

Month 24 Submission Month 23 Visit

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

			tirst middle last			
Clinic Weight						
Weight date and time: —	/ / : day	Staff initials:	first middle last			
OR Not done → Specify i	reason (use codelist below):		ms mode los			
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 fem	ales.					
$\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow \text{ If Yes: Date}$	Does participant have reproductive potential? □₀ No □₁ Yes → If Yes: Date urine pregnancy test performed: —day /—month /—year Results: □₁ Negative □₂ Positive					
Outcomes Labs						
Date and time sample col	lection started:/					
Sample If a sample is not obtained, indicate with a Not Done.	Sample Complete?	If Not Done, Reason (Use codelist belo	Statt Initials			
Blood	□ ₀ No □ ₁ Yes		first middle last			
NOTE: Before	Vaccine Administration e any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.	If Not Done, Reason (Use codelist belo	Statt			
Vaccine(s) given (check all that apply):	Hepatitis A → Check one: ☐1 Havrix (GSK) ☐2 Vaqta (Merck) ☐98 Other: Dose (check one): ☐1 Adult ☐2 Pediatric Lot #:		first middle last			
Not Done Codelist: 1 Part	ticipant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instru	ment failure 5 N	lot required			



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

	tirst middle la
Cl	nic Weight
We	ght date and time:/
	Not done → Specify reason (use Codelist below):
Clir	ic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):
We	ght 1: kg
We	ght 2: kg
We	ght 3: kg
We	ght of gown: kg
	tal Signs
Ass	essment 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):
	Natural waist measurement 1: cm
	Natural waist measurement 2: cm
	Natural waist measurement 3: cm
2	Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):
	Umbilical point waist measurement 1: cm
	Umbilical point waist measurement 2: cm
	Umbilical point waist measurement 3: cm
3	Pulse: bpm OR Not done → Specify reason (use codelist below): Staff initials: list middle lost
4	Temperature: °C OR Not done → Specify reason (use codelist below): Staff initials: 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: First middle lost
	6a Blood pressure 1:/ mm Hg Time:: OR Not done → Specify reason (use codelist below):
	6b Blood pressure 2:/ mm Hg Time:::
	6c Blood pressure 3:/ mm Hg Time:: =
No	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
	Is ECG (check only one):	first middle last	
Safety Labs Date and time of last meal:/	/ .		
Date and time of sample collection:/	onth year 00:00 to		
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 potentia □₀ No □₁ Yes → If Yes: Date urine pregnancy test Results: □₁ Negative □₂ Positive		. /	
Not Done Codelist: 1 Participant refused 2 Clini	ician unable to obtain 3 Insuf	ficient time 4 Instrument failu	ure 5 Not required



		Center Number: _	Participant Nu	mber:	Pari	ticipant's Initials:	first middle last
D	oubly Labeled W	/ater (DLW)					
1	Date and time of DLW do	osing:/ _{month} /	year 00:00 to 23:	- 59	Staff	initials:	last
	OR Not done → Specify	reason (use codelist below):	_				
2	DLW dose mixture ID and	d bottle number: –			CA		
3	Exact weight of DLW mix	ture: gro	ıms				
4	Urine samples:						
	Collection	Sample		Date an	d Time Collect	ed	
	Pre dosing (PD)	PDa	/	/_ month	year	: 00:00 to 23:59	
		PDb	/	/_ month	year	00:00 to 23:59	
	Day 0 (Visit 1)	DOa	/	/_ month	year	: 00:00 to 23:59	
		D0b	/	/_ month	year	00:00 to 23:59	
	Day 7 (Visit 2)	D7a	/	/_ month	year		
		D7b	/	/_ month	year	00:00 to 23:59	
	Day 14 (Visit 4)	D14a	/	/_ month	year	00:00 to 23:59	
		D14b	/	/_ month		00:00 to 23:59	
5	Affix CRF page label(s) co	orresponding to this urine sam	ple set:	1		·-i	
			Affix Test San	i	Affix Retest Sample		
			Label H		Label Here		
			i				

