

PAGEID = 156

	Center Number: Participant Number:	Participant's Initials: First middle last
C	linic Weight	
w	eight date and time:/ <sub>month</sub> /::: _:	Staff initials:
	R Not done → Specify reason (use Codelist below):	DATEHDR (TYPE 4)
Cli	nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time)	) <del>:</del>
W	eight 1: SAME AS PAGE 4	
W	eight 2: kg	WEIGHT (TYPE 4)
W	eight 3: kg	
W	eight of gown: kg	
V	ital Signs	
As	sessment date and time:/	
	If waist measurement not done → Specify reason (use codelist below):	VITALS (TYPE 3)
ו'	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third til	Staff initials: first middle last
	Natural waist measurement 1: cm SAME AS F	PAGE 29
	Natural waist measurement 2: cm	
	Natural waist measurement 3: cm	
2	<b>Umbilical point waist measurement</b> (if the first two measurements are more than 1.0 cm apart, measurement point waist circumference a third time):	sure
	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: first middle lost
4	Temperature: °C OR Not done → Specify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR Not done → Specify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one): □₁ Left arm □₂ Right arm	Staff initials:
	<b>6a</b> Blood pressure 1:/ mm Hg Time:: OR Not do Specify	ne → reason (use codelist below):
	6b Blood pressure 2:/ mm Hg Time:::	
	<b>6c</b> Blood pressure 3:/ mm Hg Time::	
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4	Instrument failure 5 Not required



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Center	Number: Participant N	tolliber: ra	rticipant's Initials:  first middle last		
12-Lead ECG					
Date and Time		Findings ECG (TYF	PE 4) Staff Initials		
DATEHDR (TYPE 4)		SAME AS PAGE:	first middle last		
Safety Labs					
Date and time of last meal:					
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Blood	□ <sub>0</sub> No □ <sub>1</sub> Yes		first middle last		
Urine	□₀ No □₁ Yes		first middle last		
Contraception					
If Not Done → Specify reason (use codelist below):					
Contraception method (females only):	None OR Check all that	ceptive → SpecifyOUTCM			
SAME AS PAGE 95	☐ Other → Sp	Record on Concor pecify (e.g., barrier, IUD):	mitant Medications page		
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuff	icient time 4 Instrument fail	ure 5 Not required		



(GI	=ID = 158	Center Number:	Participant Number:	Participant's Initials: first middle last
Da	te completed:/ <sub>mon</sub>	/	ACEpedity reason (use code	elist below). DATEHDR (TYPE 4)
В	DI-II			
lns	pick out the one weeks, including	statement in each group that be	est describes the way you have statement you have picked	up of statements carefully and then tve been feeling during the past two d. Be sure that you check only one
1	Sadness:	$\square_0$   do not feel sad $\square_1$   feel sad much of the tir $\square_2$   am sad all of the time $\square_3$   am so sad or unhappy		BDIQ (TYPE 4) SAME AS PAGE 39
2	Pessimism:	$\square_0$   am not discouraged at $\square_1$   feel more discouraged of $\square_2$   do not expect things to $\square_3$   feel my future is hopele	about my future than I used work out for me	
3	Past failure:	□₀ I do not feel like a failur □₁ I have failed more than □₂ As I look back, I see a lo □₃ I feel I am a total failure	I should have ot of failures	
4	Loss of pleasure:	□₀ I get as much pleasure of □₁ I don't enjoy things as m □₂ I get very little pleasure □₃ I can't get any pleasure	nuch as I used to from the things I used to	enjoy
5	Guilty feelings:	□₀ I don't feel particularly o □₁ I feel guilty over many th □₂ I feel quite guilty most o □₃ I feel guilty all of the tim	nings I have done or sho f the time	uld have done
6	Punishment feelings:	□₀ I don't feel I am being p □₁ I feel I may be punished □₂ I expect to be punished □₃ I feel I am being punishe		
7	Self-dislike:	$\square_0$ I feel the same about my $\square_1$ I have lost confidence in $\square_2$ I am disappointed in my $\square_3$ I dislike myself	myself	
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to o	btain 3 Insufficient time 4	Instrument failure 5 Not required
		CALERIE PHASE2 ANN	OTATION V8.0 24FEB	Participant's Initials:



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		Center Number: Participant Number: Participant's Initials: first middle last
В	DI-II (continued)	
8	Self-criticalness:	□₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens
9	Suicidal thoughts or w	rishes: $\square_0$ I don't have any thoughts of killing myself $\square_1$ I have thoughts of killing myself but I would not carry them out $\square_2$ I would like to kill myself $\square_3$ I would kill myself if I had the chance
10	Crying:	□₀ I don't cry any more than I used to □₁ I cry more than I used to □₂ I cry over every little thing □₃ I feel like crying, but I can't
11	Agitation:	$\square_0$ I am no more wound up or restless than usual $\square_1$ I feel more restless or wound up than usual $\square_2$ I am so restless or agitated that it's hard to stay still $\square_3$ I am so restless or agitated that I have to keep moving or doing something
12	Loss of interest:	$\square_0$ I have not lost interest in other people or activities $\square_1$ I am less interested in other people or things than before $\square_2$ I have lost most of my interest in other people or things $\square_3$ It's hard to get interested in anything
13	Indecisiveness:	□₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14	Worthlessness:	$\square_0$ I do not feel I am worthless $\square_1$ I don't consider myself as worthwhile and useful as I used to $\square_2$ I feel more worthless as compared to other people $\square_3$ I feel utterly worthless
15	Loss of energy:	<ul> <li>□₀ I have as much energy as ever</li> <li>□₁ I have less energy than I used to have</li> <li>□₂ I don't have enough energy to do very much</li> <li>□₃ I don't have enough energy to do anything</li> </ul>
	C	CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



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	Center Number:	Participant Number:	Participant's Initials: middle las
BDI-II (continued)			
16 Changes in sleeping pattern:	□₀ I have not experienc □₁ I sleep somewhat mo □₂ I sleep somewhat les □₃I sleep a lot more tha □₄I sleep a lot less than □₅ I sleep most of the do □₄I wake up 1-2 hours	ore than usual us than usual usual usual usual ay	BDIQ (TYPE 4)
17 Irritability:	$\square_0$   am no more irritable $\square_1$   am more irritable th $\square_2$   am much more irritable all of the	an usual able than usual	SAME AS PAGE 41
18 Changes in appetite:	□₀ I have not experience □₁ My appetite is somev □₂ My appetite is much □₃ My appetite is much □₄ My appetite is much □₅ I have no appetite at □₀ I crave food all of the	what less than usual what greater than usual less than before greater than usual all	petite
19 Concentration difficulty:	□₀ I can concentrate as □₁ I can't concentrate as □₂ It's hard to keep my I □₃ I find I can't concentr	s well as usual mind on anything for ver	y long
20 Tiredness or fatigue:	$\square_0$   am no more tired o $\square_1$   get more tired or fatige $\square_2$   am too tired or fatige $\square_3$   am too tired or fatige	tigued more easily than gued to do a lot of the th	ings I used to do
21 Loss of interest in sex:	$\square_0$   have not noticed ar $\square_1$   am less interested in $\square_2$   am much less interest in $\square_3$   have lost interest in	n sex than I used to be sted in sex now	nterest in sex

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Participant's Initials: first middle last



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	Center Number: Porticipo	ont Number: Participant's Initials: first_middle_last
Cli	inic Weight	
Wei	eight date and time:/ <sub>month</sub> /::	Staff initials:
	Not done → Specify reason (use Codelist below):	DATEHDR (TYPE 4)
Clin	nic weight (if the first two measurements are more than 0.1 kg apart, measure	weight a third time):
Wei	sight 1: kg SAME A	S PAGE 4
Wei	eight 2: kg	WEIGHT (TYPE 4)
Wei	sight 3: kg	
Wei	sight of gown:kg	
	ital Signs	
Ass	sessment date and time:/ <sub>month</sub> /:	-
	If waist measurement not done → Specify reason (use codelist below):	VITALS (TYPE 3)
	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist cir	Staff initials:
	Natural waist measurement 1: cm	SAME AS PAGE 29
	Natural waist measurement 2: cm	
	Natural waist measurement 3: cm	
	Umbilical point waist measurement (if the first two measurements are more than	n 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 bel	ow): Staff initials:
4	Temperature: °C OR Not done → Specify reason (use	codelist below): Staff initials:
5	Respirations: per minute OR Not done → Specify reason (use	e. W. w. l
6	Blood pressure (check only one): □₁ Left arm □₂ Right arm	Staff initials:
	<b>6a</b> Blood pressure 1:/ mm Hg	OR Not done →
	6b Blood pressure 2:/ mm Hg Time::	3.59
	<b>6¢</b> Blood pressure 3:/ mm Hg Time::	
Not	t Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 In	sufficient time 4 Instrument failure 5 Not required



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Center	Number: Participant	Number: Par	rticipant's Initials:
12-Lead ECG			
Date and Time		Findings ECG (TYP	E 4) Staff Initials
DATEHDR (TYPE 4)  ———————————————————————————————————		SAME AS PAGE ( silly significant (specify):	first middle last
Safety Labs			
Date and time of last meal: /	ofth year 00:00 fe	SAFELLL	B (TYPE 4)
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□₀ No □₁ Yes	SA 	ME AS PAGE 30
Urine	□₀ No □₁ Yes		first middle fost
Pregnancy Test			
Complete only for females.		PREGTEST (	TYPE 4)
Does participant have reproductive potential?  □0 No □1 Yes → If Yes: Date urine pregnancy test p  Results: □1 Negative □2 Positive	SAME AS PAC		
Net Dana Cadalists 1 Participant refused 2 Clinic	ian unahla ta ahtain 2 Ii	ficient time A Instrument feet	S Not required



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		Center Number:	r: Partiapont Number: Partiapont's Initials: first middle last
D	oubly Labeled V	<b>V</b> ater (DLW)	
1		osing:///	DIWLIDD (TVDE 4)
2	DLW dose mixture ID an	nd bottle number:	CA
3	Exact weight of DLW mix	xture:(	grams
4	Urine samples:	AME AS PAGE 114	DLWCHT (TYPE 4)PS
	Collection	Sample	Date and Time Collected
	Pre dosing (PD)	PDa	/
		PDb	/
	Day 0 (Visit 1)	D0a	/
		DOP	/
	Day 7 (Visit 2)	D7a	/
		D7b	
	Day 14 (Visit 4)	D14a	
		D14b	/
5	Affix CRF page label(s)	corresponding to this urine so	sample set:  Affix Affix Test Sample Label Here Label Here
No	t Done Codelist: 1 Particip	pant refused 2 Clinician unab	able to obtain 3 Insufficient time 4 Instrument failure 5 Not required



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	Center Number: Participant Num		mber: Participant's Initials:				
Physical Examination							
Date of examination:/	Date of examination:/						
OR Not done → Specify reason (use co			DACE 22	DATEHDR (TYPE 4)			
		Assessments					
Body System	Normal Abnormal No		Not Done	If Abnormal or Not Done: Explain			
General appearance:		□₀→	□ <sub>97</sub> →				
2 Head, Ears, Eyes, Nose, Throat:	$\square_1$	□₀→	□ <sub>97</sub> →	PEXAM (TYPE 4)PS			
3 Neck:		□₀→	□ <sub>97</sub> →	SAME AS PAGE 32			
4 Heart:		□₀→	□ <sub>97</sub> →	Grinie Alo I Aloe de			
5 Lungs:	$\Box_1$	□₀→	□ <sub>97</sub> →				
6 Abdomen:	□₁	□₀→	□ <sub>97</sub> →				
7 Lymph nodes:	$\Box_1$	□₀→	□ <sub>97</sub> →				
8 Extremities/Skin:		□₀→	□ <sub>97</sub> →				
9 Neurological:		□₀→	□ <sub>97</sub> →				
10 Musculoskeletal:		□₀→	<sub>97</sub> →				
	Normal	Abnormal	Not Done*				
11 Genitourinary:		□₀→	□ <sub>97</sub> →				
12 Breast:	$\square_1$	□₀→	□ <sub>97</sub> →				
Physician's Signature							
Investigator:	signatu	ire		Date:/			
t Not done at this evention at an OB Polarice							

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



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	Center Number:	Participant Number:	Participant's Initials:
DXA Scan			
Has the participant taken a calcium sup □ <sub>0</sub> No □ <sub>1</sub> Yes → If Yes: Proceed with	,		XASCAN (TYPE 4) orm the QA Center.
Were any studies involving barium or re		•	scheduled DXA exam?
□ <sub>o</sub> No □ <sub>1</sub> Yes	SAME AS F	PAGE 35	
DXA Scan		DXA Resc	an OR $\square_{96}$ NA
Date of scan:/	Date of rescan:/	month year	
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)		a Scanned all that apply
☐ Whole body		☐ Whole	body
Forearm		☐ Forearm	1
Spine		Spine	
Hip		Hip	



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		Center Number:	Participant Number	er:	Participant's In	first middle last			
Da	Date completed:/OR Not done → Specify reason (use codelist below):								
R	AND SF-36								
In	s <b>tructions:</b> This survey asks for your vie to do your usual activities. F unsure about how to answe	lease answer every quer a question, give the	estion by placing	a check "X" in th		box. If you are			
1	In general, would you say your health is:	C	ent	good 🔲 Go	od □₄ Faiı	r □₅ Poor			
2	Compared to one year ago, how would you rate your heal general now?	th in	petter now than what better now the same what worse now worse now than	than 1 year ag					
ty	e following items are about ac pical day. Does your health no so, how much?			Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All			
3	Vigorous activities, such as participating in strenuous spor		eavy objects,						
4	<b>Moderate activities</b> , such a vacuum cleaner, bowling, or p		pushing a		$\square_2$	$\square_3$			
5	Lifting or carrying groceries					$\square_3$			
6	Climbing <b>several</b> flights of sto	iirs				3			
7	Climbing <b>one</b> flight of stairs					3			
8	Bending, kneeling or stooping					3			
9	Walking more than a mile					□ <sub>3</sub>			
10	Walking several blocks					$\square_3$			
11	Walking one block								
12	Bathing or dressing yourself								
N	ot Done Codelist: 1 Participant refused	2 Clinician unable to ob	tain 3 Insufficient	time 4 Instrumer		ot required			
	CALERIE	PHASE2 ANNOT	<b>ATION V8.0 2</b>	4FEB2012	Participant's Ir	nitials:			



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	Cente	r Number:	Participant Number:	P	articipant's Init	tials:
Rand SF-36 (continue	ed)					
During the past 4 wed	-	-	<b>-</b>	s RAND	SF2 (TY	′PE 3)
physical health?	ioi rogorai aaii,		AS PAGE 37		Yes	No
13 Cut down on the a	mount of time	you spent on	work or other acti	vities		
14 Accomplished le	ss than you wou	ıld like				
15 Were limited in the	kind of work o	r other activit	ies			
16 Had difficulty per (for example, it took	•	rk or other ac	tivities			
During the past 4 wee		-	<u> </u>			
your work or other re problems (such as feeli	-		uit of any emotion	eai	Yes	No
17 Cut down on the a	mount of time y	ou spent on w	ork or other activit	ries		
18 Accomplished less	than you would	like				
19 Didn't do work or	other activities a	s <b>carefully</b> as	usual			
20 During the <b>past 4 v</b> problems interfered neighbors or group	d with your norn				☐₁ Not a ☐₂ Sligh ☐₃ Mod ☐₄ Quite ☐₅ Extre	tly erately e a bit
21 How much <b>bodily</b> (	pain have you h	ad during the	past 4 weeks?		☐1 None ☐2 Very ☐3 Mild ☐4 Mod ☐5 Seve ☐6 Very	mild erate re
22 During the past 4 vinterfere with your and housework)?	•	•	ork outside the home		☐ <sub>1</sub> Not o ☐ <sub>2</sub> A littl ☐ <sub>3</sub> Mod ☐ <sub>4</sub> Quite ☐ <sub>5</sub> Extre	e bit erately e a bit
	CALERIE PHA	SE2 ANNOTA	TION V8.0 24FEB2	2012		



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	Center Number: _	Part	icipant Numbe	er:	Parti	icipant's Initials	first middle last
RAND SF-36 (continued)							
These questions are about how yo weeks. For each question, please been feeling.	give the one		that come	s closest	to the wa		e e
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?				Пз	4		□ <sub>6</sub>
24 Have you been a very nervous	person?			$\square_3$	4	$\square_5$	□ <sub>6</sub>
25 Have you felt so down in the do nothing could cheer you up?	umps that			$\square_3$	4		□6
26 Have you felt calm and peaceful	ıl?			$\square_3$	4	$\square_5$	□ <sub>6</sub>
27 Did you have a lot of energy?				Пз	4	5	□ <sub>6</sub>
28 Have you felt downhearted and	d blue?		$\square_2$	Пз	$\square_{4}$	$\square_5$	□6
29 Did you feel worn out?				Пз	4	$\square_5$	□ <sub>6</sub>
30 Have you been a happy persor	1?	$\Box_1$		$\square_3$	$\square_{4}$	$\square_5$	
31. Did you feel tired?				$\square_3$	4	5	
32 During the past 4 weeks, how muyour physical health or emotion interfered with your social activity relatives, etc)?	al 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 followi	ng statement:	s 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.			$\square_3$		$\square_5$
34 I am healthy as anybody I know	w.				$\square_3$		5
35 I expect my health to get worse					Пз		
36 My health is excellent.					З		$\square_5$

