year	Date: month day / wear —	Month day / year	Date:	Date: month / day / year	month / day / year
Time:	Time: ☐, AM ☐2 PM	Time: ☐, AM ☐ ₂ PM	Time:	Time: 1 AM 2 PM	Time: 1 AM 2 PM	Time: 1 AM 2 PM
		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