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



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

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

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



	Center Number:	Participant Number:	Participant's Initials:	first middle last	
DXA Scan					
Has the participant taken a calcium supplies No	•	n the Subject Scan Log to infor	m the QA Center.		
Were any studies involving barium or □ No □ Yes	radioisotopes performed	I within 4 weeks prior to the so	:heduled DXA exam?		
DXA Scan DXA Rescan OR					
Date of scan:/ _{month} / _{year}		Date of rescan:/	onth year		
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		Scanned I that apply		
☐ Whole body		☐ Whole be	ody		
Forearm		Forearm			
Spine		Spine			
Hip		ПНір			
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtai	n 3 Insufficient time 4 Instru	ment failure 5 Not requ	ired	



	Center N	Number: Participant Numb	er:	Participant's Ini	first middle last		
Do	ite completed:/ _{month} /	OR Not done → Specify reason	(use codelist belov	v):			
R	AND SF-36						
In	structions: This survey asks for your views abo to do your usual activities. Please a unsure about how to answer a ques	nswer every question by placing	a check "X" in th				
1	In general, would you say your health is:		good 🔲 Go	ood 🔲 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	The following items are about activities you might do during a typical day. Does your health now limit you in these activities? A Lot A Little Limited At All All A Little At All A Little Limited At All All All A Little Limited At All All All All All All All All All						
3	Vigorous activities, such as running participating in strenuous sports	ng, lifting heavy objects,					
4	Moderate activities , such as movi vacuum cleaner, bowling, or playing						
5	Lifting or carrying groceries				\square_3		
6	Climbing several flights of stairs						
7	Climbing one flight of stairs				\square_3		
8	Bending, kneeling or stooping			\square_{2}	\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						
N	ot Done Codelist: 1 Participant refused 2 Clinici	an unable to obtain 3 Insufficient	time 4 Instrume	nt failure 5 No	t 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 y				
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 war 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 past	4 weeks	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23 Did you feel full of pep?				\square_3	4	5	
24 Have you been a very nervou	s person?			\square_3	4	5	
25 Have you felt so down in the conthing could cheer you up?	lumps that			\square_3	4	5	
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 ar	nd blue?			\square_3	4	5	6
29 Did you feel worn out?				\square_3	4	5	6
30 Have you been a happy perso	on?			\square_3	4	5	6
31. Did you feel tired?					4	5	6
32 During the past 4 weeks, how myour physical health or emotion interfered with your social activatives, etc.)?	nal 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 follow	ving statements	for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easier	than other p	eople.				4	
34 I am healthy as anybody I kno	ow.						
35 I expect my health to get wors	e.					4	5
36 My health is excellent.					\square_3	4	5



		Center Number: Participant Number: Participant's Initials: middle last
Do	ite completed:/	/ OR Not done → Specify reason (use codelist below):
В	DI-II	
In	pick out the on- 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:	 □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: first middle last



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



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



	Center Number:	Participant N	Number:	Participant's Ir	nitials:
Date completed:/	/ OR Not dor	ne → Specify re	ason (use codelist be	low):	
Profile of Mood Stat					
Instructions: Please describe h	ow you feel right now by c	hecking one bo	x for each of the wo	ords listed below.	
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
1 Friendly					4
2 Tense				\square_3	4
3 Angry					4
4 Worn out				\square_3	
5 Unhappy					4
6 Clear-headed					
7 Lively					4
8 Confused					4
9 Sorry for things done					4
10 Shaky					4
11 Listless					4
12 Peeved	\square_{o}		\square_{2}	\square_3	4
13 Considerate					4
14 Sad	\Box_{o}			\square_3	4
15 Active					4
16 On edge	\square_{o}		\square_{2}	\square_3	4
17 Grouchy					4
18 Blue	\square_{o}		\square_{2}	\square_3	4
19 Energetic					4
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				\square_3	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:
Profile of Mood States (continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy				\square_3	4
45 Desperate					4
46 Sluggish	o				4
47 Rebellious					4
48 Helpless					
49 Weary					4
50 Bewildered				\square_3	
51 Alert					4
52 Deceived				\square_3	
53 Furious					4
54 Efficient				\square_3	
55 Trusting					4
56 Full of pep				\square_3	
57 Bad-tempered					4
58 Worthless				\square_3	
59 Forgetful				\square_3	4
60 Carefree					
61 Terrified				\square_3	4
62 Guilty					4
63 Vigorous				\square_3	4
64 Uncertain about things				\square_3	
65 Bushed					4

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Participant's Initials: first middle last