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\GI	=ID = 169	Center Number:	Participant Number:	Participant's Initials:
Da	te completed:/		e → Specify reason (use code S PAGE 36	list below): DATEHDR (TYPE 4)
ВІ	DI-II			
lns	pick out the one weeks, includin	e statement in each group that be	est describes the way you ha e statement you have picked	up of statements carefully and then we been feeling during the past two l. Be sure that you check only one BDIQ (TYPE 4)
1	Sadness:	$\square_0$ I do not feel sad $\square_1$ I feel sad much of the tir $\square_2$ I am sad all of the time $\square_3$ I am so sad or unhappy		SAME AS PAGE 39
2	Pessimism:	$\square_0$ I am not discouraged about $\square_1$ I feel more discouraged about $\square_2$ I do not expect things to $\square_3$ I feel my future is hopeles	about my future than I used work out for me	
3	Past failure:	$\square_0$ I do not feel like a failure $\square_1$ I have failed more than $\square_2$ As I look back, I see a lo $\square_3$ I feel I am a total failure	I should have ot of failures	
4	Loss of pleasure:	□₀ I get as much pleasure o □₁ I don't enjoy things as m □₂ I get very little pleasure □₃ I can't get any pleasure	nuch as I used to from the things I used to	enjoy
5	Guilty feelings:	$\square_0$ I don't feel particularly $\square_1$ I feel guilty over many the $\square_2$ I feel quite guilty most of $\square_3$ I feel guilty all of the time	nings I have done or shou f the time	uld have done
6	Punishment feelings:	□₀ I don't feel I am being p □₁ I feel I may be punished □₂ I expect to be punished □₃ I feel I am being punishe		
7	Self-dislike:	□₀ I feel the same about my □₁ I have lost confidence in □₂ I am disappointed in my □₃ I dislike myself	myself	
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to o	btain 3 Insufficient time 4	Instrument failure 5 Not required
		CALEDIE DUACES ANNOT	ATION VO O DAFEDOOA	0



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

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		tast mode fast
В	DI-II (continued)	
8	Self-criticalness:	□₀ I don't criticize or blame myself more than usual □₁ I am more critical of myself than I used to be □₂ I criticize myself for all of my faults □₃ I blame myself for everything bad that happens BDIQ (TYPE 4)
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  SAME AS PAGE 40
10	Crying:	□₀ I don't cry any more than I used to □₁ I cry more than I used to □₂ I cry over every little thing □₃ I feel like crying, but I can't
11	Agitation:	$\square_0$ I am no more wound up or restless than usual $\square_1$ I feel more restless or wound up than usual $\square_2$ I am so restless or agitated that it's hard to stay still $\square_3$ I am so restless or agitated that I have to keep moving or doing something
12	Loss of interest:	$\square_0$ I have not lost interest in other people or activities $\square_1$ I am less interested in other people or things than before $\square_2$ I have lost most of my interest in other people or things $\square_3$ It's hard to get interested in anything
13	Indecisiveness:	□₀ I make decisions about as well as ever □₁ I find it more difficult to make decisions than usual □₂ I have much greater difficulty in making decisions than I used to □₃ I have trouble making my decisions
14	Worthlessness:	$\square_0$   do not feel   am worthless $\square_1$   don't consider myself as worthwhile and useful as   used to $\square_2$   feel more worthless as compared to other people $\square_3$   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

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	Center Number:	Participant Number:	Participant's Initials: iniddle last
BDI-II (continued)			
<b>16</b> Changes in sleeping pattern:	□₀ I have not experienc □₁ I sleep somewhat mo □₂ I sleep somewhat les □₃I sleep a lot more tha □₄I sleep a lot less than □₅ I sleep most of the do □₀ I wake up 1-2 hours	ore than usual us than usual un usual usual usual ay	BDIQ (TYPE 4)
17 Irritability:	□₀ I am no more irritable □₁ I am more irritable th □₂ I am much more irrita □₃ I am irritable all of th	an usual able than usual	SAME AS PAGE 41
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 less than usual what greater than usual less than before greater than usual all	petite
19 Concentration difficulty:	$\square_0$   can concentrate as $\square_1$   can't concentrate as $\square_2$   It's hard to keep my   $\square_3$   find   can't concentrate	s well as usual mind on anything for ver	y long
20 Tiredness or fatigue:	$\square_0$ I am no more tired of $\square_1$ I get more tired or fatige $\square_2$ I am too tired or fatige $\square_3$ I am too tired or fatige	tigued more easily than gued to do a lot of the th	nings I used to do
21 Loss of interest in sex:	$\square_0$ I have not noticed ar $\square_1$ I am less interested ir $\square_2$ I am much less intere $\square_3$ I have lost interest in	n sex than I used to be sted in sex now	nterest in sex

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Date completed:	/	OR Not don	e → Specify re	ason (use codelist be	:low):				
Profile of Mo		SAME A	S PAGE 36		DATEHDR (	TYPE 4)			
Instructions: Please describe how you feel right now by checking one box for each of the words listed below.									
	·ling	Not At All	A Little	Moderately	POMS (T Quite A Bit	YPE 4)PS Extremely			
1 Friendly	<b>-</b>	SAME AS PA							
2 Tense				<u></u>	3	<u> </u>			
			<u>U</u> 1		3				
3 Angry			<u> </u>		3	4			
4 Worn out					3	4			
5 Unhappy					3	4			
6 Clear-headed					З	4			
7 Lively		$\square_{o}$			3	4			
8 Confused		$\square_{o}$				4			
9 Sorry for thin	gs done				3	4			
10 Shaky		$\square_{o}$	$\square_1$	$\square_{2}$		$\square_4$			
11 Listless						4			
12 Peeved		$\square_{o}$	$\square_1$			4			
13 Considerate					3	4			
14 Sad		$\square_{o}$	$\square_1$	$\square_{2}$		$\square_4$			
15 Active						4			
16 On edge		$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_4$			
17 Grouchy					$\square_3$	$\square_4$			
18 Blue		$\square_{o}$			$\square_3$	$\square_4$			
19 Energetic					$\square_3$	4			
<b>20</b> Panicky				$\square_2$	$\square_3$				
		cNair Ph.D., and JW P. Heuchert, Victoria Park Ave., Toronto, ON A		license to Multi-Health System	ns Inc. All rights reserved. I	n 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 No	ot required			

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Participant's Initials: first middle last

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Send to DCRI I



PAGEID = 173	Center Number: _	Participant	Number:	Participant's	Initials:
Profile of Mood States	(continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless	□₀		∟_2	MS (TYPE 4)	PS □₄
22 Relaxed	□ <sub>o</sub> SAMI	E AS PAGE 43		$\square_3$	$\square_{4}$
23 Unworthy	$\square_{o}$			$\square_3$	4
24 Spiteful	$\square_{\circ}$	$\square_1$		$\square_3$	$\square_{4}$
25 Sympathetic	$\square_{o}$			$\square_3$	4
<b>26</b> Uneasy	$\square_{o}$			$\square_3$	_4
27 Restless	□₀			3	4
28 Unable to concentrate	$\square_{o}$			$\square_3$	4
29 Fatigued	□₀			$\square_3$	4
30 Helpful	$\square_{o}$	$\square_1$		$\square_3$	$\square_{4}$
31 Annoyed	□₀			$\square_3$	4
<b>32</b> Discouraged	$\square_{o}$	$\square_1$		$\square_3$	$\square_{4}$
33 Resentful	□₀			$\square_3$	4
34 Nervous	$\square_{o}$	$\square_1$		$\square_3$	$\square_{4}$
35 Lonely	$\square_{o}$			$\square_3$	4
36 Miserable	$\square_{\circ}$			$\square_3$	4
37 Muddled	□₀			3	4
38 Cheerful	$\square_{\circ}$			$\square_3$	4
39 Bitter	□₀			3	4
40 Exhausted			$\square_2$	$\square_3$	4
41 Anxious	□₀			$\square_3$	4
42 Ready to fight	$\square_{\circ}$		$\square_2$	$\square_3$	4
43 Good-natured		Π,	П	П.	Π,

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PAGEID = 174	Center Number: _	Participant	Number:	Participant's	Initials: first middle last
Profile of Mood States	continued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
44 Gloomy	$\Box_{\circ}$		$\bigsqcup_{2}$		PS □₄
45 Desperate	SAME 	E AS PAGE 44		3	4
46 Sluggish	$\square_{o}$			$\square_3$	
47 Rebellious				3	4
48 Helpless				□₃	
49 Weary					
50 Bewildered					
51 Alert					
52 Deceived				Пз	
53 Furious					
54 Efficient				Пз	
55 Trusting					
<b>56</b> Full of pep				Пз	
<b>57</b> Bad-tempered					4
58 Worthless					
59 Forgetful				3	
60 Carefree				$\square_3$	
61 Terrified	□₀			$\square_3$	4
62 Guilty	$\square_{o}$			$\square_3$	□4
63 Vigorous			$\square_2$	$\square_3$	4
64 Uncertain about things				$\square_3$	
65 Bushed				□₃	

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Participant's Initials:

first middle last



PAGEID = 175	Center Number: Participan	t Number:		Participant'	s Initials:	iest midella last			
Date completed:/	SAME AS PAGE 3 OR Not done → Specify	<mark>6</mark> <b>eason</b> (use code	list below.	Γ <u>EHD</u>	R (TY	PE 4)			
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.								
	SAME AS PAGE 45	Never	Almost Never	Some- times	Fairly Often	Very Often			
In the last month, how often he unable to control the important	경에 발견하다 프라이 아이를 하는데 하나 하나 나를 하나 하나 하는데 그렇게 되었다.	$\square_{0}$							
2 In the last month, how often he your ability to handle your per	어느 아내는 아내는 그는 것이 있는데 아내는 아내는 이 사람들이 없는데 아내는데 하나 아니는데 아내는데 아내는데 아내는데 아내는데 아내는데 아내는데 아내는데 아내	oto	$\square_1$	$\square_2$	$\square_3$	$\square_4$			
3 In the last month, how often he going your way?	ave you felt that things wer	re				□4			
4 In the last month, how often he piling up so high that you could	100 mm and	e							
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Ins	ufficient time 4	Instrument f	ailure 5	Not requi	red			



P	AGEID = 176  Center Number: Participa	ant Number:	Partic	ipant's Initials	first middle last
Da	te completed: $\phantom{aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa$	<b>reason</b> (use codel <mark>36</mark>	ist below): DATEH	ĪDR (TY	PE 4)
Pi	ttsburgh Sleep Quality Index (PSQI)				
lns	tructions: The following questions relate to your usual sleep habits du the most accurate reply for the majority of days and nights				
Dυ	ring the past month SAME AS PAG	E 46	PSQI'	I(TYPE	4)
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?	: 0 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>b</b> Wake up in the middle of the night or early morning	□₀	$\square_1$		$\square_3$
	c Have to get up to use the bathroom	$\square_{0}$			$\square_3$
	d Cannot breathe comfortably	$\square_{o}$	$\square_1$		$\square_3$
	e Cough or snore loudly		$\square_1$		$\square_3$
	f Feel too cold	$\square_{o}$			
	g Feel too hot				3
	h Have bad dreams	$\square_{o}$	$\Box_1$		3
	i Have pain				$\square_3$
	j Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):	□ <sub>0</sub>	$\square_1$		$\square_3$
6	During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	o			Пз
	39, with permission from Elsevier Science.  of Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 In	sufficient time 4 l	nstrument failure	5 Not re	quired 1
.10	CALERIE PHASE2 ANNOTATION V8.0		_	cipant's Initials	

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		Center Number:	Participant I	Number:	Parti	cipant's Initials:	first middle last
Pi	ttsburgh Sleep Quality I	ndex (PSQI) (continue	ed)				
	SAME AS PAGE 47	PSQI2(TY	PE 3)	Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how oft staying awake while driving, essocial activity?	•		$\square_{0}$			
				No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8	During the past month, how n been for you to keep up enth	•		$\square_{0}$			$\square_3$
				Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how vi quality overall?	vould you rate your	sleep	$\square_{o}$			Пз

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FAOLID = 170	Center Number:	Participant Number:	Participant's Initials:	first middle last

Date completed: — oR Not done → Specify reason (use codelist below): —DATEHDR (TYPE 4) SAME AS PAGE 36

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

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience. DISFEM1 (TYPE 4)PS

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

SAME AS PAGE 48

#### Section 1—Sexual Cognition/Fantasy Not at Less 1 or 2 1 per 2 or 3 4 to 6 1 per 2 or 3 4 or During the past 30 days or since the last time all than 1 per per week per day per more you filled out this inventory, how often have month week week day per per you had thoughts, dreams, or fantasies about: month day 1.1 A sexually attractive person 1.2 Erotic parts of a man's body (e.g., face, shoulders, legs) 1.3 Erotic or romantic situations 1.4 Caressing, touching, undressing, or foreplay 1.5 Sexual intercourse, oral sex, touching to orgasm Copyright © 1987 by Leonard R. Derogatis, PhD.

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2 Clinician unable to obtain

Participant's Initials: first middle last

5 Not required

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4 Instrument failure

3 Insufficient time

Not Done Codelist: 1 Participant refused



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Center N	lumber:	Po	articipant N	umber: _		Par	rticipant's	Initials: _	rst middle last
Derogatis Interview for Sexual	Functi	on (DIS	F-SR) (F)	Female \	/ersion (	continued	)		
Section 2—Sexual Arousal SAME AS	PAGE 4	19	4		DIS	SFEM1	(TYF	PE 4)F	PS .
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		□,		□8
2.2 Actively seek sexual satisfaction	□。						□。		□8
2.3 Feel sexually aroused with a partner							□₀		□.
	Never	Rarely	Sometimes	Usually	Always	DISFE	M2 (	ГҮРЕ	4)PS
2.4 Have normal lubrication with masturbation	□。				□ <sub>4</sub>				
2.5 Have normal lubrication throughout sexual relations	□₀								

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Center Nu	mber:	Po	articipant N	lumber: _		Po	ırticipant's	Initials:	rst middle last
Derogatis Interview for Sexual I	Functi	on (DIS	F-SR) (F)	Female \	ersion (	ontinue	d)		
Section 3—Sexual Behavior/Experiences	SAM	E AS P	AGE 50	)	DIS	SFEM <sup>.</sup>	1 (TYF	PE 4)F	PS
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	l or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	l per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	□.			□₃		5	□ <sub>6</sub>	□ <sub>7</sub>	□8
3.2 Masturbation				□₃	□₄	$\square_5$	□6	□7	□8
3.3 Casual kissing and petting				□₃	□₄	□ <sub>5</sub>	□ <sub>6</sub>	□ <sub>7</sub>	□8
3.4 Sexual foreplay	□,			□₃	□₄	$\square_5$	□6	□,	□8
3.5 Sexual intercourse, oral sex, etc.					□4	□ <sub>5</sub>	□ <sub>6</sub>	□ <sub>7</sub>	□8
Section 4—Orgasm					DIS	FEM:	3 (TYF	PE 4)F	PS
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									
<b>4.2</b> The intensity of your orgasm	□.			□₃	□₄				
4.3 The ability to have multiple orgasms (if typical for you)					_4				
<b>4.4</b> Feelings of closeness and togetherness with your partner	□,			3					
4.5 Your sense of control (timing) of your orgasm									
<b>4.6</b> Feeling a sense of relaxation and well-being after orgasm	□.			□₃	□4				

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	Center Number:		Participant	Number:		P	'articipant's	s Initials:	irst middle last
Derogatis Interview for Se	xual Fund	tion (	DISF-SR) (	F) Female	Version	(continue	ed)		
Section 5—Drive and Relationship	SAME	AS PA	GE 51		ISFE	M1 (T	YPE 4	)PS	
	Not at all	Less than 1 per month	1 or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	l per day	2 or 3 per day	4 or more per day
5.1 With the partner of your choice what would be your ideal frequency of sexual intercours					4	5	□6		□ <sub>8</sub>
	Not at all	Slightly	Moderately	Highly	Extren <mark>iel</mark> y	SFEM	13 (TY	PE 4)F	PS
5.2 During this period, how interested have you been in se	ex? □.				4				
5.3 During this period, how satisfi have you been with your personal relationship with you sexual partner?				Пз	□₄ DI	SFEM	14 (TY	PE 4)F	PS .
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would repre- the best description of the quo of your sexual functioning?							□6		

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DATEHDR (TYPE 4)

PAGEID = 182	Center Number:	Participant Number:	Participant's Initials:	first middle last
<b>-</b>		4 1 1 1 1		

#### Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

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

DISMALE1 (TYPE 4)PS

Section 1—Sexual Cognition/Fantasy	SAME A	AS PAG	SE 52						
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	□₀				□4		□6		□8
1.2 Erotic parts of a woman's body (e.g., face, genitals, legs)	□₀		$\square_{2}$	$\square_3$	□4	$\square_5$	□6		□8
1.3 Erotic or romantic situations	□₀			□₃	□ <sub>4</sub>		□6		□8
1.4 Caressing, touching, undressing, or foreplay	□₀		$\square_2$	$\square_3$	□₄	$\square_5$	□6		□8
1.5 Sexual intercourse, oral sex, touching to orgasm	□.			□₃	□4				□8
Copyright © 1987 by Leonard R. Derogatis, PhD.	•								
Not Done Codelist: 1 Participant refused 2 Clinician un	able to ob	otain 3	Insufficier	nt time	4 Instrun	nent failur	e 5 N	ot require	ed l

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Participant's Initials:



**PAGFID** = 183

Center Num	ber:	Part	ticipant Nu	mber:		Part	ricipant's I	nitials: _	st middle last
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal SAME AS P.	AGE 53	3		DI	SMAL	.E1 (T`	YPE 4	)PS	
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	□₀			3	4		□6		□8
2.2 A full erection during a sexual fantasy or daydream	□₀			Пз	□4	$\square_5$	□₀		□8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	□₀			□₃	4		□ <sub>6</sub>		
2.4 A full erection during masturbation	□.			Пз	a			$\square_{7}$	□₅
2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm	□₀				4				□ <sub>8</sub>

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Center Num	ber:	Par	ticipant Nu	mber:		Pa	rticipant's	Initials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 3—Sexual Behavior/Experiences	SAME	AS PA	AGE 54	D	ISMA	LE1 (	TYPE	4)PS	
During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities?	Not at all	Less than 1 per month	l or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	1 per day	2 or 3 per day	4 or more per day
3.1 Reading or viewing romantic or erotic books or stories	□,				4		6		8
3.2 Masturbation	□.			$\square_3$			□6		
3.3 Casual kissing and petting	□,						□ <sub>6</sub>		<b>□</b> 8
3.4 Sexual foreplay	□.				4	□₅	□6		□ <sub>8</sub>
3.5 Sexual intercourse, oral sex, etc.	□.			$\square_3$	4		□6		
Section 4—Orgasm					DIS	MALE	E2 (TY	<b>PE</b> 4)	PS
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	□,				4				
4.2 The intensity of your orgasm	□.		$\square_2$	$\square_3$	4				
4.3 The length or duration of your orgasm	□.			$\square_3$	4				
<b>4.4</b> The amount of seminal liquid that you ejaculate	□.			$\square_3$	□₄				
4.5 Your sense of control (timing) of your orgasm	По				4				
<b>4.6</b> Feeling a sense of relaxation and well-being after orgasm	По								
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Center	Number:		Participant	Number:		P	'articipant's	Initials:	irst middle last
Derogatis Interview for Sexua	ıl Fund	tion (	DISF-SR) (	M) Male \	ersion (	ontinue	4)		
Section 5—Drive and Relationship	SA	ME AS	PAGE !	55	DI	SMAL	.E1 (T`	YPE 4)	)PS
	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		□,		
	Not at all	Slightly	Moderately	Highly	Extremely				
					DI	SMAL	.E2 (T`	YPE 4)	PS
5.2 During this period, how interested have you been in sex?		П		Пз	□ <sub>4</sub>				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?	□.			□₃	□₄    □	ISMA	LE3 (1	ΓΥΡΕ 4	4)PS
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represent the best description of the quality of your sexual functioning?	□。			□3	□₄	$\square_5$	□6		□8

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Participant's Initials: first middle last



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PAGEID = 186		
FAGEID = 100		ant's Initials:
Date completed:day //	OR Not done → Specify reason (use codelist below): DATEHE	OR (TYPE 4)

#### Food Cravings Questionnaire—State (FCQ-S)

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment right now, at this very moment. Notice that some questions refer to foods in general while others refer to one or more specific foods. Please respond to each item as honestly as possible.