	Center Number:	Participant Numb	er:		Participant'	s Initials:	irst middle last				
Date completed:/	OR Not done =	→ Specify reason	(use code	list below):							
Perceived Stress Scale (PSS)											
	Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question.										
			Never	Almost Never	Some- times	Fairly Often	Very Often				
In the last month, how often h unable to control the importar	•						4				
2 In the last month, how often h your ability to handle your pe	-	ent about	\Box_{o}			\square_3	4				
3 In the last month, how often h going your way?	ave you felt that thi	ngs were	□ _o			\square_3	4				
4 In the last month, how often h piling up so high that you coul	-					\square_3					
Not Done Codelist: 1 Participant refused	2 Clinician unable to obto	in 3 Insufficien	t time 4	Instrument f	ailure 5	Not requi	red				



	Center Number: Participal	nt Number:	Partic	cipant's Initials	first middle last
Do	te completed:/OR Not done → Specify	reason (use code	elist below):		
P	ttsburgh Sleep Quality Index (PSQI)				
In	structions: 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	o			\square_3
	b Wake up in the middle of the night or early morning	$\square_{\mathbf{o}}$			\square_3
	c Have to get up to use the bathroom				\square_3
	d Cannot breathe comfortably				\square_3
	e Cough or snore loudly				\square_3
	f Feel too cold	\square_{o}			\square_3
	g Feel too hot				\square_3
	h Have bad dreams	\square_{o}			\square_3
	i Have pain				\square_3
	i Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):			\square_{2}	\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.	***************************************			
N	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Ins	sufficient time 4	Instrument failure	5 Not re	
			Fulli	apam a minais	first middle last



	Center Number: Particip	oant Number:	Parti	cipant's Initials	first middle last
Pi	ttsburgh Sleep Quality Index (PSQI) (continued)				
		Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	l □ ₀			\square_3
		No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8	During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done	? □₀			3
		Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how would you rate your sleep quality overall?				



								•	9 11 1			
Cen	iter Number:	_ Partic	ipant Num	ber:		_ Partic	cipant's Ir	itials:	t middle last			
Date completed: OR	Not done → Spe	ecify reas	on (use co	delist bel	low):							
Derogatis Interview for Sexu	ual Functio	n (DISF-S	R) (F) Fe	male Ve	rsion							
Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.												
On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "O = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "O = could not be worse" to "8 = could not be better." Other satisfaction scales go from "O = not at all satisfied," to "4 = extremely satisfied."												
In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.												
If you have any questions, please ask the pers	on who gave yo	u the inve	ntory for	help.								
Section 1—Sexual Cognition/Fantasy	У											
During the past 30 days or since the last you filled out this inventory, how often h you had thoughts, dreams, or fantasies a	ave	t Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day			
1.1 A sexually attractive person					4		6	7	8			
1.2 Erotic parts of a man's body (e.g., shoulders, legs)	face,				4	5	6	7	8			
1.3 Erotic or romantic situations					4		6		8			
1.4 Caressing, touching, undressing, foreplay	or				4	5	6		8			
1.5 Sexual intercourse, oral sex, touc to orgasm	ching				4	5	6		8			
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4 Instrument failure

5 Not required

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

3 Insufficient time



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

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throughout sexual relations

2.5 Have normal lubrication

2.4 Have normal lubrication with

masturbation



Center Nu	mber:	Po	articipant N	lumber:		Pa	irticipant's	Initials:	rst middle last		
Derogatis Interview for Sexual	Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)										
Section 3—Sexual Behavior/Experiences											
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day		
3.1 Reading or viewing romantic or erotic books or stories	o			\square_3	4	5	6		8		
3.2 Masturbation	По			\square_3	□ ₄						
3.3 Casual kissing and petting	□ _o			\square_3	4	5					
3.4 Sexual foreplay	По			\square_3	4	₅			8		
3.5 Sexual intercourse, oral sex, etc.				\square_3	4	5			8		
Section 4—Orgasm											
During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely						
4.1 Your ability to have an orgasm	□ _o			\square_3	4						
4.2 The intensity of your orgasm	По				4						
4.3 The ability to have multiple orgasms (if typical for you)					4						
4.4 Feelings of closeness and togetherness with your partner	По			\square_3	4						
4.5 Your sense of control (timing) of your orgasm					4						
4.6 Feeling a sense of relaxation and well-being after orgasm					_4						

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Center Number:	Participant Number:	 Participant's Initials:	first middle la	ıst

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued) Section 5—Drive and Relationship Not at 1 or 2 2 or 3 4 to 6 1 per 2 or 3 Less 1 per 4 or all than 1 day per week per per per more month week week day per per month day 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse? Slightly Moderately Highly Extremely Not at all 5.2 During this period, how interested have you been in sex? 5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner? Above Could Poor Somewhat Adequate Good Could Very Very not be inadequate not be poor average good better worse 5.4 In general, what would represent the best description of the quality of your sexual functioning?

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Participant's Initials:

first middle last



Center Numb	er:	Partici	pant Num	ber:		Partic	cipant's Ir	nitials:			
								firs	st middle last		
Date completed: — doy / — month / — year OR Not do	ne → Spec	ify reaso	on (use co	delist bel	ow):						
Derogatis Interview for Sexual Fu	ınction	(DISF-S	R) (M) N	lale Ver	sion						
Instruction: Below you will find a brief set of question sections that ask about different aspects of your sexual while another inquires about the kinds of sexual expsexual arousal and the quality of your orgasm . The relationship.	ıl experien eriences	that you	section of have. You	asks abo ou are a	out sexu Iso aske	a l fante d about t	isies or he natu	daydre re of you	ams, ur		
On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied." In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience. If you have any questions, please ask the person who gave you the inventory for help.											
Section 1—Sexual Cognition/Fantasy											
During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day		
1.1 A sexually attractive person				\square_3		5			8		
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	\Box_{o}			\square_3	4	5	□ ₆		8		
1.3 Erotic or romantic situations				\square_3	4	5	□ ₆	7	8		
1.4 Caressing, touching, undressing, or foreplay				\square_3	4	5			8		
1.5 Sexual intercourse, oral sex, touching to orgasm				\square_3		5	□ ₆		8		

5 Not required

4 Instrument failure

2 Clinician unable to obtain

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

3 Insufficient time



Center Non	iber:	ran	iicipani ivu	inber:		Pari	icipani s i	fir	rst middle last
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal									
During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences?	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
2.1 A full erection upon awakening									

2.3 A full erection while looking at a sexually arousing person, movie, or picture					4		6		8
------------------------------------------------------------------------------------	--	--	--	--	---	--	---	--	---

2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm			4	5	6	 8

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2.2 A full erection during a sexual fantasy or daydream

2.4 A full erection during masturbation



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	По				4		6		8
3.2 Masturbation				\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	6		8
3.5 Sexual intercourse, oral sex, etc.				\square_3	4	5	6		8
Section 4—Orgasm									
During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following?	Not at all	Slightly	Moderately	Highly	Extremely				
4.1 Your ability to have an orgasm	o				4				
4.2 The intensity of your orgasm	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	Number:		Participant	Number:		Participant's Initials:			
Derogatis Interview for Sexua	l Func	tion (DISF-SR) (M) Male \	/ersion (d	ontinue	d)		
Section 5—Drive and Relationship									
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse?					□ 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?				\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: I	Participant	Number:		Participa	nt's Initials:	first middle last
Da	te completed:/	year OR Not done → S	Specify r	eason (use d	codelist belo	w):	_	
Fc	ood Cravings Questionn	aire—State (FCQ—S)						
ho	ow is a list of comments made by peo w much you agree with the comment ile others refer to one or more specific	right now, at this very m	oment.	Notice that	some quest	ions refer t		
				Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I have an intense desire to easpecific foods].	at [one or more				3	4	5
2	I'm craving [one or more spe	ecific foods].				\square_3	4	5
3	I have an urge for [one or me	ore specific foods]				\square_3	4	5
4	Eating [one or more specific face seem just perfect.	foods] would make thi	ings		\square_{2}	\square_3		5
5	If I were to eat what I am crawould improve.	ıving, I am sure my mo	ood			3	4	5
6	Eating [one or more specific for wonderful.	foods] would feel				\square_3	4	5
7	If I ate something, I wouldn't and lethargic.	feel so sluggish				\square_3	4	5
8	Satisfying my craving would and irritable.	make me feel less gro	ouchy			\square_3	4	5
9	I would feel more alert if I co	uld satisfy my craving	 •			3	4	5
10	If I had [one or more specific eating it.	foods], I could not sto	рр			\square_3	4	5
11	My desire to eat [one or mor seems overpowering.	e specific foods]				\square_3	4	5
12	I know I'm going to keep on more specific foods] until I ac		r			\square_3	4	5
13	I am hungry.						4	5
14	If I ate right now, my stomac	h wouldn't feel as emp	oty.			\square_3	4	
15	I feel weak because of not ed	ating.				\square_3	4	5