	<u>'</u>		′ ' F	CQSTA	ATE (T)	<u> (PE 4)PS</u>
	SAME AS PAGE 58	Strongly Disagree	Disasso		,	Strongly Agree
1	I have an intense desire to eat [one or more specific foods].					
2	I'm craving [one or more specific foods].			Пз		
3	I have an urge for [one or more specific foods]			3		5
4	Eating [one or more specific foods] would make things seem just perfect.			$\square_3$		
5	If I were to eat what I am craving, I am sure my mood would improve.			□₃		
6	Eating [one or more specific foods] would feel wonderful.			□₃		
7	If I ate something, I wouldn't feel so sluggish and lethargic.			□₃		
8	Satisfying my craving would make me feel less grouchy and irritable.			□₃		
9	I would feel more alert if I could satisfy my craving.			3		
10	If I had [one or more specific foods], I could not stop eating it.			□₃		
11	My desire to eat [one or more specific foods] seems overpowering.			3		
12	I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			□₃		
13	I am hungry.			□₃		
14	If I ate right now, my stomach wouldn't feel as empty.			□₃	□₄	
15	I feel weak because of not eating.			3		
No	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu	fficient time	4 Instrume	ent failure	5 Not rea	uired

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



					A 1211 1
PAGEID = 187 Center No.	umber: Pa	rticipant Number:		Participant's i	Initials:
Date completed:/					
Food Craving Inventory (FCI-II)					
For each of the foods listed below, please check the	appropriate box.		С	RAVE (T	YPE 4)PS
Note: A craving is defined as an intense desire to co					
Over the past month, how often have you experienced a craving for	Never	Rarely (once or twice)	Sometimes	Often	Always/Almost Every Day
1 Cake SAME AS PAGE 59			□₃		
2 Pizza					
3 Fried chicken					
4 Gravy					
5 Sandwich bread					
6 Sausage					
7 French fries					
8 Cinnamon rolls			□₃		
9 Rice			□₃		
10 Hot dog			□₃		
11 Hamburger			□₃		
12 Biscuits			□₃		
13 Ice cream			□₃		
14 Pasta			□₃		
15 Fried fish			□₃		
16 Cookies			□₃	$\square_{4}$	
17 Chocolate			□₃		
18 Pancakes or waffles			□₃	$\Box_{4}$	
19 Corn bread			₃	□₄	
20 Chips			$\square_3$	$\square_{4}$	
21 Rolls			₃	□₄	
22 Cereal			₃	$\square_{4}$	
23 Donuts			₃		5
24 Candy			□₃	$\square_{4}$	
25 Brownies			□₃		
26 Bacon			□₃		
27 Steak			$\square_3$		
28 Baked potato			□₃		
Not Done Codelist: 1 Participant refused 2 Clinicia	n unable to obtain	3 Insufficient tim	ne 4 Instrumer	nt failure 5 N	Not required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



**PAGEID** = 188

		Center Number:	Participant Number:		first middle fast
	ompleted:/ <sub>month</sub> /	OR Not done → SAME AS	Specify reason (use codelist below	ÄT <del>EHD</del> R (	TYPE 4)
Eati	ng Inventory				
1	When I smell a sizzling sta difficult to keep from eatin	eak or see a juicy pie ng, even if I have just	ece of meat, I find it very finished a meal.	TFEQA (T)	PE 4)PS
2	I usually eat too much at	social occasions, like	•		□₀ False
3	I am usually so hungry th	at I eat more than th	SAME AS F ree times a day.	True	o False
4	When I have eaten my que not eating anymore.	ota of calories, I am	usually good about	1 True	□₀ False
5	Dieting is so hard for me	because I just get too	hungry.	☐ <sub>1</sub> True	□₀ False
6	I deliberately take small h	nelpings as a means o	of controlling my weight.	1 True	o False
7	Sometimes things just tast I am no longer hungry.	re so good that I keep	on eating even when	□₁ True	□₀ False
8	Since I am often hungry, I expert would tell me that something more to eat.			□₁ True	□₀ False
9	When I feel anxious, I find	d myself eating.		☐₁ True	o False
10	Life is too short to worry	about dieting.		, True	o False
11	Since my weight goes up more than once.	and down, I have go	ne on reducing diets	□₁ True	□₀ False
12	I often feel so hungry tha	t I just have to eat so	mething.	☐₁ True	o False
13	When I am with someone	who is overeating, I	usually overeat too.	☐₁ True	□₀ False
14	I have a pretty good idea	of the number of cal	ories in common food.	☐₁ True	□₀ False
15	Sometimes when I start e	ating, I just can't seer	m to stop.	☐₁ True	□₀ False
16	It is not difficult for me to	leave something on r	my plate.	☐₁ True	o False
17	At certain times of the day to eating then.	y, I get hungry becau	se I have gotten used	□₁ True	□₀ False
18	While on a diet, if I eat fo for a period of time to mo		d, I consciously eat less	☐₁ True	□₀ False
Not D	one Codelist: 1 Participant refused	2 Clinician unable to obta	in 3 Insufficient time 4 Instrume	ent failure 5 N	lot required

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



**PAGEID** = 189

	Center Number: Participant N	lumber:	Participant's In	first middle last			
Eating Inventory (continued)							
19	Being with someone who is eating often makes me hung	•		□₀ False			
20	When I feel blue, I often overeat.	T		PE 4)PS  Gralse			
21	I enjoy eating too much to spoil it by counting calories or my weight.	watching	□₁ True	□₀ False			
22	When I see a real delicacy, I often get so hungry that I h right away.	ave to eat	□₁ True	□₀ False			
23	I often stop eating when I am not really full as a conscious limiting the amount I eat.	us means of	□₁ True	□₀ False			
24	I get so hungry that my stomach often seems like a botto	omless pit.	□₁ True	o False			
25	My weight has hardly changed at all in the last ten years	5.	□₁ True	□₀ False			
26	I am always hungry so it is hard for me to stop eating be the food on my plate.	efore I finish	□₁ True	□₀ False			
27	When I feel lonely, I console myself by eating.		□₁ True	□₀ False			
28	I consciously hold back at meals in order not to gain wei	ght.	□₁ True	o False			
29	I sometimes get very hungry late in the evening or at nig	ıht.	□₁ True	□₀ False			
30	I eat anything I want, any time I want.		□₁ True	o False			
31	Without even thinking about it, I take a long time to eat.		□₁ True	□₀ False			
32	I count calories as a conscious means of controlling my w	veight.	□₁ True	□₀ False			
33	I do not eat some foods because they make me fat.		□₁ True	□₀ False			
34	I am always hungry enough to eat at any time.		□₁ True	o False			
35	I pay a great deal of attention to changes in my figure.		□₁ True	□₀ False			
36	While on a diet, if I eat a food that is not allowed, I ofter eat other high calorie foods.	splurge and		o False			
	CALEDIE DHASE2 ANNOTATION V8 0 22	1EEB2012	Participant's Initials:				

# calerie Phase 2

## Month 12 Submission Visit 1

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	Center Number:	Participant Number:	Participant's Initials: first middle las			
Eat	ing Inventory (continued)					
Please check one answer that is most appropriate to you for each question below. TFEQB (TYPE 3)						
37	How often are you dieting in a conscious effort to control your weight?	ASPAGF662 Sometime	es 🗔 Usually 🖂 Always			
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	$\square_1$ Rarely $\square_2$ Sometime	as □₃ Usually □₄ Always			
39	How often do you feel hungry?	☐₁ Rarely ☐₂ Sometime	es 🔲 3 Usually 🔲 4 Always			
40	Do your feelings of guilt about overeating help you to control your food intake?	□₁ Rarely □₂ Sometime	es 🔲 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?	Easy  Moderately difficult	☐₂ Slightly difficult ☐₄ Very difficult			
42	How conscious are you of what you are eating?	Not at all Moderately	□ <sub>2</sub> Slightly □ <sub>4</sub> Extremely			
43	How frequently do you avoid "stocking up on tempting foods?	o" □₁ Almost never □₃ Usually	□₂ Seldom □₄ Almost always			
44	How likely are you to shop for low calorie foods?	□₁ Unlikely □₃ Moderately likely	□ <sub>2</sub> Slightly likely □ <sub>4</sub> Very likely			
45	Do you eat sensibly in front of others and splurge alone?	□₁ Never □₂ Rarely [	3 Often			
46	How likely are you to consciously eat slow in order to cut down on how much you eat	ly □₁ Unlikely ? □₃ Moderately likely	□₂ Slightly likely □₄ Very likely			
47	How frequently do you skip dessert because you are no longer hungry?	se □₁ Almost never □₃ At least once a week	□₂ Seldom □₄ Almost every day			
48	How likely are you to consciously eat less than you want?	□₁ Unlikely □₃ Moderately likely	□ <sub>2</sub> Slightly likely □ <sub>4</sub> Very likely			
49	Do you go on eating binges though you are not hungry?	re Never	2 Rarely 4 At least once a week			
50	To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I wa promising myself to start dieting again tomorrow."	☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of me ☐₄ Describes me perfectly				
51	On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself?	o Eat whatever you want, whenever you want it usually eat whatever you want, whenever you want it often eat whatever you want, whenever you want it often limit food intake, but often "give in" usually limit food intake, rarely "give in" often limit food intake, rarely "give in" often limit food intake, rarely "give in"				

Participant's Initials: first middle last

Durham NC 27705



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	Center N	Center Number: Participant Number:		Participant's Ir	nitials:
Date completed:	_/		Specify reason (use codelise	st below): DATEHDR (	TYPE 4)

#### 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. SAME AS PAGE 63 WELQ (TYPE 4)PS

I am confident that:		Not confident at all that you can resist the desire to eat					<b>Very confident</b> 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).	□₀			3	_4	5	□ <sub>6</sub>		□ <sub>8</sub>				
2	I can control my eating on the weekends.	$\square_{o}$			З	$\square_{4}$	$\square_5$	□ <sub>6</sub>	_ <sub>7</sub>	□8	□ <sub>9</sub>			
3	I can resist eating even when I have to say "no" to others.	По			$\square_3$	4		6		□ <sub>8</sub>	□ <sub>9</sub>			
4	I can resist eating when I feel physically run down.	□₀			$\square_3$	$\square_{4}$				□,8				
5	I can resist eating when I am watching TV.				З	4		6		□ <sub>8</sub>				
6	I can resist eating when I am depressed (or down).	$\square_{o}$			$\square_3$	$\square_{4}$	$\square_{5}$	6	_ <sub>7</sub>	□8				
7	I can resist eating when there are many different kinds of food available.	□₀			З	4		□ <sub>6</sub>		□,	□ <sub>9</sub>			
8	I can resist eating even when I feel it is impolite to refuse a second helping.				$\square_3$	_4		□ <sub>6</sub>		□ <sub>8</sub>	□,			
9	I can resist eating even when I have a headache.													
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time				nt time	1 Inc	trumant	failure	5 Not	t required					

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Participant's Initials:



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	Center Number:	_	Particip	ant Num	nber:			Particip	ant's Initi	ials:	middle fast
Weight Efficacy Lifestyle	Questionnaire	<b>)</b> (W	EL) (co	ntinued	1)						
I am confident that:	NGE 64 y			<b>nt</b> at a t the de	ll that esire to	eat	-	u can r	Very co	desire	
		0	1	2	3	4	VVEL 5	<b>6</b> (1	YPE 7	4)PS 8	9
10 I can resist eating when I am	reading.	$\Box_{\circ}$			Пз		$\square_5$	□ <sub>6</sub>	$\square_7$	□ <sub>8</sub>	□,
11   can resist eating when I am (or irritable).	angry				Пз		5			□8	
12 I can resist eating even when a party.	I am at		$\square_1$		$\square_3$	$\square_{4}$	$\square_5$	6		□,	
13 I can resist eating even when pressuring me to eat.	others are	$\Box_{o}$			Пз	_4				□,	
14 I can resist eating when I am	in pain.	$\Box_{\circ}$			$\square_3$	$\square_{4}$	$\square_5$	□ <sub>6</sub>	$\square_{7}$	□,	9
15 I can resist eating just before bed.	going to	$\Box_{\circ}$			З	4	5			□ <sub>8</sub>	
16 I can resist eating when I have experienced failure.	<b>′e</b>	$\Box_{o}$				$\Box_{4}$	□ <sub>5</sub>	6			□ <u>,</u>
17 I can resist eating when high- are available.	calorie foods	o				4		6		□ <sub>8</sub>	
18 I can resist eating even when others will be upset if I don't		$\Box_{\circ}$						6		□8	
19 I can resist eating when I feel uncomfortable.						4		□ <sub>6</sub>		□ <sub>8</sub>	
20 I can resist eating when I am	happy.										