5 Not required

4 Instrument failure

2 Clinician unable to obtain

Not Done Codelist: 1 Participant refused

3 Insufficient time



Center Numb	oer: Po	rticipant Number:		Participant's	Initials: middle last
Date completed:/OR	Not done → S	pecify reason (us	se codelist below	·):	
Food Craving Inventory (FCI-II)					
For each of the foods listed below, please check the ap					
Note: A craving is defined as an intense desire to cons Over the past month, how often	ume a particulo	_	ype that is diff	icult to resist.	Always/Almost
have you experienced a craving for	Never	Rarely (once or twice)	Sometimes	Often	Every Day
1 Cake			\square_3		
2 Pizza			\square_3	4	
3 Fried chicken			\square_3		
4 Gravy					
5 Sandwich bread				4	
6 Sausage			\square_3		5
7 French fries					
8 Cinnamon rolls					
9 Rice					
10 Hot dog					
11 Hamburger				4	
12 Biscuits					
13 lce cream				4	
14 Pasta					
15 Fried fish					
16 Cookies					
17 Chocolate					
18 Pancakes or waffles				4	
19 Corn bread					
20 Chips				4	
21 Rolls					
22 Cereal					
23 Donuts				4	
24 Candy					
25 Brownies			\Box_3		
26 Bacon					
27 Steak			\square_3		
28 Baked potato					
Not Done Codelist: 1 Participant refused 2 Clinician u	nable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	lot required

Participant's Initials: first middle last



		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	☐₀ False
12	I often feel so hungry that	I just have to eat so	mething.			o False
13	When I am with someone	who is overeating, I	usually overeat to	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:	Participant Number:	Participant's In	itials: middle last
Eat	ing Inventory (continued)				
19	Being with someone who is	eating often make	s me hungry to eat also.	, True	o False
20	When I feel blue, I often over	ereat.		☐₁ True	o False
21	I enjoy eating too much to s my weight.	poil it by counting	calories or watching	, True	o False
22	When I see a real delicacy, right away.	I often get so hung	ry that I have to eat	, True	o False
23	I often stop eating when I a limiting the amount I eat.	m not really full as	a conscious means of	☐, True	o False
24	I get so hungry that my stor	mach often seems l	ike a bottomless pit.		o False
25	My weight has hardly chan	ged at all in the las	st ten years.	☐₁ True	o False
26	I am always hungry so it is the food on my plate.	hard for me to stop	o eating before I finish		o False
27	When I feel lonely, I console	e myself by eating.		, True	o False
28	I consciously hold back at n	neals in order not to	o gain weight.	1 True	o False
29	I sometimes get very hungr	y late in the evenin	g or at night.	, True	o False
30	I eat anything I want, any ti	me I want.		1 True	o False
31	Without even thinking abou	t it, I take a long ti	me to eat.		o False
32	I count calories as a conscio	ous means of contro	olling my weight.	1 True	o False
33	I do not eat some foods bed	cause they make m	e fat.	1 True	□₀ False
34	I am always hungry enougl	n to eat at any time	.		o False
35	I pay a great deal of attenti	on to changes in m	ny figure.		o False
36	While on a diet, if I eat a fo eat other high calorie foods		ved, I often splurge and	☐₁ 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?	\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?	□₁ Rarely □₂ Sometimes □₃ Usually □₄ Always
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult
42	How conscious are you of what you are eating?	\square_1 Not at all \square_2 Slightly \square_3 Moderately \square_4 Extremely
43	How frequently do you avoid "stocking up" on tempting foods?	\square_1 Almost never \square_2 Seldom \square_3 Usually \square_4 Almost always
44	How likely are you to shop for low calorie foods?	☐, Unlikely ☐, Slightly likely ☐, Moderately likely ☐, 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?	☐, Unlikely ☐, Slightly likely ☐, Moderately likely ☐, 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?	☐₁ Never ☐₂ Rarely ☐₃ Sometimes ☐₄ At least once a week
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow."	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of me ☐₄ Describes me perfectly
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	□₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in"