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Participant's Initials: first middle last



PAGEID = 193	Number: Participa	nt Numbe	er:		Partici	oant's Ini	tials:	
Date completed:/	SAME AS PAGE 3 OR Not done → Specify		luse code	DA	<b>ATFHI</b>			
				IV	IAED	S (TY	'PE 4	)PS
Multiaxial Assessment of Eating Instructions: Using the scale shown, please rate the					vor as tri	بالدالد	as nossi	blo
SAME AS PA		Never	Very	Rarely	Some-	Often		Always
			Rarely		times		Often	
1 Fasting is a good way to lose weight		Ш	2	<u>3</u>	4	<u></u> 5	<u></u>	<u></u>
2 My sleep isn't as good as it used to l	oe.			3	4	5	6	7
3 I avoid eating for as long as I can.				$\square_3$	4		G	
4 Certain foods are "forbidden" for m	e to eat.	$\square_1$		$\square_3$	$\square_{4}$	$\square_5$	6	
5 I can't keep certain foods in my house binge on them.	because I will			Пз	4		6	
6 I can easily make myself vomit.				$\square_3$	$\square_{4}$	$\square_5$		
7 I can feel that being fat is terrible.				Пз		5	6	
8 I avoid greasy foods.				$\square_3$	$\square_{4}$	$\square_{5}$		
9 It's okay to binge and purge once in	a while.			$\square_3$	4	5	6	
10 I don't eat certain foods.				Пз			6	
11 I think I am a good person.						5	□ <sub>6</sub>	
12 My eating is normal.				Пз			□₀	
13 I can't seem to concentrate lately.				Пз		5	6	
14 I try to diet by fasting.				Пз		5	6	
15 I vomit to control my weight.				З	4	5	6	
16 Lately nothing seems enjoyable any	nore.			З			6	
17 Laxatives help keep you slim.				Пз		5	6	
18 I don't eat red meat.				Пз			6	
19 I eat so rapidly I can't even taste my	food.			З	□ <sub>4</sub>		□ <sub>6</sub>	
Not Done Codelist: 1 Participant refused 2 Clinici	an unable to obtain 3 In:	sufficient	time 4	Instrume	nt failure	5 No	t require	d

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PAGEID = 194

MAEDS (TYPE 4)PS

Center Number: Par	ticipant N	umber: _		Pa	rtiapant's	Initials:	irst middle last
Multiaxial Assessment of Eating Disorder Sy	mpto	ms (	MAEDS)	(continue	ed)		
SAME AS PAGE 66	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being overweight.						□,	
21 When I feel bloated, I must do something to rid myself of that feeling.				□₄		□6	□ <sub>7</sub>
22 I overeat too frequently.						6	
23 It's okay to be overweight.			$\square_3$			6	$\square_{7}$
24 Recently I have felt that I am a worthless person.			Пз			6	
25 I would be very upset if I gained 2 pounds.			Пз			□,	
26 I crave sweets and carbohydrates.					5	6	
27 I lose control when I eat.			Пз		5	□6	
28 Being fat would be terrible.			3		5	6	
29 I have thought seriously about suicide lately.			Пз	□₄		□6	
30 I don't have any energy anymore.						6	
31 I eat small portions to control my weight.			Пз	□₄		□,	
32 l eat 3 meals a day.			3		5	□6	
33 Lately I have been easily irritated.			Пз			6	
34 Some foods should be totally avoided.			3		5	6	
35 I use laxatives to control my weight.			Пз			6	
36 I am terrified by the thought of being overweight.			3			□,	
37 Purging is a good way to lose weight.			Пз			□6	
38 I avoid fatty foods.					5	□6	
CALERIE PHASE2 ANNOTATION \	/8.0 24	FEB20	12	Po	rticipant's	Initials:	first middle last



# Month 12 Submission

MAEDS (TYPE 4)PS

**PAGEID** = 195

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

Multiaxial Assessment of Eating Disorder Sy	mpto	ms (	MAEDS) (	continue	d)		is side to
SAME AS PAGE 67	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.			]3		5	6	
40 I am obsessed with becoming overweight.	П		З			6	
41 I don't eat fried foods.	П		3			6	
42 I skip meals.	□₁		Пз	□₄	5	_6	
43 Fat people are unhappy.			_3	<b>□</b> ₄	5	6	
44 People are too concerned with the way I eat.			Пз	□₄	5	□6	
45 I feel good when I skip meals.			_3	□ <sub>4</sub>	5	6	
46 I avoid foods with sugar.			Пз		5	_6	
47 I hate it when I feel fat.			_3	4	5	6	
48 I am too fat.			_3	$\square_{4}$	5	_6	
49 I eat until I am completely stuffed.			_3	_4	5	6	
50 I hate to eat.	□₁		Пз	□₄	5	□6	
51 I feel guilty about a lot of things these days.			Пз	4	5	6	
52 I'm very careful of what I eat.			Пз	□₄	5	□6	
53 I can "hold off" and not eat even if I am hungry.			Пз	□₄	5		
54 I eat even when I am not hungry.			Пз	□₄	$\square_{5}$		
55 Fat people are disgusting.			З			□ <sub>6</sub>	
56 I wouldn't mind gaining a few pounds.			Пз		5		

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# Month 12 Submission

	10717					Vi	sit 1
Р	AGEID = 196  Center Number: Participant N	Number: _		Par	ticipant's I	nitials:	middle last
Da	te completed:/OR Not done → Specify re SAME AS PAGE 36	<b>ason</b> (use	codelist b	DATE	HDR (	TYPE	4)
В	ody Shape Questionnaire (BSQ)						
	would like to know how you have been feeling about your appearance or ase read each question and check the box for the appropriate choice. Plea					YPE 4	)PS
Ov	er the Past Four Weeks SAME AS PAGE 68	Never	Rarely	Some- times	Often	Very Often	Always
1	Has feeling bored made you brood about your shape?			З			□ <sub>6</sub>
2	Have you been so worried about your shape that you have been feeling that you ought to diet?			$\square_3$	□₄		□,
3	Have you thought that your thighs, hips, or bottom are too large for the rest of you?			3			□ <sub>6</sub>
4	Have you been afraid that you might become fat (or fatter)?			$\square_3$			
5	Have you worried about your flesh not being firm enough?			З	□₄		□ <sub>6</sub>
6	Has feeling full (e.g., after eating a large meal) made you feel fat?			З	□₄		
7	Have you felt so bad about your shape that you have cried?			3	□₄		□6
8	Have you avoided running because your flesh might wobble?			Пз			
9	Has being with thin women/men made you feel self-conscious about your shape?			3	□₄		□6
10	Have you worried about your thighs spreading out when sitting down?			З	□₄		□,
11	Has eating even a small amount of food made you feel fat?						□ <sub>6</sub>
	Have you noticed the shape of other women/men and felt that your own shape compared unfavorably?			Пз			
13	Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)?				4		
14	Has being naked, such as when taking a bath, made you feel fat?			Пз			
15	Have you avoided wearing clothes which make you						

2 Clinician unable to obtain CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

5 Not required

4 Instrument failure

Not Done Codelist: 1 Participant refused

body?

particularly aware of the shape of your body? 16 Have you imagined cutting off fleshy areas of your

3 Insufficient time



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Center Number: \_\_\_ Participant Number: \_

 $\underset{\text{Participant's Initials:}}{\mathsf{BSQ}} \underbrace{(\mathsf{TYPE}\ 4)}_{\mathit{first}} \underbrace{\mathsf{niddlo}}_{\mathit{last}}$ 

Body Shape Questionnaire (BSQ) (continued)						
Over the Past Four Weeks SAME AS PAGE 69	Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?			Пз			□6
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?			□₃	□₄	$\square_5$	□6
19 Have you felt excessively large and rounded?			З	_4		6
20 Have you felt ashamed of your body?			□₃	□₄	5	□6
21 Has worry about your shape made you diet?				4		6
22 Have you felt happiest about your shape when your stomach has been empty?			□₃			□6
23 Have you thought that you are the shape you are because you lack self-control?			Пз	_4		6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?			□₃	□₄	$\square_{5}$	6
25 Have you felt that it is not fair that other women/men are thinner than you?			Пз	4		6
26 Have you vomited in order to feel thinner?			□₃	□₄	5	
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?			Пз	4		6
28 Have you worried about your flesh being dimply?			□₃		$\square_5$	_6
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?			З	4	5	□ <sub>6</sub>
30 Have you pinched areas of your body to see how much fat is there?			□₃	□₄	$\square_5$	□6
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?			□₃	4		□ <sub>6</sub>
32 Have you taken laxatives in order to feel thinner?			□₃	□₄	$\square_5$	6
33 Have you been particularly self-conscious about your shape when in the company of other people?			Пз			
34 Has worry about your shape made you feel you ought to exercise?						6

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Participant's Initials: first middle last



PAGEID = 198

		Center Number	: Participant Num	ber: Part	first middle last				
Hai	ndgrip Strength								
	and time of assessment: ot done → Specify reaso			Staff DATEHDF	initials:  R (TYPE 4)				
<b>1</b> D	ynometer handle positior	n:							
	ominant hand (check only andgrip strength:	one): 🔲 Left 🔲 Right		HANDGRIP (T	YPE 4)PS				
	Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand				
	Test 1—peak force		kg	$\Box$ °	kg				
	Test 2—peak force		kg	$\Box_{\circ}$	kg				
	Test 3—peak force		kg	$\Box_{o}$	kg				
Not D	ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required								



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			Center Number:	Participant 1	Number: _		Particip	oant's Initials: first middle last
ls	ometric/Isokinet	ic Knee	Extension and	Flexion	1			
	ite and time of assessment R Not done → Specify reas				2	DATEH		tials:
1 2 3	Recent injury or pain—rig Recent injury or pain—lef Specify machine used (PE	t knee?	SAME AS	PAGE 78			C (TY	PE 4)PS
	All values corrected	for gravity	y effect torque	Right	Leg	Left l	Leg	If Not Done, Specify Reason (Use codelist below)
3	60°/sec knee extension		peak torque		N.m	E 25 10	_ N.m	
			total work		N.m		_ N.m	
			average power		watts		_ watts	
4	$60^{\circ}/\text{sec}$ knee flexion		peak torque		N.m	-	_ N.m	
			total work		N.m		_ N.m	
			average power		_ watts	58 89 M	_ watts	
5	180°/sec knee extension		peak torque	<del>1100 - 100 </del>	N.m		_ N.m	
			total work		N.m	<del></del>	_ 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	<del>11 34 32</del>	_ N.m	u <del></del>
		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	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



PAGEID = 200

	Center Number:	Participant Number:	Participant's Initials:
Clinic Weight			
15 FF. 100 S	day /	: : : :	Staff initials:  DATEHDR (TYPE 4)
	ify reason (use codelist below): o measurements are more than 0.1 kg	apart, measure weight a third time):	5/11 Z 11 Z 17
Weight 1:	kg	SAME AS PAGE 4	WEIGHT (TYPE 4)
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Not Done Codelist: 1	Participant refused 2 Clinician unal	ble to obtain 3 Insufficient time	4 Instrument failure 5 Not required

Center Number:

Participant Number:

Participant's Initials: first middle last PARHDR (TYPE 4)

Very Hard

Mod.

Very Hard

PARCHT (TYPE 4)PS

Evening (in minutes) Hard

Affernoon (in minutes) Hard

Sun Sun

first middle last

Interviewer initials:

OR Not done → Specify reason (use codelist below):

Phase 2

calerie

Se	ven-L	Seven-Day Physical Activity Recall (PAR)	rity Reca	II (PAR)							
Tod	Today's date:		Day	Day (check only one): Mon Trues Wed Thurs Hri Sat Sun OR Not do	Mon Tue	es   wed	] Thurs	]Fri	at Sun	OR Not	용
_	Were yo	yed in the last sev	ın days?		² □	$\square_0 \text{ No} \rightarrow \text{Skip to question 3} \qquad \square_1 \text{ Yes}$	stion 3	, Yes			
ч		If Yes: Which days (check all that apply)?	٥.		Mon	Mon Tues Wed Thurs	/ved	$\Box$	E.	Sat	Sun
ಣ		Which days do you consider your weekend, or non-work, days?	veekend, or n	on-work, days?	Mon	☐ Tues	☐ wed	☐ Thurs	Ē.	Sat	Sun
Dav	Day of		Sleel	Sleep Time	Work	Work Time	Morr	Morning (in minutes)	notes)	Affernoc	۱ĕ۱
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	エ
yester.			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					PA
٧		day / north / year	0.00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					
ĸ			00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	69:82 P4 00:00					
4		yurou / kop	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		SAN	SAME AS PAGE 71	AGE 7	_
m		- doy / no.nth - / - 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					
7			00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					
(? week ago)	ی	day / north / 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					

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 ...... Not Done Codelist: 1 Participant refused

5 Not required

CRF, page 201



PAGEID = 202

	Center Number: Participant Number: Participant's Initials:
S	even-Day Physical Activity Recall (PAR) (continued)
4	Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?  More Less About the same  SAME AS PAGE 72
In 5	Were there any problems with the Seven-Day PAR interview?  \[ \bigcup_0 \text{No} \\ \bigcup_1 \text{Yes} \]
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?  \[ \bigcup_0 \text{ No} \\ \Bigcup_1 \text{ Yes} \]



# Month 12 Submission

PAGEID = 203

		Center Number:	Partic	cipant Number: Particip	pant's Initials:				
6-D	ay Food Record								
Com	Complete below OR Not done → Specify reason (use Codelist below): Staff initials:								
	SAME AS PAGE	73		Replacement Value					
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	FOODRCD (TYPE	Record Quality (check only one)				
1		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	8	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing				
2		☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	9	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing				
з	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	10	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing				
4	/	1 Reliable 2 Unreliable 3 Missing	11	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing				
5	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	12	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing				
6		1 Reliable 2 Unreliable 3 Missing	13	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing				
Not l	Done Codelist: 1 Participant refused	2 Clinician unable to ob	otain 3	Insufficient time 4 Instrument failure	5 Not required				



PAGEID = 204

		Center Number:	Participant Number: _	Participant's Initials: first middle last			
V	O <sub>2</sub> Max						
1	Date and time of test:/	SAME AS PAGE		DATEHDR (TYPE 4) Staff initials: first middle last			
	OR Not done → Specify reason (use a			VOMAX (TYPE 3)			
2	At what time was the participant's las	st meal/snack eaten?	00:00 to 23:59				
3	Rest ECG: Rhythm (check only one):  Ventricular conduction (che	$\square_1$ Sinus	a Atrial fibrillatio	on			
4	Heart rate (HR) data: Resting heart ra Age-predicted heart rate (max	neart rate:	bpm				
5	Reason(s) for termination of testing (c  Symptom limited (dyspnea, fatigue)  Angina/ischemia → Complete all th  Serious arrhythmias (VT or SVT)  Changes in blood pressure  Ventricular ischemia (schedule stress ii  Orthopedic/extremity complaints (pai	nat apply: HR when tru HR when isc mage study, complete ven ins/cramps)	nemic ECG changes oc	rred:bpm OR <sub>96</sub> NA ccurred:bpm OR <sub>96</sub> NA			
6	Did frequent ventricular ectopy occur  □₀ No □₁ Yes → If Yes: When did it occur (c	(e.g., ≥ 7 PVCs/min, bi/tr					
7	<b>Peak VO<sub>2</sub>:</b> mL/kg/min	L/min					
8	Did the participant meet at least 2 of  □ <sub>0</sub> No □ <sub>1</sub> Yes → If Yes: VO <sub>2</sub> max:  Exercise time:	_	ь ь R	Achieve a plateau in $VO_2$ (change $\leq$ 150 mL) between the final two stages $ER \geq 1.1$ kR $\max \pm 5$ bpm of age-predicted maximum			
10	9 Exercise time::: : :						
11	Borg RPE score at VO <sub>2</sub> peak/VO <sub>2</sub> max	<b>x:</b> (6-20)					
12	2 Peak RER:						
13	3 VE at VO <sub>2</sub> peak/VO <sub>2</sub> max:	L/min					
14	VE/VO <sub>2</sub> at VO <sub>2</sub> peak/VO <sub>2</sub> 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

# Month 12 Submission Visit 3

PAGEID = 205

	Center Number: Po	rticipant Number: Partici	pant's Initials: first middle las
Core Temp	erature		
Staff Initials	Provide Date of Sample Collection/Procedure	Time of Sample Collection/Procedure	If Not Done, Reason (Use codelist below)
		ADMIT (TYPE 3)	
	Start Date:	Start Time	
	/		AS PAGE 87
first middle last	Stop Date:	Stop Time	Ī
	/		
Inpatient A	Admission and Discharge		
1 Inpatient adr	mission date and time:/		
2 Inpatient disc	charge date and time://	00:00 to 23:59	

3 Insufficient time

4 Instrument failure

5 Not required

2 Clinician unable to obtain



PAGEID = 206

			Center Nun	nber: Pa	rticipant Numbe	r:	Participant's Initial	first middle last
D	elay	ed-type Hypers	<b>ensitivity</b> (D	тн)				
1	□₀ 1	the DTH worksheet compl No ′es → If Yes: Were any Exc		of? $\Box_0$ No → Pro $\Box_1$ Yes → STC	oceed with te DP. Do not ad	st	M1 (TYPE 3	)
2	Date	of injection:/ <sub>mon</sub>	/	_ OR Not done →	Specify reasor	(use codelist below):	_	
3	Inject	tion by (initials): first middle lost		SAME AS PA	GE 85			
4	Arm	injected: □1 Right □2 L	eft					
5	Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm.  A = Largest diameter  DTHADM2 (TYPE 4)PS  B = Second diameter perpendicular to A						the long ive if the	
24 Hour (@ Visit 4) 48 Hour (@ Vis					Hour (@ Visit 5)			
		Antigen	A (diameter)	B (diameter)	Read By:	A (diameter)	B (diameter)	Read By:
	1	Normal saline	mm	mm		mm	mm	
	2	Tetanus toxoid (TT) (check only one):	mm	mm		mm	mm	
	3	Candida (check only one):	mm	mm	first middle last (initials)	mm	mm	first middle test (initials)
	4	Trichophyton (check only one):  1 Trichophyton Allergic Extract (AllerMed)  98 Other: Lot #:	mm	mm		mm	mm	

5 Not required

nt failure

Not Done Codelist: 1 Particip



PAGEID = 207

	Center Number:	Participant Number:	Particip	pant's Initials:				
Clinic Weight								
Weight date and time:/								
OR Not done → Specify reason (use codelist below): DATEHDR (TYPE 4)								
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):								
Weight 1:	kg	SAME AS PAGE 4	WEIGHT (	TYPE 4)				
Weight 2:	kg							
Weight 3:	TO PAGE 207A							
Weight of gown: kg								
Outcomes Labs								
Date and time of last meal:/month /OUTCMELB (TYPE 4)PS								
Date and time sample collection started:/								
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials				
Са	techolamines	□ <sub>0</sub> No □ <sub>1</sub> Yes		first middle last				
	Blood	□ <sub>0</sub> No □ <sub>1</sub> Yes						
Oral glucose tolerance test (OGTT)  Ono  In Yes  In This middle lost								
If a sample is not obtained, indicate with a Not Done.								
24-hour Urine (	Collection							
Total Volume	Date of	Time of	If Not Don Reason	Staff Initials				
Collected	Sample Collection	Sample Collection	(Use codelist b	elow)				
	Start Date:	Start Time:	`	PAGE 90				
	/	:: _	OAIVIE AO	TAGE 30				
mL	Stop Date:	Stop Time:		first middle last				
	/	:::						
	CALERIE PHASE2 ANN	OTATION V8.0.24FFR	2012					
Not Done Codelist: 1 Pa	rticipant retused 2 Clinician unab			5 Not required				



PAGEID = 207A

Layout of data entry screen has changes also Center Number: \_\_\_ Participant Number: \_\_\_ \_\_

AGEID = 207A	•	Number: Participant Number	•	Participant's Initio	first middle last
Sex Hormone					
If Not Done → Specify reason (use code	list below)	:	DATEHI	OR (TYPE	4)
Contraception method (females only):		None OR Check all that apply:		2 (TYPE 4	1)
SAME AS PAGE S	AOA	Oral contraceptive		ncomitant Medic	ations page
ON WE NOT NOT	7071	☐ Other → Specify			
Day 1		Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Day 1 of menses (females enly)					
Date and time of last meal <b>(males only</b>	1)	/	00:00 to 23:59		
Hormone level blood draw 1 (males or	nly)	/	00:00 to 23:59		first middle last
Hormone level blood draw 2 (females of Progesterane level	only)				
Day 2		Date	Time	If Not Done, Reason (use codelist)	Staff Initials
Date and time of last meal					
Hormone level blood draw 3 (females of Progesterone level	o <del>nly)</del>				
Metabolic Rate					
Sample		Date of Collection	If Not Done, R (Use codelist be	elow)	f Initials
Resting Metabolic Rate (RMR)—Visit 4	_			YPE 4)PS S PAGE 153	middle last
Cart ID		-003 (623-002)		PBRC-016 (623 PBRC-017 (623	•
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	me <b>4</b> Instrument	failure 5 Not	required

PARHDR (TYPE 4) first middle last

Participant Number:

Center Number:

**Calerie** Phase 2 PAGEID = 208

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Se	ven-D	Seven-Day Physical Activity Recal	rity Reca	II (PAR)											
Tod	Today's date:	////////	Day	Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Tue	es Wed	] Thurs	Fri S	at Sun	OR No	t done →	Specify re	esn) uosp	odelist beld	w):
-	Were yo	oyed in the last sev	ən days?		² □	$\square_0 \ No \to Skip \ to \ question \ 3 \qquad \square_1 \ Yes$	stion 3	, Yes				Intervi	Interviewer initials:		first middle last
8	If Yes: W	If Yes: Which days (check all that appty)?	۵.		Mon	Mon Tues Wed Thurs Fri	Wed	Thurs		Sat Sun	Sun				
က	Which d	Which days do you consider your weekend, or non-work, days?	veekend, or n	on-work, days?		Mon Tues Wed Thurs Fri	Wed	Thurs	닏	Sat	Sun				
200	Day of		Slee	Sleep Time	Work	Work Time	Morn	Morning (in minutes)	nutes)	After	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	utes)
#	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
<b>7</b> (yester- dαy)		day / month / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59					PAR	SCHT (	PARCHT (TYPE 4)PS	4)PS	
v		day / mosth / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
rų.		day / month / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
4		day / month / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59			SAME	SAME AS PAGE 71	E 71				
м			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									
71		day / month year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
() week	- J	day / mouth / year	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00.00 to 23:59									

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

5 Not required



**PAGEID = 209** 

	Center Number: Participant Number: Participant's Initials:
S	even-Day Physical Activity Recall (PAR) (continued)
4	Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?  PARQ (TYPE 4)  About the same  SAME AS PAGE 72
In	aterviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview?  One No  Types
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



**PAGEID = 210** 

	Center Number: Participant Number: _	Particip	oant'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

SAME AS PAGE 90

**BIOPSY (TYPE 4)** 



# Month 18 Submission Month 17 Visit

PAGEID = 211

	Center Number: Po	articipant Number:	Participant's Initials	first middle last
Clinic Weight				
Weight date and time:	//	_	Staff initials: first mid	ddle last
	y reason (use codelist below):		EHDR (TYPE	
Clinic weight (if the two i	measurements are more than 0.1 kg apart, measur SAN	e weight a third time): NE AS PAGE 4		
Weight 1:	kg	\A/ <b>-</b> 1		4\
Weight 2:	kg	VVEI	GHT (TYPE 4	+)
Weight 3:	kg			
Weight of gown:	kg			
Pregnancy Tes	<u>t</u>			
$\square_0$ No $\square_1$ Yes $\rightarrow$ If Yes: Do	males.  Ive reproductive potential?  ate urine pregnancy test performed:/_  esults:1 Negative	/	T (TYPE 4)	
Outcomes Lab	s	CANA	E AS PAGE 33	
Date and time sample o	collection started:/ <sub>month</sub> / <sub>year</sub>	<u> </u>		4)PS
<b>Sample</b> If a sample is not obtained, indicate with a Not Done.	Sample Comple	te?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□₀ No □₁ Yes	SAME AS PAGE	102	first middle last
note: Ba	Vaccine Administration  efore any vaccine is administered, review the vaccin  and protocol for participant eligibility.	ne questionnaire	If Not Done, SAM <b>E 973 97</b> AGE (Use codelist below)	Staff <sup>9</sup> Initials
Vaccine(s) given (check all that apply):  TD <xye< td=""><td>Dose (check one): 1 Adult</td><td>ck)  IEPSPEC V:30 </td><td>UHDOS&gt;</td><td></td></xye<>	Dose (check one): 1 Adult	ck)  IEPSPEC V:30	UHDOS>	
ID <xye< td=""><td>Tetanus/diphtheria → Check one: □<sub>1</sub> De</td><td>covac (Sanofi-Pasteur) TETVAC her: <u>TETSPEC V:30</u></td><td>∢TUT<del>VAC&gt;</del></td><td>first middle last</td></xye<>	Tetanus/diphtheria → Check one: □ <sub>1</sub> De	covac (Sanofi-Pasteur) TETVAC her: <u>TETSPEC V:30</u>	∢TUT <del>VAC&gt;</del>	first middle last
PV <xy DO NOT DISPLAY LMEALDT LMEALTI</xy 	Pneumococcal vaccine → Check one: □1 □98			



**PAGEID = 212** 

		Center Number:	Participant Number:	Participant's Initials: first middle last
C	linic Weight			
W	eight date and time:/ <sub>mor</sub>	/	: 22.50	Staff initials:
	R Not done → Specify reason (use			ATEHDR (TYPE 4)
Cli	nic weight (if the first two measureme	ents are more than 0.1 kg ap	part, measure weight a third time):	
W	eight 1:	kg	SAME AS PAGE 4	
W	eight 2:	kg	V	/EIGHT (TYPE 4)
W	eight 3:	kg		
W	eight of gown:	. · kg		
V	ital Signs			
As	sessment date and time:/_	month year	00:00 to 23:59	
	If waist measurement not done -	→ Specify reason (use code	ist below):	VITALS (TYPE 3)
1	Natural waist measurement (if the first two measurements are more	than 1.0 cm apart, measure n	natural waist circumference a third time):	Staff initials:
	Natural waist measurement 1:		SAME AS PA	GE 29
	Natural waist measurement 2:	·_	_ cm	
	Natural waist measurement 3:		_ cm	
2	Umbilical point waist measurement umbilical point waist circumference a th		s are more than 1.0 cm apart, measure	
	Umbilical point waist measureme	ent 1:	cm	
	Umbilical point waist measureme	ent 2:	_ cm	
	Umbilical point waist measureme	ent 3:	_ cm	
3	Pulse: bpm OR No	t done → Specify reason	(use codelist below):	Staff initials: first middle last
4	Temperature:	°C OR Not done → Speci	ify reason (use codelist below):	Staff initials: first middle last
5	Respirations: per minute	OR Not done → Specify	y reason (use codelist below):	Staff initials: first middle last
6	Blood pressure (check only one):		rm	Staff initials:
	<b>6a</b> Blood pressure 1:	./ mm Hg Tim	e:: OR Not done Specify red	→ ason (use codelist below):
	6b Blood pressure 2:systolic	./ mm Hg Tim	<b>е:</b> :	
	<b>6c</b> Blood pressure 3:	/ mm Hg <b>Tim</b>	e::::	
No	ot Done Codelist: 1 Participant refus	ed 2 Clinician unable to	obtain 3 Insufficient time 4 Inst	rument failure 5 Not required



**PAGEID** = 213

Center	Number:	Participant N	Number: _	Par	ticipant's Initio	first middle last
12-Lead ECG						
Date and Time			Findin	95 ECG (TYP	E 4)	Staff Initials
DATEHDR (TYPE 4)  ———————————————————————————————————	□ <sub>1</sub> No □ <sub>2</sub> Abr	normal, not clinical	lly signific	ME AS PAGE 3 ant (specify):		first middle last
Date and time of last meal:						
Date and time of sample collection:/						
Sample	Sample	Complete?		Done, Reason codelist below)	Staff	Initials
Blood	□₀ No □₁ Yes			SAM <b>E</b> 	AS PAG	E 30
Urine	□₀ No □₁ Yes				first m	iddle fast
Outcomes Labs						
Date and time of last meal:	//	year	00:00 to 23:		B (TYP	E 4)PS
	// month		00:00 to 23:		S PAGE	
Sample		Sample Com	plete?	If Not Done, Reason (Use codelist belov	I .	if Initials
Blood		□ <sub>0</sub> No □ <sub>1</sub> Yes			first	middle last
If a sample is not obtained, indicate with a Not Done.						

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



PAGEID = 214

		Center Number:	Participant Number: Participant's Initials: first middle last						
D	oubly Labeled V	<b>Vater</b> (DLW)							
1	Date and time of DLW d	osing:/ <sub>month</sub> /	DLWHDR (TYPE 4)						
	OR Not done $\rightarrow$ Specify	reason (use codelist below): _							
2	DLW dose mixture ID an	d bottle number:	CA						
3	Exact weight of DLW mix	kture:(	SAME AS PAGE 114 grams						
4	Urine samples:		DLWCHT (TYPE 4)PS						
	Collection	Sample	Date and Time Collected						
	Pre dosing (PD)	PDa	/						
		PDb	/						
	Day 0 (Visit 1)	D0a	/						
		DOb	/						
	Day 7 (Visit 2)	D7a	/						
		D7b	/						
	Day 14 (Visit 4)	D14a	/						
		D14b	/						
5	Affix CRF page label(s) corresponding to this urine sample set:      Affix     Test Sample     Label Here     Label Here								
No	t Done Codelist: 1 Particip	pant refused 2 Clinician unal	ble to obtain 3 Insufficient time 4 Instrument failure 5 Not required						



# Month 18 Submission CR Visit 1

PAGEID = 215

	Center Number:	Participant Number:	Participant's Initials:	e last			
Pregnancy Test							
Complete only for females.		PREGTEST (TYPE 4)					
Does participant have reproductive potential?  □₀ No □₁ Yes → If Yes: Date urine pregnancy test performed: ————————————————————————————————————		/SAN	ME AS PAGE 33				
DXA Scan							
Has the participant taken a calcium	supplement today?	DXAS	CAN (TYPE 4)				
No □₁ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.							
	or radioisotopes performed	d within 4 weeks prior to the scheduled DXA exam?					
□ <sub>0</sub> No □ <sub>1</sub> Yes		SAME AS PAGE 35					
DXA Scan		DXA Resca	n OR □ <sub>96</sub> NA				
Date of scan:/	ar	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 bo	ody				
☐ Forearm		Forearm					
☐ Forearm		☐ Forearm					
Spine		Spine					



## Month 18 Submission CR Visit 2

**PAGEID = 216** 

Center	Number: Participant Number:	Participant's Initials: iniddle last
Clinic Weight		
Weight date and time:/ <sub>month</sub> /	gr 0000 to 23:59	Staff initials:
OR Not done → Specify reason (use Codelist belo		DATEHDR (TYPE 4)
Clinic weight (if the first two measurements are more  Weight 1: kg	than 0.1 kg apart, measure weight a third time): SAME AS PAGE 4	:
Weight 2:kg		WEIGHT (TYPE 4)
Weight 3:kg		
Weight of gown: kg		
Contraception		
If Not Done → Specify reason (use codelist below)	):	
Contraception method (females only):  SAME AS PAGE 95	_	ify: ord on Concomitant Medications page rier, IUD):
Not Done Codelist: 1 Participant refused 2 Clinic	cian unable to obtain 3 Insufficient time 4 I	nstrument failure 5 Not required

# CR Visit 2 Month 18 Submission

first middle last

Participant's Initials:

Participant Number:

### Day (check only one): Mon Tues Wed Thurs Fri Sat $\square_0 \ No \ ightharpoonup Skip to question 3 \qquad \square_1 \ Yes$ SAME Mod. Center Number: Wed Wed 00:00 to 23:59 00:00 % 23:59 00:00 to 23:59 00:00 to 23:59 \_\_\_\_\_\_Ines \_\_\_\_\_Ines Stop Work Time Mon Won 00:00 to 23:59 00:00 to 23:59 00:00 to 23:59 00:00 to 23:59 Start Which days do you consider your weekend, or non-work, days? 00:00 to 23:59 Ч Seven-Day Physical Activity Recall (PAR) 00:00 to 23:59 Bed calerie Phase 2 Were you employed in the last seven days? 므 year 2 If Yes: Which days (check all that apply)? year year year year Date month month Today's date: \_\_\_\_\_ PAGEID = 217 day day day day Day of Week

Day #

Very Hard

Mod.

Very Hard

Mod.

Very Hard

Hard

(TYPE|4)PS

PARCHT

S PAG

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59 00:00 to 23:59 00:00 to 23:59

00:00 to 23:59 00:00 to 23:59 00:00 to 23:59

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Evening (in minutes) Hard

Affernoon (in minutes) Hard

Sun

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☐ Thurs

Morning (in minutes)

first middle last

Interviewer initials:

☐ PARHDR (TYPE 4)

Sat Sat

Thurs Fri

Sun OR Not done → Specify reason (use codelist below): \_

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## Month 18 Submission CR Visit 2

**PAGEID** = 218

	Center Number: Participant Number: Participant's Initials:
S	even-Day Physical Activity Recall (PAR) (continued)
4	Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)?  PARQ (TYPE 4)  About the same  SAME AS PAGE 72
In	terviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview?
6	Do you think this was a valid Seven-Day PAR interview?
7	Were there any activities reported by the participant that you don't know how to classify? $\square_0$ No $\square_1$ Yes



**PAGEID = 219** 

Center Number: Participant			cipant Number: Particip	pant's Initials:	
6-D	ay Food Record				
Com	plete below OR Not done → Specif	<b>y reason</b> (use Codelist b	elow): _	Staff init	tials: First middle last
	SAME A	S PAGE 73		Replacement Value	
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	FOODRCD (TYPE	Record Quality (check only one)
1	/	1 Reliable 2 Unreliable 3 Missing	8	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing
2	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	9	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
3	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	10	/	☐ <sub>1</sub> Reliable ☐ <sub>2</sub> Unreliable ☐ <sub>3</sub> Missing
4	/	Reliable Danieliable Base 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 I	Done Codelist: 1 Participant refused	2 Clinician unable to ob	tain 3	Insufficient time 4 Instrument failure	5 Not required

# calerie Phase 2

# Month 18 Submission CR Visit 2/Control Visit

**PAGEID = 220** 

		Center Number:	Participant Number: _	Participant's Initials:
Da	te completed:/	OR Not done -	→ Specify reason (use PAGE 36	codelist below): DATEHDR (TYPE 4)
В	DI-II			
lna	pick out the one weeks, including	statement in each group that best	describes the way yo statement you have pi	group of statements carefully and then u have been feeling during the past two icked. Be sure that you check only one
1	Sadness:	□₀ I do not feel sad		BDIQ (TYPE 4)
		$\Box_1$ I feel sad much of the time $\Box_2$ I am sad all of the time $\Box_3$ I am so sad or unhappy the		SAME AS PAGE 39
2	Pessimism:	□₀ I am not discouraged abo □₁ I feel more discouraged abo □₂ I do not expect things to w □₃ I feel my future is hopeless	out my future than I work out for me	
3	Past failure:	□₀ I do not feel like a failure □₁ I have failed more than I s □₂ As I look back, I see a lot □₃ I feel I am a total failure a	of failures	
4	Loss of pleasure:	□₀ I get as much pleasure as □₁ I don't enjoy things as muc □₂ I get very little pleasure fro □₃ I can't get any pleasure fro	ch as I used to om the things I used	I to enjoy
5	Guilty feelings:	$\square_0$ I don't feel particularly gu $\square_1$ I feel guilty over many thin $\square_2$ I feel quite guilty most of the last $\square_3$ I feel guilty all of the time	igs I have done or	should have done
6	Punishment feelings:	$\square_0$ I don't feel I am being pur $\square_1$ I feel I may be punished $\square_2$ I expect to be punished $\square_3$ I feel I am being punished		
7	Self-dislike:	□₀ I feel the same about myse □₁ I have lost confidence in n □₂ I am disappointed in myse □₃ I dislike myself	nyself	

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2 Clinician unable to obtain

Participant's Initials: first middle last

.... NC 27705

5 Not required

4 Instrument failure

Not Done Codelist: 1 Participant refused

3 Insufficient time



**PAGEID = 221** 

		Center Number:	Participant Number:	Participant's Initials: middle last
ΒI	<b>DI-II</b> (continued)			
8	Self-criticalness:	$\square_1$ I am more critical o $\square_2$ I criticize myself for	plame myself more than use of myself than I used to be all of my faults everything bad that happe	ns
9	Suicidal thoughts or w	,	tilling myself but I would no nyself	BDIQ (TYPE 4) ot carry them out SAME AS PAGE 40
10	Crying:	$\Box_0$   don't cry any more $\Box_1$   cry more than   us $\Box_2$   cry over every little $\Box_3$   feel like crying, but	sed to e thing	
11	Agitation:	$\Box_1$ I feel more restless $\Box_2$ I am so restless or $\Box_2$	nd up or restless than usual or wound up than usual agitated that it's hard to sto agitated that I have to keep	
12	Loss of interest:	1 am less interested	est in other people or activ in other people or things t my interest in other people rested in anything	than before
13	Indecisiveness:		lt to make decisions than u r difficulty in making decis	
14	Worthlessness:		self as worthwhile and use ss as compared to other pe	
15	Loss of energy:			
	(	CALERIE PHASE2 ANNOTAT	ION V8.0 24FEB2012	Participant/s Initials