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

Weight Efficacy Lifestyle Questionnaire (WEL)

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

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

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



	Center Number:	Participant Number:					Participant's Initials: first 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	5	6			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						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	articipant Number:			Participant's Initials: first middle last				
Date completed:/ OR Not done → Specify reason (use codelist below):										
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)										
Instructions: Using the scale shown, pleas	se rate the following items	on a scal	a scale from 1 to 7. Please answer as truthfully as possible.							
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always	
1 Fasting is a good way to lose	weight.				\square_3	4	5		7	
2 My sleep isn't as good as it u	sed to be.				\square_3	\square_{4}	5			
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	6		
11 I think I am a good person.					\square_3	4	5	6		
12 My eating is normal.					\square_{3}	\square_4	5	6		
13 I can't seem to concentrate la	tely.				3	4	5	6		
14 I try to diet by fasting.					\square_3	\square_4	5	6		
15 I vomit to control my weight.					\square_3		5			
16 Lately nothing seems enjoyab	le anymore.				$\square_{_3}$	\square_{4}	5	6		
17 Laxatives help keep you slim.							5	6		
18 I don't eat red meat.					\square_3		5	6	7	
19 I eat so rapidly I can't even to	aste my food.				\square_3					
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										



	Center Number:	Participant N	umber: _		Participant's Initials:				
Multiaxial Assessment of	tiaxial 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			
22 I overeat too frequently.				\square_3	4	5	6		
23 It's okay to be overweight.					4	5	6		
24 Recently I have felt that I am	a worthless person.			\square_3	4	5	6		
25 I would be very upset if I gain	ned 2 pounds.			3	4	5	6	7	
26 I crave sweets and carbohyde	rates.			\square_3	4	5	6		
27 I lose control when I eat.				\square_3	4	5	6	7	
28 Being fat would be terrible.				\square_3	4	5	6		
29 I have thought seriously abou	ut suicide lately.			3	4	5	6		
30 I don't have any energy anymo	ore.			3	4	5	6	7	
31 I eat small portions to control	my weight.			3	4	5	6	7	
32 I eat 3 meals a day.				\square_3			6	7	
33 Lately I have been easily irrit	ated.			\square_3	4	\square_5	6	7	
34 Some foods should be totally	avoided.			3	4	5	6	7	
35 I use laxatives to control my	weight.			3	4	5	6	7	
36 I am terrified by the thought	of being overweight.			\square_3	4	5	6		
37 Purging is a good way to lose	e weight.				4	5	6	7	
38 I avoid fatty foods.									



	Center Number:	Participant No	umber:		Pa	rticipant's	nitials:	irst middle last		
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)										
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always		
39 Recently I have felt pretty blue	е.			\square_3	4	5				
40 I am obsessed with becoming	overweight.			\square_3	4	5	6			
41 I don't eat fried foods.				\square_3	4	5				
42 I skip meals.				3	4	5				
43 Fat people are unhappy.				\square_3	4	5				
44 People are too concerned wit	h the way I eat.			3	4	5	6	7		
45 I feel good when I skip meals	•			\square_3	4	5				
46 I avoid foods with sugar.				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 stu	ffed.			\square_3	4	5				
50 I hate to eat.				3	4	5				
51 I feel guilty about a lot of thin	gs these days.			\square_3	4	5				
52 I'm very careful of what I eat				\square_3	4	5				
53 I can "hold off" and not eat e	ven if I am hungry.			\square_3	4		6			
54 I eat even when I am not hun	gry.			$\qquad \qquad \square_3$	4	5				
55 Fat people are disgusting.				\square_3	4	5				
56 I wouldn't mind gaining a few	v pounds.				4	5				