PAGEID = 222

	Center Number:	Participant Number:	Participant's Initials: initials: initials
BDI-II (continued)			
16 Changes in sleeping pattern:	□₀ I have not experience □₁ I sleep somewhat mo □₂ I sleep somewhat less □₃ I sleep a lot more tha □₄ I sleep a lot less than □₅ I sleep most of the do □₀ I wake up 1-2 hours	ore than usual s than usual n usual usual ay	BDIQ (TYPE 4)
17 Irritability:	$\square_0$ I am no more irritable $\square_1$ I am more irritable th $\square_2$ I am much more irrita $\square_3$ I am irritable all of th	an usual ıble than usual	SAME AS PAGE 41
18 Changes in appetite:	□₀ I have not experience □₁ My appetite is somew □₂ My appetite is somew □₃ My appetite is much □₄ My appetite is much □₅ I have no appetite at □₆ I crave food all of the	what less than usual what greater than usual less than before greater than usual all	petite
19 Concentration difficulty:	☐₀ I can concentrate as ☐₁ I can't concentrate as ☐₂ It's hard to keep my r ☐₃ I find I can't concentr	s well as usual mind on anything for very	y long
20 Tiredness or fatigue:	$\square_0$ I am no more tired or $\square_1$ I get more tired or fail $\square_2$ I am too tired or fatig $\square_3$ I am too tired or fatig	tigued more easily than u jued to do a lot of the thi	ings 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 intere $\square_3$ I have lost interest in	sex than I used to be sted in sex now	iterest in sex

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Participant's Initials: first middle last



<b>D</b> A	$\sim$		000
$\mathbf{D}^{\Lambda}$		u ) _	
-	GE	_	

PAGEID = 223 Center Num	ber: Participa	nt Numbe	r:		Partici	pant's Ini	tials: _	
Data completed:	SAME AS PAGE : R Not done → Specify				(TYF	PE 4)	first	t middle fast
day month year				N	MAED:	S (TY	'PE 4	)PS
Multiaxial Assessment of Eating [	Disorder Sym <sub>l</sub>	ptom	S (MAE	DS)				
<b>Instructions:</b> Using the scale shown, please rate the fo	llowing items on a sca	le from 1	to 7. Ple				_	
SAME AS	PAGE 65	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose weight.				3	4	5	6	
2 My sleep isn't as good as it used to be.	,	1		3	4		6	
3 I avoid eating for as long as I can.				3	4		6	
4 Certain foods are "forbidden" for me to	o eat.			$\square_3$	$\square_{4}$	$\square_{5}$		$\square_{7}$
5 I can't keep certain foods in my house bed binge on them.	cause I will			$\square_3$			6	
6 I can easily make myself vomit.				$\square_3$	$\square_{4}$	$\square_5$	_6	□ <sub>7</sub>
7 I can feel that being fat is terrible.				3	4	5	6	
8 I avoid greasy foods.				$\square_3$	$\square_4$	5	6	$\square_{7}$
9 It's okay to binge and purge once in a	while.				4	5	6	
10 I don't eat certain foods.				$\square_3$	$\square_{4}$	5	6	
11 I think I am a good person.				3	4	5	6	
12 My eating is normal.				$\square_3$		5	6	
13 I can't seem to concentrate lately.				$\square_3$	4	5	6	
14 I try to diet by fasting.				$\square_3$	$\square_{4}$	5	6	
15 I vomit to control my weight.				3	4	5	6	
16 Lately nothing seems enjoyable anymo	re.			$\square_3$	$\square_{4}$	5	6	
17 Laxatives help keep you slim.				З		5	6	
18 I don't eat red meat.				Пз		5		
19 I eat so rapidly I can't even taste my fo	od.							
Not Done Codelist: 1 Participant refused 2 Clinician	unable to obtain 3 In	sufficient	time 4	Instrume	nt failure	5 No	t require	ıd

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	Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	rst middle last
Multiaxial Assessment of	<b>Eating Disorder</b>	Sympto	oms (	MAEDS)	(continue	d)		
		Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid	being overweight.				EDS (	TYPE	4)PS	
21 When I feel bloated, I must do of that feeling.	something to rid myse E AS PAGE 66	If					6	
22 I overeat too frequently.				3	□₄		6	
23 It's okay to be overweight.				Пз				
24 Recently I have felt that I am	a worthless person.			3			6	
25 I would be very upset if I gain	ned 2 pounds.			3	□₄		6	
26 I crave sweets and carbohyd	rates.			Пз	□₄		□ <sub>6</sub>	
27 I lose control when I eat.				З	□₄		□,	
28 Being fat would be terrible.				3	□₄		□ <sub>6</sub>	
29 I have thought seriously abou	ut suicide lately.			$\square_3$	□₄		6	
30 I don't have any energy anymo	ore.			3	□₄		□ <sub>6</sub>	
31 I eat small portions to control	my weight.			Пз	□₄		□,	
32 I eat 3 meals a day.				3			6	
33 Lately I have been easily irrit	ated.			_3	□₄		□,	7
34 Some foods should be totally	avoided.			$\square_3$			6	
35 I use laxatives to control my	weight.			$\square_3$			6	
36 I am terrified by the thought	of being overweight.			3	□₄		6	
37 Purging is a good way to lose	e weight.			3	□₄		6	
38 I avoid fatty foods.				3				

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Center Number:	Participant N	umber: _		Pa	rticipant's	Initials:	irst middle last
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued)							
	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.				MAE 4	DS (T □₅	YPE	4)PS
40 I am obsessed with becoming overweight.  SAME AS PAGE 67			З	□₄		□6	
41 I don't eat fried foods.			3	□₄		□ <sub>6</sub>	
42 I skip meals.			Пз	□₄		□6	
43 Fat people are unhappy.					5	6	
44 People are too concerned with the way I eat.			З	□₄	□₅	□6	
45 I feel good when I skip meals.			$\square_3$	□₄		6	
46 I avoid foods with sugar.			Пз	□₄		6	
47 I hate it when I feel fat.			Пз	□₄		□ <sub>6</sub>	
48 I am too fat.			Пз	□₄		□,	
49 I eat until I am completely stuffed.			З				
50 I hate to eat.			Пз	□₄	5	□ <sub>6</sub>	
51 I feel guilty about a lot of things these days.			3	□₄		□ <sub>6</sub>	
52 I'm very careful of what I eat.			□3	□₄			
53 I can "hold off" and not eat even if I am hungry.			Пз	□₄			
54 I eat even when I am not hungry.			Пз	□₄		6	
55 Fat people are disgusting.			З	□₄			
56 I wouldn't mind gaining a few pounds.			Пз	□₄			

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PAGEID = 226

	Center Number: Participant Number	: Рагпар	first middle last
Inpatient Admission and	Discharge		
1 Inpatient admission date and time:	day month year 00.00 to 23	ADMIT (TYP	Ξ 3)
2 Inpatient discharge date and time:	No Display SINTIALS, CT	STRDT, CTSTPDT,  GOVERNMENT  G	CTSTRTM, CTND
Clinic Weight			
Weight date and time:/ <sub>month</sub>	/	Staff init	ials:
OR Not done → Specify reason (use cod			
Clinic weight (if the two measurements are	more than 0.1 kg apart, measure weight a third i	time): DATEHDR (T	YPE 4)
Weight 1:	kg SAME AS PAGE 4	WEIGHT (T	YPE 4)
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Metabolic Rate			
Sample	Date of Collection	If Not Done, Reason (Use codelist below)	Staff Initials
Resting Metabolic Rate (RMR)—Visit 5	//	RMR (TYPE 4	
ADD CARTID TO RMR PANE	day //	E 153	first middle last
Cart ID	☐ Tufts-003 (623-002) ☐ WASH U-001	(623-003) PBRC-0	016 (623-005) 017 (623-001)
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Insufficient ti	me <b>4</b> Instrument failure	5 Not required

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# CR Visit 4 Month 18 Submission

PARHDR (TYPE 4) first middle last

Participant Number:

Center Number:

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0	,

Today's date:/	Were you employed in the last seven days?	2 If Yes: Which day	Jan Can and Jan Co	# Week	day)	,—/— <u>, —</u>	,	,—/———————————————————————————————————	3	<b>2</b>	(1 week
/	red in the last seve	If Yes: Which days (check all that apply)? Which days do you consider your weekend, or non-work, days?	loof longings of	Date	month /year	month year	month year	monthyear	month year	month year	month year
Day	ven days?	? veakand or no	Sleek	ln Bed	00:00 to 23:59	00:00 to 23:59	00:00 to 23.59	00:00 to 23.59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59
Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below): _		syork days	Sleep Time	Up	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00.00 to 23:59 00.00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59
Mon Tue	°Z □	Won Z	]	Start	00:00 to 23:59	00:00 % 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 % 23:59
Dew Se	$\square_0 \ No \to Skip$ to question 3 $\qquad \square_1 \ Yes$	Ues Lies	Time	Stop	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 to 23:59	00:00 % 23:59
] Thurs	stion 3	Wed Thurs	Morni	Mod.							
Fri Sat	n Yes	lhurs	기를	Hard				()			
Sun		iii C	4	Very Hard				SAME AS			
OR Not d			Afferno	Mod.				AS PAGE 71			
one → Sp		<u> </u>	Afternoon (in minutes)	Hard	PARC			. 71			
ecify rea:	Intervie		tes)	Very Hard	PARCHT (TYPE 4)PS						
o esn) uos	Interviewer initials:		Eveni	Mod.	ГҮРЕ						
odelist belov	als: first middle last		Evening (in minutes)	Hard	4)PS						
:( w	niddle I		rtes)	Very Hard							

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



#### Month 18 Submission CR Visit 4

PAGEID = 228

		Center Number:	Participant Number:	Participant's Initials:
S	even-Day Physical Activ	vity Recall (PAR)	continued)	
4	Compared to your physical activity or about the same (check only one)?	over the past three mon		l activity more, less, PARQ (TYPE 4)
ī	terviewer: Please answer questions	below and note any co	mments on interview.	
5	Were there any problems with the S $\square_0$ No $\square_1$ Yes	Seven-Day PAR interviev	v?	
6	Do you think this was a valid Seven  one No  one Tes	-Day PAR interview?		
7	Were there any activities reported by $\square_0$ No $\square_1$ Yes	by the participant that yo	ou don't know how to classif	·y?

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# Month 24 Submission Month 23 Visit

**PAGEID = 229** 

	Center Number: Participant Number:	Participant's Initi	als: first middle last
Clinic Weight			
Weight date and time: —	day month year 00:00 to 23:59	Staff initials:	middle last
	roman (usa asalalist balaus).	TEHDR (TYP	
Clinic weight (if the two me	asurements are more than 0.1 kg apart, measure weight a third time):	`	,
Weight 1:	SAME AS PAGE 4		
Weight 2:	kg WE	EIGHT (TYPE	4)
Weight 3:	kg		
Weight of gown:	kg		
<b>Pregnancy Test</b>			
Complete only for fem	ules.		
□ <sub>a</sub> No		EST (TYPE 4)	)
	e urine pregnancy test performed:/		
Kes	ults: □₁ Negative □₂ Positive SAM	ME AS PAGE 33	3
Outcomes Labs			
Date and time sample col	lection started:/	CMELB (TYP	E 4)PS
Sample If a sample is not obtained, indicate with a Not Done.	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials
Blood	□₀ No □₁ Yes		first middle last
NOTER	Vaccine Administration	If Not Done, AS Regson211	Staff
NOTE: Before	e any vaccine is administered, review the vaccine questionnaire  and protocol for participant eligibility.	(Use codelist below)	Initials
Vaccine(s) given (check all that apply):	Hepatitis A → Check one: ☐1 Havrix (GSK) ☐2 Vaqta (Merck) ☐98 Other:		first middle last
	Dose (check one): 1 Adult 2 Pediatric HEPDO	S <tuhdos></tuhdos>	
Not Done Codelist: 1 Par	icipant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrur	ment failure 5 Not	required
25.2.5.5.5.5.6.6.6.6.6.6.6.6.6.6.6.6.6.6	Vaccine Display same as page 211 and N Display: TD PV		1
	·		

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012



PAGEID = 230

	Center Number: Participant Number:	Participant's Initials:
Cl	Clinic Weight	
w	Weight date and time:/	Staff initials:  first middle last
	OR Not done → Specify reason (use Codelist below):	DATEHDR (TYPE 4)
Cli	Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a thir	d time):
w	Weight 1: kg SAME AS PAGE	4
W	Weight 2:kg	WEIGHT (TYPE 4)
W	Weight 3: kg	
W	Weight of gown: kg	
٧	Vital Signs	
As	Assessment date and time://	
Г	If waist measurement not done → Specify reason (use codelist below):	VITALS (TYPE 3)
ין	Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a	third time): Staff initials:
	Natural waist measurement 1: cm SAME	AS PAGE 29
	Natural waist measurement 2: cm	
	Natural waist measurement 3: cm	
2	2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apar umbilical point waist circumference a third time):	t, measure
	Umbilical point waist measurement 1: cm	
	Umbilical point waist measurement 2: cm	
	Umbilical point waist measurement 3: cm	
3	3 Pulse: bpm OR Not done → Specify reason (use codelist below):	Staff initials:
4	<b>1</b> Temperature: °C OR Not done → Specify reason (use codelist below):	Staff initials: first middle last
5	5 Respirations: per minute OR Not done → Specify reason (use codelist below):	Staff initials: first middle last
6	<b>5 Blood pressure</b> (check only one): $\square_1$ Left arm $\square_2$ Right arm	Staff initials: first middle last
	<b>6a</b> Blood pressure 1:/ mm Hg Time:: OR N	ot done → pecify reason (use codelist below):
	<b>6b</b> Blood pressure 2:/ mm Hg Time:::	· · · · · · · · · · · · · · · · · · ·
	<b>6c</b> Blood pressure 3:/ mm Hg Time::: _	
No	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time	4 Instrument failure 5 Not required



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Center	Number: Participant	Number: Pa	rticipant's Initials: first middle last		
12-Lead ECG					
Date and Time		Findings ECG (TY	(PE 4) Staff Initials		
DATEHDR (TYPE 4)		SAME AS PAGE :  illy significant (specify):  significant (specify):	30		
Safety Labs					
Date and time of last meal: day /	neth year 00:00 to	SAFETY	LB (TYPE 4)		
Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Blood	□₀ No □₁ Yes	SAMI 	E AS PAGE 30		
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:/					
Not Done Codelist: 1 Participant refused 2 Clinic	ian unable to obtain 3 Insuf	ficient time 4 Instrument fail	ure 5 Not required		



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		Center Number:	Participant Number: Participant's Initials: first middle last					
D	oubly Labeled V	<b>V</b> ater (DLW)						
1	Date and time of DLW do	osing:/ <sub>month</sub> /	DLWHDR (TYPE 4)					
	OR Not done → Specify	reason (use codelist below):	_					
2	DLW dose mixture ID an	d bottle number:	CA					
3	Exact weight of DLW mix	dure:	SAME AS PAGE 114 grams					
4	Urine samples:		DLWCHT (TYPE 4)PS					
	Collection	Sample	Date and Time Collected					
	Pre dosing (PD)	PDa	/					
		PDb	/					
	Day 0 (Visit 1)	DOa	/					
		DOb	/					
	Day 7 (Visit 2)	D7a	/					
		D7b	/					
	Day 14 (Visit 4)	D14a	/					
		D14b	/					
5	5 Affix CRF page label(s) corresponding to this urine sample set:  Affix  Test Sample  Label Here  Label Here							
No	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required							

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	Center Nu	mber:	Participant Nu	mber: Participant's Initials:middle last			
Physical Examination							
Date of examination: $\{day}$ / $\{month}$ / $\{year}$ Staff initials: $\{fint}$ $middle$ $last$ OR Not done $\rightarrow$ Specify reason (use codelist below): SAME AS PAGE 32							
De la Carata de		Assessments	<b>3</b>	MAL			
Body System	Normal Abnormal		Not Done	If Abnormal or Not Done: Explain			
General appearance:		□₀→	□ <sub>97</sub> →	PEXAM (TYPE 4)PS			
2 Head, Ears, Eyes, Nose, Throat:		□₀→	□ <sub>97</sub> →	SAME AS PAGE 32			
3 Neck:		□₀→	□ <sub>97</sub> →				
4 Heart:		□₀→	□ <sub>97</sub> →				
5 Lungs:		□₀→	□ <sub>97</sub> →				
6 Abdomen:		□₀→	□ <sub>97</sub> →				
7 Lymph nodes:		□₀→	□ <sub>97</sub> →				
8 Extremities/Skin:		□₀→	□ <sub>97</sub> →				
9 Neurological:		□₀→	□ <sub>97</sub> →				
10 Musculoskeletal:	$\square_1$	□₀→	□ <sub>97</sub> →				
	Normal	Abnormal	Not Done*				
11 Genitourinary:		□₀→	□ <sub>97</sub> →				
12 Breast:	$\square_1$	□₀→	□ <sub>97</sub> →				
Physician's Signature							
Investigator:	signatu	ire		Date:/			
* Not done at this examination OR Referred	Not done at this examination OR Referred participant to primary care physician for exam.						

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2 Clinician unable to obtain

5 Not required

Not Done Codelist: 1 Participant refused

3 Insufficient time 4 Instrument failure



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	Center Number:	Participant Number: Participant's Initials:					
DXA Scan							
	Has the participant taken a calcium supplement today? DXASCAN (TYPE 4) □ No □ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center.						
Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam?  SAME AS PAGE 35							
DXA Scan		DXA Rescan OR					
Date of scan:/	_	Date of rescan:/					
Area Scanned Check all that apply	If Not Done, Reason (Use codelist below)	Area Scanned Check all that apply					
☐ Whole body		☐ Whole body					
Forearm		☐ Forearm					
☐ Spine		Spine					
☐ Hip		Hip					
Not Done Codelist: 1 Participant refused 2	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required						

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		Center Number:	Participant Number:		Participant's Ir	nitials: first middle last		
Da	te completed:/	OR Not done -	→ <b>Specify reason</b> (use PAGE 36	codelist belov	w): ATEHDR (	TYPE 4)		
R	AND SF-36							
In	Instructions: This survey asks for your views about your health. This information will help keep track of how well you are able to do your usual activities. Please answer every question by placing a check "X" in the appropriate box. If you are unsure about how to answer a question, give the best answer you can.  SAME AS PAGE 36							
1	In general, would you say your health is:		nt □₂ Very goo	d □₃ Go	ood 🔲 Fair	r 🔲 5 Poor		
2	Compared to one year ago, how would you rate your hed general now?	□₂ Somew □₃ About t □₃ Somew	etter now than 1 y hat better now tha he same hat worse now tha vorse now than 1 y	n 1 year ag un 1 year ag				
ty	e following items are about a pical day. Does your health no so, how much?		- 14	es, Limited A Lot	Yes, Limited A Little	No, Not Limited At All		
3	Vigorous activities, such a participating in strenuous spo		avy objects,					
4	Moderate activities, such o vacuum cleaner, bowling, or p	as moving a table, p olaying golf	oushing a			$\square_3$		
5	Lifting or carrying groceries					$\square_3$		
6	Climbing <b>several</b> flights of st	airs				3		
7	Climbing <b>one</b> flight of stairs					□ <sub>3</sub>		
8	Bending, kneeling or stooping	3				3		
9	Walking more than a mile					$\square_3$		
10	Walking several blocks					3		
11	Walking one block					3		
12	Bathing or dressing yourself				$\square_{2}$	3		
N	ot Done Codelist: 1 Participant refused	2 Clinician unable to obto	ain 3 Insufficient time	4 Instrume	ent failure 5 N	ot required		
	CALERI Send to DCRI For 24FEB2	E PHASEE2 ANNO 012	TATION V8.0		Participant's I	first middle fast		



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	Center Number:	Participant Number:	P	articipant's In	first middle last
Rand SF-36 (continued)					
During the past 4 weeks, have with your work or other regu		• -	RAND	SF2 (T	YPE 3)
physical health?	-	AS PAGE 37		Yes	No
13 Cut down on the amount	of time you spent on	work or other activi	ties		
14 Accomplished less than	you would like			$\square_1$	
15 Were limited in the <b>kind</b> o	of work or other activit	ries			
16 Had <b>difficulty</b> performing (for example, it took extra eff	-	tivities			
During the past 4 weeks, have		• •			
<b>problems</b> (such as feeling depre	-	•		Yes	No
17 Cut down on the amount of	of time you spent on w	ork or other activitie	s		
18 Accomplished less than yo	ou would like			$\square_1$	
19 Didn't do work or other ac	ctivities as <b>carefully</b> as	susual			
20 During the past 4 weeks, to problems interfered with y neighbors or groups?	-			<u> </u>	ntly derately e a bit
21 How much <b>bodily</b> pain ha	ve you had during the	past 4 weeks?		☐ <sub>1</sub> Non ☐ <sub>2</sub> Very ☐ <sub>3</sub> Mild ☐ <sub>4</sub> Mod ☐ <sub>5</sub> Seve	mild Jerate
22 During the past 4 weeks, he interfere with your normal and housework)?	•	ork outside the home			le bit derately e a bit
	ERIE PHASEE2 ANNO EB2012	TATION V8.0		articipant's In	first middle last



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	Center Number:				Parti	cipant's Initials	first middle last
RAND SF-36 (continued)							
These questions are about how y		-		-	-	-	
weeks. For each question, please been feeling.	•	<b>ne answer</b> : SAME AS P				i <b>y you nav</b> 3 (TYPE	
		All of the	Most of	A Good		A Little of	,
How much of the time during the past	4 weeks	Time	the Time	Bit of the Time	the Time	the Time	the Time
23 Did you feel full of pep?				З	4	5	□ <sub>6</sub>
24 Have you been a very nervous	s person?		$\square_{2}$	$\square_3$	$\square_{4}$	5	□ <sub>6</sub>
25 Have you felt so down in the conthing could cheer you up?	lumps that			З	_4	5	□ <sub>6</sub>
26 Have you felt calm and peaced	ful?		$\square_2$	$\square_3$	$\square_{4}$	$\square_5$	
27 Did you have a lot of energy?				$\square_3$	4	5	
28 Have you felt downhearted ar	nd blue?		$\square_{2}$	$\square_3$	$\square_{4}$	$\square_5$	
29 Did you feel worn out?				□₃	4		
30 Have you been a happy perso	n?			$\square_3$	$\square_{4}$	$\square_5$	
31. Did you feel tired?				□₃	4		
32 During the past 4 weeks, how m your physical health or emotio interfered with your social acti relatives, etc)?	nal probler	ns	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	ring stateme	nts for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33 I seem to get sick a little easier	than other	people.			З		
34 I am healthy as anybody I kno	ow.				$\square_3$		
35 I expect my health to get wors	e.				3		
36 My health is excellent.					Пз		$\square_5$

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Participant's Initials: first middle last



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٩GI	=ID = 238	Center Number:	_ Participant Number:	Participant's Initials: first middle las
Da	te completed:/ <sub>mon</sub>		e → Specify reason (use c S PAGE 36	odelist below): DATEHDR (TYPE 4)
В	DI-II			
Ins	pick out the one weeks, includin	e statement in each group that be	est describes the way you e statement you have pic	group of statements carefully and then have been feeling during the past two ked. Be sure that you check only one BDIQ (TYPE 4)
1	Sadness:	$\square_0$ I do not feel sad $\square_1$ I feel sad much of the tin $\square_2$ I am sad all of the time $\square_3$ I am so sad or unhappy		SAME AS PAGE 39
2	Pessimism:	$\square_0$ I am not discouraged at $\square_1$ I feel more discouraged at $\square_2$ I do not expect things to $\square_3$ I feel my future is hopele	about my future than I us work out for me	
3	Past failure:	<ul> <li>□₀ I do not feel like a failur</li> <li>□₁ I have failed more than</li> <li>□₂ As I look back, I see a I</li> <li>□₃ I feel I am a total failure</li> </ul>	l should have ot of failures	
4	Loss of pleasure:	□₀ I get as much pleasure of □₁ I don't enjoy things as n □₂ I get very little pleasure □₃ I can't get any pleasure	nuch as I used to from the things I used	to enjoy
5	Guilty feelings:	□₀ I don't feel particularly on the state of the land of the time. □₁ I feel guilty over many the land of the time. □₃ I feel guilty all of the time.	nings I have done or s f the time	hould have done
6	Punishment feelings:	□₀ I don't feel I am being p □₁ I feel I may be punished □₂ I expect to be punished □₃ I feel I am being punishe		
7	Self-dislike:	□₀ I feel the same about my □₁ I have lost confidence in □₂ I am disappointed in my □₃ I dislike myself	myself	
No	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable to c	btain 3 Insufficient time	4 Instrument failure 5 Not required
				Donat do mosto lotatolo.

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Participant's Initials:

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_	AGEID = 239		Center Number:	Participant Number:	Participant's Initials:
В	DI-II (continued)				
8	Self-criticalness:		] <sub>1</sub> I am more critical of ] <sub>2</sub> I criticize myself for	ame myself more than us myself than I used to be all of my faults verything bad that happe	
9	Suicidal thoughts		oldon't have any tho thave thoughts of ki thave thoughts of ki thave to kill myself if thave any thave any self if	lling myself but I would n yself	ot carry them out SAME AS PAGE 40
10	Crying:		oldon't cry any more than I use	ed to thing	
11	Agitation:		] <sub>1</sub> I feel more restless o ] <sub>2</sub> I am so restless or a	d up or restless than usual or wound up than usual gitated that it's hard to st gitated that I have to kee	
12	Loss of interest:		], I am less interested i	est in other people or action other people or things ny interest in other people ested in anything	than before
13	Indecisiveness:			t to make decisions than difficulty in making deci	
14	Worthlessness:			elf as worthwhile and use s as compared to other p	
15	Loss of energy:		] <sub>3</sub> I don't have enough	nan I used to have energy to do very much energy to do anything	Porticip cost/s laitivil.
		CALERIE PH	ASEE2 ANNOTATIO	N VO.U 24FEDZU12	Participant's Initials: first middle last

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	Center Number:	Participant Number:	Participant's Initials:
BDI-II (continued)			
16 Changes in sleeping pattern:	□₀ I have not experience □₁ I sleep somewhat mo □₂ I sleep somewhat less □₃ I sleep a lot more tha □₄I sleep a lot less than □₅ I sleep most of the do □₀ I wake up 1-2 hours	ore than usual s than usual n usual usual ay	BDIQ (TYPE 4)
17 Irritability:	$\square_0$ I am no more irritable $\square_1$ I am more irritable th $\square_2$ I am much more irrita $\square_3$ I am irritable all of th	an usual ıble than usual	SAME AS PAGE 41
18 Changes in appetite:	☐₀ I have not experience ☐₁ My appetite is somew ☐₂ My appetite is somew ☐₃ My appetite is much ☐₄ My appetite is much ☐₅ I have no appetite at ☐₀ I crave food all of the	what less than usual what greater than usual less than before greater than usual all	petite
19 Concentration difficulty:	$\square_0$   can concentrate as $\square_1$   can't concentrate as $\square_2$   It's hard to keep my r $\square_3$   find   can't concentr	s well as usual mind on anything for ver	ry long
20 Tiredness or fatigue:	$\square_0$   am no more tired or $\square_1$   get more tired or far $\square_2$   am too tired or fatig $\square_3$   am too tired or fatig	tigued more easily than jued to do a lot of the th	nings 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 intere $\square_3$ I have lost interest in	sex than I used to be sted in sex now	nterest in sex

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AGEID = 241	Center Number:	Participant Number:		Participant's Initials: first middle last		
Date completed:///_	OR Not dor	e → Specify re	ason (use codelist be	low):	T/DE //	
Profile of Mood States	SAIVIE F	AS PAGE 36		DATEHDR (	TYPE 4)	
Instructions: Please describe how	<b>you feel right now</b> by cl	necking one box	c for each of the w	ords listed below.		
Feeling	Not At All	A Little	Moderately	Quite A Bit	YPE 4)PS Extremely	
1 Friendly	SAME AS PA	GE 42			4	
2 Tense						
3 Angry						
4 Worn out						
5 Unhappy				$\square_3$	4	
6 Clear-headed	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_{4}$	
7 Lively	$\square_{o}$			$\square_3$	4	
8 Confused	$\Box_{o}$		$\square_{2}$	$\square_3$	4	
9 Sorry for things done				3	4	
10 Shaky				$\square_3$		
11 Listless				3		
12 Peeved	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_{4}$	
13 Considerate				$\square_3$	4	
14 Sad	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$		
15 Active	$\square_{o}$			$\square_3$	4	
16 On edge	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_{4}$	
17 Grouchy	$\square_{o}$			3	4	
<b>18</b> Blue	$\Box_{o}$	$\square_1$	$\square_{2}$	$\square_3$		
19 Energetic						
20 Panicky						
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Not Done Codelist: 1 Participant refus	ed 2 Clinician unable to	obtain 3 Insuff	icient time 4 Instru	ment failure 5 N	ot required	
				Participant's I	nitials:	

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	Center Number: _	Participant N	Number:	Participant's I	nitials: first middle last
Profile of Mood States (a	ontinued)				
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely
21 Hopeless				MS (TYPE 4)	PS
22 Relaxed	□ <sub>o</sub> SAM	E AS PAGE 43		Пз	
23 Unworthy	$\square_{o}$			$\square_3$	
24 Spiteful	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	□₄
25 Sympathetic	$\square_{o}$			$\square_3$	4
<b>26</b> Uneasy	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	
27 Restless	$\square_{0}$			□ <sub>3</sub>	□₄
28 Unable to concentrate	$\Box_{o}$			Пз	□₄
29 Fatigued	$\Box_{0}$			$\square_3$	$\square_4$
30 Helpful	$\Box_{0}$			□ <sub>3</sub>	
31 Annoyed	О			3	
32 Discouraged	О			3	4
33 Resentful	$\square_{0}$			3	4
34 Nervous				$\square_3$	4
35 Lonely				3	4
36 Miserable	$\Box_{0}$			□ <sub>3</sub>	4
37 Muddled	О			3	4
38 Cheerful	$\square_{o}$				4
39 Bitter	$\square_{0}$			3	
40 Exhausted				3	4
41 Anxious				$\square_3$	
42 Ready to fight	$\Box_{0}$			$\square_3$	4
43 Good-natured	$\square_{0}$				4
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	Center Number: Participant Number:				Participant's Initials:			
Profile of Mood S	itates (continued)							
Feeling	Not At All	A Little	Moderately	Quite A Bit	Extremely			
44 Gloomy				MS (TYPE 4)	PS			
45 Desperate	□, SA	ME AS PAGE 44		3	□ <sub>4</sub>			
<b>46</b> Sluggish	$\square_{o}$	$\square_1$	$\square_2$	$\square_3$	4			
47 Rebellious		□,		$\square_3$	_4			
48 Helpless	$\square_{o}$	$\square_1$		$\square_3$	_4			
49 Weary				$\square_3$	4			
50 Bewildered	$\square_{o}$	$\square_1$		$\square_3$	4			
51 Alert				3	_4			
52 Deceived	$\square_{o}$	$\Box_1$	$\square_{2}$	$\square_3$	4			
53 Furious				$\square_3$	4			
54 Efficient	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$				
55 Trusting				3	4			
<b>56</b> Full of pep	$\square_{o}$	$\square_1$	$\square_{2}$	Э				
<b>57</b> Bad-tempered				$\square_3$	4			
58 Worthless	$\square_{o}$	$\square_1$		$\square_3$	4			
59 Forgetful				□₃	4			
<b>60</b> Carefree	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_4$			
61 Terrified		$\Box_1$		$\square_3$	4			
<b>62</b> Guilty	$\square_{o}$	$\Box_1$	$\square_{2}$	□₃	4			
63 Vigorous				□₃	4			
<b>64</b> Uncertain about th	ings			3	4			
<b>65</b> Bushed				3	4			
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CA	LERIE PHASEE2 ANN	OTATION V8.0		Participant's I	nitials: middle last			

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		Center Number:	Participant Number	er:		Participant'	s Initials:	est midella last		
Da	ite completed:/ <sub>month</sub> /	SAME AS I OR Not done →	PAGE 36 Specify reason	(use code	list below):	EHDR	(TYPE	<b>E</b> 4)		
P	<b>erceived Stress Scale</b> (PSS	)								
ln	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.  PSS (TYPE 4)									
		SAME AS PAGE 45		Never	Almost Never	Some- times	Fairly Often	Very Often		
1	In the last month, how often h unable to control the importa							□ <sub>4</sub>		
2	In the last month, how often by your ability to handle your pe		nt about	$\square_{o}$	$\square_1$	$\square_{2}$	$\square_3$	$\square_{4}$		
3	In the last month, how often h going your way?	nave you felt that thi	ngs were					□ <sub>4</sub>		
4	In the last month, how often h piling up so high that you cou									
No	ot Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n <b>3</b> Insufficient	time 4	Instrument f	ailure 5	Not requir	red		

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Participant's Initials: first middle last



PA

AGEID = 245	Center Number: Participant	Number:	Partic	cipant's Initials	first middle last			
Date completed:/	OR Not done → Specify r SAME AS PAGE 36	eason (use codeli	ist below): DATEH	ĪDR (TY	PE 4)			
Pittsburgh Sleep Quality Index (PSQI)								
Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.								
During the past month	Ouring the past month SAME AS PAGE 46 PSQI1(TYPE 4)							
1 When have you usually gone	to bed? : : : : : : : : : : : : : : : : : : :							
2 How long (in minutes) has it to	aken you to fall asleep each	night?	minutes	5				
3 When have you usually gotte	n up in the morning?	23:59						
4 How many hours of actual sleep (This may be different than the number of hours								
5 During the past month, how a sleeping because you (check	•	Not during the past month	Less than once a week	Once or twice a week	3 or more times a week			
<ul> <li>Cannot get to sleep within</li> </ul>	30 minutes	$\square_{0}$			З			
<b>b</b> Wake up in the middle of the	ne night or early morning	$\square_{\circ}$			З			
• Have to get up to use the b	athroom	$\square_{o}$			$\square_3$			
d Cannot breathe comfortable	у	$\square_{\circ}$			З			
e Cough or snore loudly		$\square_{o}$			$\square_3$			
f Feel too cold		$\square_{o}$	$\square_1$	$\square_{2}$	З			
g Feel too hot		$\square_{o}$			$\square_3$			
h Have bad dreams		$\square_{\circ}$			З			
i Have pain		$\square_{\circ}$			$\square_3$			
i Other reason(s), please de you have had trouble sleep reason(s):	scribe, including how often ing because of this	$\square_{o}$			$\square_3$			
6 During the past month, how a medicine (prescribed or "over the cou					$\square_3$			
1989, with permission from Elsevier Science.  Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain 3 Insu	fficient time 4 I	nstrument failure	5 Not re	quired 1			
	PHASEE2 ANNOTATION V8		Partie	cipant's Initials				