		Center Number:	Participant N	Number: _		Par	ticipant's I	nitials:	middle last
Da	te completed:/ _{month} /	OR Not done =	Specify re	ason (use	codelist b	elow):			
В	ody Shape Questionna	ire (BSQ)							
	would like to know how you have base read each question and check th								
Ov	er the Past Four Weeks			Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you	brood about your sh	nape?			\square_3		5	
2	Have you been so worried a have been feeling that you o		t you			\square_3	4	5	
3	Have you thought that your too large for the rest of you?		m are				4	5	6
4	Have you been afraid that y fatter)?	ou might become fat	(or				4	5	
5	Have you worried about you enough?	ur flesh not being firm	1				4	5	6
6	Has feeling full (e.g., after eating fat?	a large meal) made you	feel				4	5	6
7	Have you felt so bad about cried?	your shape that you l	nave				4	5	6
8	Have you avoided running k wobble?	pecause your flesh mi	ght			\square_3	4	5	6
9	Has being with thin women/ self-conscious about your sho					\square_3	4	5	
10	Have you worried about you sitting down?	ur thighs spreading o	ut when			\square_3	4	5	
11	Has eating even a small amofat?	ount of food made yo	ou feel			\square_3	4	5	
	Have you noticed the shape felt that your own shape con	npared unfavorably?				\square_3	4	5	6
13	Has thinking about your sha ability to concentrate (e.g., whit to conversations)?					\square_3	4		
14	Has being naked, such as w feel fat?	hen taking a bath, mo	ade you			\square_3	4	5	6
15	Have you avoided wearing a particularly aware of the sho		συ			\square_3	4	5	6
16	Have you imagined cutting obody?	off fleshy areas of you	Jr			\square_3	4	5	6
No	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required								



	Center Number: Participant N	Number: _		Pai	rticipant'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 a you feel fat?	other high calorie food made				4	5	
18 Have you not gone out on so because you have felt bad al				\square_3	4	5	6
19 Have you felt excessively lar	ge and rounded?				4	5	6
20 Have you felt ashamed of yo	our body?			3	4	5	6
21 Has worry about your shape	made you diet?			\square_3		5	
22 Have you felt happiest about stomach has been empty?	t your shape when your			\square_3	4	5	6
23 Have you thought that you a because you lack self-control				\square_3	4	5	
24 Have you worried about other flesh around your waist or st				\square_3	4	5	6
25 Have you felt that it is not fai thinner than you?	r that other women/men 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 o				\square_3	4	5	
28 Have you worried about you	r flesh being dimply?			\square_3	4	5	6
29 Has seeing your reflection (e.g you feel bad about your sha				\square_3		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 changing					4	5	
32 Have you taken laxatives in	order to feel thinner?					5	6
33 Have you been particularly s shape when in the company	elf-conscious about your of other people?			\square_3		5	
34 Has worry about your shape to exercise?	made you feel you ought					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	pant's Initials:
ls	ometric/Isokine	tic Kne	e Extension and	Flexion		
Do	ate and time of assessment	:/_		00:00 to 23:59	Staff ini	first middle last
	R Not done → Specify reas					
1	Recent injury or pain—rig	ht knee?	O No O Yes			
2	Recent injury or pain—lef	t knee?	No , Yes			
3	Specify machine used (PE					
	Specify indefinite used (1)	oke only).			,	
	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	
				ı	1	ı

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

5 Not required



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

		Ioday's date://		Day (check only one):		Mon Tues Wed Thurs Fri Sat Sun OR Not done → Speaffy reason (use codelist below):	Thurs	Fri S	at Sur	OR No	done →	Specify re	eason (use	codelist bel	ow):
	ere yc	oyed in the last sev	ın days?		N N	$\square_{0} \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	estion 3	7es				Interv	Interviewer initials:	ials:	first middle last
	Yes: W	If Yes: Which days (check all that apply)?	0.		Mon	Tues Wed		Thurs	Œ	Sat	Sun				
# \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	/hich d	Which days do you consider your weekend, or non-work, days?	reekend, or no	on-work, days?	Mon	Tues	Med	Thurs	Fri	Sat	Sun				
	Day of		Sleek	Sleep Time	Work Time	Time	Mori	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	ninutes)	Ever	Evening (in minutes)	utes)
	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
▼ ester- day)		day month year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
•		day month year		00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
r)		day /		00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
4		day month year		00:00 to 23:59	00:00 to 23:59										
m				00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
7		day /	00:00 to 23:59		00:00 to 23:59										
■ week ago)		day month year	00:00 to 23:59		00:00 to 23:59	00:00 to 23:59									

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

5 Not required

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		Center Number:	Participant Number:	Participant's Initials:	first middle last					
Se	even-Day Physical Activi	ty Recall (PAR) (co	ntinued)							
4	Compared to your physical activity or or about the same (check only one)?	ver the past three months	s, was last week's physical c	activity more, less,						
Int	Interviewer: Please answer questions below and note any comments on interview.									
5	Were there any problems with the Se	ven-Day PAR interview?								
6	Do you think this was a valid Seven-Do No	Day PAR interview?								
7	Were there any activities reported by One No	the participant that you	don't know how to classify?	?						



		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 late of the late	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	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing	11	/	☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing
5	/	n Reliable number unreliable number unreliable number unreliable number unreliable	12	/	Reliable Unreliable Missing
6	/	n Reliable number to the lambda lambd	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 bpm OR 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 VO₂: 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



	Center Nu	umber: Parti	cipant Numl	oer: Particip	ant's Initials:
Outcomes Lo		,			
Date and time sam	ple collection started:/_	month year	00:0	_ : 0 to 23:59	
If a sample is not ob	Sample tained, indicate with a Not Done.	Sample Comp	lete?	If Not Done, Reason (Use codelist below)	Staff Initials
	Blood	□ ₀ No □ ₁ Yes			first middle last
Core Tempe	rature				
Staff Initials		Provide Date of ample Collection/Procedure		Time of Sample lection/Procedure	If Not Done, Reason (Use codelist below)
	Start Date:	year	Start Time:		
first middle last	Stop Date:	year		Stop Time:00:00 to 23:59	
Inpatient Ac	lmission and Discha	rge			
1 Inpatient admis	sion date and time:/	month year	00:00 t	: 	
2 Inpatient discha	arge date and time:/	/	: 00:00 to	23:59	
Not Done Codelist:	1 Participant refused 2 Clinicia	n unable to obtain	3 Insufficier	nt time 4 Instrument failure	5 Not required



		Center Num	ber: Pa	rticipant Numbe	r:	Participant's Initial	first middle last
D	elayed-type Hyperso	ensitivity (D1	ГН)				
1	Was the DTH worksheet comple □ ₀ No □ ₁ Yes → If Yes: Were any Exc		$\begin{array}{c} ? \Box_0 \text{No} \to \text{Pro} \\ \Box_1 \text{ Yes} \to \text{STO} \end{array}$				
2	Date of injection:/	/	OR Not done →	Specify reason	(use codelist below):	_	
3	Injection by (initials): First middle last						
4	Arm injected: \square_1 Right \square_2 L	eft					
5	DTH results: Note: For each reaction, measured because the induration measured diameter and then the diameter are diameter is equal to the diameter of the diameter and the diameter are second diameter per	nay not be in the s ameter 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	the long
		24	Hour (@ 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): 1 Tetanus toxoid (Sanofi- Pasteur) 98 Other: Lot #:	mm	mm		mm	mm	
	Candida (check only one): Candin (AllerMed) Lot #:	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	day /		Staff init	ials:
Clinic weight (if the two m	neasurements are more than 0.1 kg apa	rt, 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	eal:/ _{month}	/:::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::: _:	- <u></u> -	
Date and time sample co		/; year;; 23:		
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Cc	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	l, 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:		
	/	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

Stop Date:

Stop Time:



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 Con (e.g., barrier, IUD):	ncomitant	Medico	
Day 1		Date	Time	If Not I Reas (use co	son ´	Staff Initials
Day 1 of menses (females only)						
Date and time of last meal (males only	r)	/	: :: : : : :			
Hormone level blood draw 1 (males o	nly)	/	00:00 to 23:59			first middle last
Hormone level blood draw 2 (females of Progesterone level	o nly)					
Day 2		Date	Time	If Not I Reas (use co	son	Staff Initials
Date and time of last meal						
Hormone level blood draw 3 (females of Progesterone level	o nly)					
Metabolic Rate						
Sample		Date of Collection	If Not Done, Ro (Use codelist be		Staff	f Initials
Resting Metabolic Rate (RMR)—Visit 4		day /			first	middle last
Cart ID	l	-003 (623-002)		PBRC-01	•	
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	ime 4 Instrument	failure	5 Not re	equired

Month 24 Submission

Participant's Initials: first middle last

Participant Number:

Center Number:

calerie Phase 2

?				2221 (11)	(NIC)											
90.	oday's date:)			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	F.	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	 	 									
αy)		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:	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: 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