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Durham NC 27705

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		Center Number: P	articipant N	Number:	Porti	cipant's Initials:	first middle last
Pi	ttsburgh Sleep Quality	ndex (PSQI) (continued	)				
	SAME AS PAGE 47	PSQI2(TYP	E 3)	Never	Once or twice	Once or twice each week	3 or more times each week
7	During the past month, how of staying awake while driving, e 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 r been for you to keep up enth	•					З
				Very good	Fairly good	Fairly bad	Very bad
9	During the past month, how valuality overall?	vould you rate your sl	eep	$\square_{o}$			$\square_3$

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PAGFID = 247

AGEID = 241	Center Number:	Participant Number:	Participant's Initials:	first middle	last

Date completed: — Journ — OR Not done → Specify reason (use codelist below): —DATEHDR (TYPE 4)

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

**Instruction:** Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

DISFEM1 (TYPE 4)PS

SAME AS PAGE 48

Less

than 1

1 or 2

1 per

2 or 3

4 to 6

1 per

2 or 3

4 or

Not at

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

you filled out this inventory, how often have you had thoughts, dreams, or fantasies about:	u"	per month	month	WOOK	week	week	uuy	day	per day
1.1 A sexually attractive person	По			3	4		6		□8
<b>1.2 Erotic parts of a man's body</b> (e.g., face, shoulders, legs)	□₀			□₃	_4		□₀		□.
1.3 Erotic or romantic situations					4		6		

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1.4 Caressing, touching, undressing, or

1.5 Sexual intercourse, oral sex, touching

Section 1—Sexual Cognition/Fantasy

During the past 30 days or since the last time

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

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Participant's Initials: \_\_\_\_

foreplay

to orgasm



**PAGEID** = 248 Participant Number: \_

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)									
Section 2—Sexual Arousal SAME AS F	PAGE 4	9			DIS	SFEM1	(TYP	PE 4)P	'S
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	l or 2 per month	1 per week	2 or 3 per week	4 to 6 per week	l per day	2 or 3 per day	4 or more per day
2.1 Feel sexually aroused while alone					4	5	□ <sub>6</sub>		□ <sub>8</sub>
2.2 Actively seek sexual satisfaction					□4	$\square_5$	□ <sub>6</sub>		□8
2.3 Feel sexually aroused with a partner					4		□ <sub>6</sub>		□ <sub>8</sub>
	Never	Rarely	Sometimes	Usually	Always	DISFE	M2 (1	TYPE	4)PS
2.4 Have normal lubrication with masturbation	□。								
2.5 Have normal lubrication throughout sexual relations									

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Participant's Initials: first middle last



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Center Nu	ımber:	P	articipant N	umber: _		Po	rticipant's	Initials:	rst middle fast
Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued)									
Section 3—Sexual Behavior/Experiences	SAM	E AS F	AGE 50	)	DIS	SFEM	1 (TYF	PE 4)F	PS
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	□₀				□ <sub>4</sub>		□6		
3.2 Masturbation	□,			$\square_3$	□4	$\square_5$	$\Box_{6}$	$\square_{7}$	□8
3.3 Casual kissing and petting				$\square_3$	□4				
3.4 Sexual foreplay				□₃	□₄	□ <sub>5</sub>	□6	□ <sub>7</sub>	□8
3.5 Sexual intercourse, oral sex, etc.		□,		$\square_3$	□4	$\square_5$	□6		
Section 4—Orgasm					DIS	SFEM	3 (TYF	PE 4)F	PS
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					□ <sub>4</sub>				
4.2 The intensity of your orgasm				□₃	□₄				
4.3 The ability to have multiple orgasms (if typical for you)				□₃					
4.4 Feelings of closeness and together- ness with your partner				□₃	□₄				
4.5 Your sense of control (timing) of your orgasm									
4.6 Feeling a sense of relaxation and well-being after orgasm				□₃	□₄				
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Participant's Initials: first middle last

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	enter Number:		Participant	Number:		F	articipant's	s Initials:	irst middle last
Derogatis Interview for Sex	cual Fund	tion (	DISF-SR) (	F) Female	Version	(continue	ed)		
Section 5—Drive and Relationship	SAME	AS PA	GE 51	С	ISFE	M1 (T	YPE 4	)PS	
	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		□6		□8
	Not at	Slightly	Moderately	Highly	Extrentely	SFEM	13 (TY	PE 4)F	PS
5.2 During this period, how interested have you been in se	×? □.				4				
5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner?				$\square_3$	□₄ DI	SFEN	14 (TY	PE 4)F	PS .
	Could not be worse	Very poor	Poor	Somewhat inadequate	Adequate	Above average	Good	Very good	Could not be better
5.4 In general, what would represe the best description of the qual of your sexual functioning?									□ <sub>8</sub>

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Participant's Initials: First middle last



DATEHDR (TYPE 4)

P

AGEID = 251	Center Number:	Participant Number:	Participant's Initials:
Date completed:/	OR Not done → Specif SAME AS	y reason (use codelist below):	TEHDR (TYPE 4)

#### Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

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

DISMALE1 (TYPE 4)PS

Section 1—Sexual Cognition/Fantasy	SAME A	AS PAG	SE 52						
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	□₀				□₄	$\square_5$	□6		□8
<b>1.2</b> Erotic parts of a woman's body (e.g., face, genitals, legs)	□₀			$\square_3$	□ <sub>4</sub>	$\square_5$	□6		□8
1.3 Erotic or romantic situations	□,				□ <sub>4</sub>	$\square_5$			8
1.4 Caressing, touching, undressing, or foreplay	□₀			$\square_3$		$\square_5$		□ <sub>7</sub>	□8
1.5 Sexual intercourse, oral sex, touching to orgasm	□,				□4				8
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Not Done Codelist: 1 Participant refused 2 Clinician un	able to ol	otain 3	Insufficier	nt time	4 Instrun	nent failur	e 5 N	ot require	d

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Participant's Initials:



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Center Num			ticipant Nu			- 1 1000000	ticipant's l	nitials:	st middle last
Derogatis Interview for Sexual F	unctio	n (DISF	-SR) (M)	Male Ve	rsion (co	ntinued)			
Section 2—Sexual Arousal SAME AS P	Section 2—Sexual Arousal SAME AS PAGE 53 DISMALE1 (TYPE 4)PS								
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	□.				4		□,		
2.2 A full erection during a sexual fantasy or daydream	□.				□4		□,		□8
2.3 A full erection while looking at a sexually arousing person, movie, or picture	□.						□.		□8
2.4 A full erection during masturbation	□.				□4		□6		
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				

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Participant's Initials: first middle last

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Center Nu	mber:	Pa	rticipant Nu	ımber:		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	SAME	AS P	AGE 54	D	ISMA	LE1 (	TYPE	4)PS	
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				Пз	_4		6		□ <sub>8</sub>
3.2 Masturbation	□₀			Пз	□4	□ <sub>5</sub>	□6		□8
3.3 Casual kissing and petting				Пз	_4		□ <sub>6</sub>		<u>*</u>
3.4 Sexual foreplay				$\square_3$	_4		□ <sub>6</sub>		□*
3.5 Sexual intercourse, oral sex, etc.				3			□ <sub>6</sub>		□,
Section 4—Orgasm					DIS	MALE	=2 (T)	'PE 4)	PS
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					
4.2 The intensity of your orgasm				Пз	_4				
4.3 The length or duration of your orgasm					_4				
4.4 The amount of seminal liquid that you ejaculate					_4				
4.5 Your sense of control (timing) of your orgasm				3					
4.6 Feeling a sense of relaxation and well-being after orgasm									
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Center	Number:		Participant	Number:		r	articipant's	initials:	irst middle last
Derogatis Interview for Sexua	l Func	tion (	DISF-SR) (	M) Male \	ersion (	ontinue	4)		
Section 5—Drive and Relationship	SA	ME AS	PAGE :	55	DI	SMAL	.E1 (T	YPE 4	)PS
	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?				□ <sub>3</sub>	□₄		□₀		□8
	Not at all	Slightly	Moderately	Highly	Extremely				
					DI	SMAL	.E2 (T	YPE 4	)PS
5.2 During this period, how interested have you been in sex?	□₀			□₃	<b>□</b> <sub>4</sub>				
5.3 During this period, how satisfied									
have you been with your personal relationship with your	□₀	□₁		Пз	$\square_4$				
sexual partner?					D	ISMA	LE3 (	ΓΥΡΕ <sup>4</sup>	4)PS
	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?	□₀			3	□₄				

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CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012



# Month 24 Submission

•	6	A	G		G		

GEID = 255				1	Visit
Center Number: Participan SAME AS PAGE 3	t Number: 6		Participa	nt's Initials:	
Date completed: $_{day}$ / $_{month}$ / $_{year}$ OR Not done $\rightarrow$ Specify to	<b>eason</b> (use	codelist belo	XTEHD	R (TYF	PE 4)
Food Cravings Questionnaire—State (FCQ—S)					
Below is a list of comments made by people about their eating habits. Please now much you agree with the comment <b>right now, at this very moment.</b> while others refer to one or more specific foods. Please respond to each item	Notice that	some ques y as possib	tions refer t le.	to foods ir	gener
SAME AS PAGE 58	Strongly Disagree	Disagree	Neutral	_	Stron Agre
I have an intense desire to eat [one or more specific foods].			3	4	
I'm craving [one or more specific foods].			З	4	
I have an urge for [one or more specific foods]			Пз	4	
Eating [one or more specific foods] would make things seem just perfect.			$\square_3$	$\Box_{4}$	
If I were to eat what I am craving, I am sure my mood would improve.			3	_4	
Eating [one or more specific foods] would feel wonderful.			3	_4	
If I ate something, I wouldn't feel so sluggish and lethargic.			$\square_3$	4	
Satisfying my craving would make me feel less grouchy and irritable.			Пз	_4	
I would feel more alert if I could satisfy my craving.			$\square_3$		
10 If I had [one or more specific foods], I could not stop eating it.			$\square_3$		
11 My desire to eat [one or more specific foods] seems overpowering.			3	4	
12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it.			$\square_3$	4	
I3 I am hungry.					
14 If I ate right now, my stomach wouldn't feel as empty.					

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

Participant's Initials: first middle last

15 I feel weak because of not eating.



P

AGE	EID = 256 Center Numb	er: Pai	ticipant Number:		Participant's I	nitials: first middle last
Dat						
	re completed:/	AME AS PA	GE/36	D/A	(TEHDR	TYPE 4)
	ood Craving Inventory (FCI-II)				D A) (E (T)	VDE 4\D0
	each of the foods listed below, please check the ap		v faad av faad t		•	YPE 4)PS
INO	te: A craving is defined as an intense desire to consi 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 SAME AS PAGE 59			₃		5
2	Pizza			3	4	
3	Fried chicken			□₃	$\Box_4$	
4	Gravy			$\square_3$	$\square_{4}$	$\square_{5}$
5	Sandwich bread			₃	4	5
6	Sausage			$\square_3$		
7	French fries			3		
8	Cinnamon rolls			3		
9	Rice			3		
10	Hot dog			3	$\square_{4}$	
11	Hamburger			□₃		
12	Biscuits			□₃	□₄	
13	Ice cream			□₃		
14	Pasta			□₃	□₄	
15	Fried fish			□₃		
16	Cookies			□₃		
17	Chocolate					
18	Pancakes or waffles					
19	Corn bread			□₃		
20	Chips			□₃		
21	Rolls			□₃		
22	Cereal			□₃		
23	Donuts					
24	Candy			□₃		
25	Brownies			□₃		
26	Bacon			□₃		
27	Steak			3		
28	Baked potato			З		
No	t Done Codelist: 1 Participant refused 2 Clinician ur	nable to obtain	3 Insufficient tim	e 4 Instrume	nt failure 5 N	lot required
	CALERIE PHASEE2 AN	NOTATION	/8 0 24EEB3	0012	Participant's I	aitiala.

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	Cent	er Number:	Participant Number:		Participant's I	nitials:
	completed:/	_ OR Not done → SAME AS	Specify reason (use co PAGE 36	odelist below):	Γ <del>ΈΗD</del> R (	TYPE 4)
Eati	ng Inventory					
1	When I smell a sizzling steak o difficult to keep from eating, ev	r see a juicy pie en if I have just	ece of meat, I find finished a meal.	it very TF	EQA (T)	PE 4)PS  Gralse
2	I usually eat too much at social	occasions, like	•	s. <mark>ME AS PA</mark>		o False
3	I am usually so hungry that I e	at more than th		WE NOT A		o False
4	When I have eaten my quota on not eating anymore.	f calories, I am	usually good abo	out	☐ <sub>1</sub> True	□₀ False
5	Dieting is so hard for me becau	se I just get too	hungry.		☐₁ True	□₀ False
6	I deliberately take small helpin	gs as a means o	of controlling my v	weight.	, True	o False
7	Sometimes things just taste so q I am no longer hungry.	good that I keep	o on eating even v	vhen	☐, True	□₀ False
8	Since I am often hungry, I some expert would tell me that I have something more to eat.			g, an	☐₁ True	o False
9	When I feel anxious, I find mys	elf eating.			☐₁ True	o False
10	Life is too short to worry about	dieting.				o False
11	Since my weight goes up and o more than once.	lown, I have go	ne on reducing di	ets	□₁ True	□₀ False
12	I often feel so hungry that I just	have to eat so	mething.		☐₁ True	□₀ False
13	When I am with someone who	is overeating, I	usually overeat to	00.	☐₁ True	□₀ False
14	I have a pretty good idea of th	e number of cal	ories in common	food.	☐₁ True	□₀ False
15	Sometimes when I start eating,	l just can't seer	n to stop.		☐₁ True	o False
16	It is not difficult for me to leave	something on r	my plate.		☐₁ True	□₀ False
17	At certain times of the day, I ge to eating then.	t hungry becau	se I have gotten u	used	☐₁ True	□₀ False
18	While on a diet, if I eat food the for a period of time to make up		d, I consciously ec	ıt less		□₀ False
Not D	one Codelist: 1 Participant refused 2 Cli	nician unable to obta	in 3 Insufficient time	4 Instrument	failure 5 N	lot required

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Participant's Initials: first middle last



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	Center Number: Participant Number:	Participant's In	first middle last
Eati	ng Inventory (continued)		
19	Being with someone who is eating often makes me hungry to eat also.	☐₁ True	o False
20	SAME AS PAGE 61 When I feel blue, I often overeat.	TFEQA (TY	PE 4)PS  Graise
21	I enjoy eating too much to spoil it by counting calories or watching my weight.	☐₁ True	□₀ False
22	When I see a real delicacy, I often get so hungry that I have to eat right away.	☐₁ True	□₀ False
23	I often stop eating when I am not really full as a conscious means of limiting the amount I eat.	☐₁ True	□₀ False
24	I get so hungry that my stomach often seems like a bottomless pit.	☐₁ True	□₀ False
25	My weight has hardly changed at all in the last ten years.	☐₁ True	□₀ False
26	I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	☐₁ True	□₀ False
27	When I feel lonely, I console myself by eating.	☐₁ True	□₀ False
28	I consciously hold back at meals in order not to gain weight.	☐₁ True	o False
29	I sometimes get very hungry late in the evening or at night.	☐₁ True	□₀ False
30	I eat anything I want, any time I want.	☐₁ True	□₀ False
31	Without even thinking about it, I take a long time to eat.	☐₁ True	□₀ False
32	I count calories as a conscious means of controlling my weight.	☐₁ True	o False
33	I do not eat some foods because they make me fat.	☐₁ True	□₀ False
34	I am always hungry enough to eat at any time.	☐₁ True	o False
35	I pay a great deal of attention to changes in my figure.	☐₁ True	□₀ False
36	While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods.	□ <sub>1</sub> True	□₀ False

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Participant's Initials: first middle last



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	Center Number:	Participant Number: Participant's Initials: first middle last						
Eat	ing Inventory (continued)							
Please check one answer that is most appropriate to you for each question below. TFEQB (TYPE 3)								
37	How often are you dieting in a conscious As effort to control your weight?	SPARF62 _2 Sometimes _3 Usually _4 Always						
38	Would a weight fluctuation of 5 pounds affect the way you live your life?	$\square_1$ Rarely $\square_2$ Sometimes $\square_3$ Usually $\square_4$ Always						
39	How often do you feel hungry?	$\square_1$ Rarely $\square_2$ Sometimes $\square_3$ Usually $\square_4$ Always						
40	Do your feelings of guilt about overeating help you to control your food intake?	$\square_1$ Rarely $\square_2$ Sometimes $\square_3$ Usually $\square_4$ Always						
41	How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours?	☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult						
42	How conscious are you of what you are eating?	☐₁ Not at all ☐₂ Slightly ☐₃ Moderately ☐₄ Extremely						
43	How frequently do you avoid "stocking up" on tempting foods?	$\square_1$ Almost never $\square_2$ Seldom $\square_3$ Usually $\square_4$ Almost always						
44	How likely are you to shop for low calorie foods?	☐, Unlikely ☐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?	☐, Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely						
47	How frequently do you skip dessert because you are no longer hungry?	$\square_1$ Almost never $\square_2$ Seldom $\square_3$ At least once a week $\square_4$ Almost every day						
48	How likely are you to consciously eat less than you want?	☐, 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"						

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012 Send to DCRI Fo

Participant's Initials: first middle last

rham NC 27705



P

										W I A	311 1
=ID <b>= 260</b>	Center Number: _		Particip	ont Nur	nber: _			Particip	ant's Init	ials:	middle last
te completed:/ <sub>month</sub> /	OR Not	done –	Specif	fy reaso	on (use )	codelist	below): DA	TEHE	ŌR (T	YPE	4)
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.  SAME AS PAGE 63  WELQ (TYPE 4)PS											
m confident that:						eat <b>4</b>	уо <b>5</b>				
I can resist eating when I am (nervous).	anxious	□₀								□8	□ <sub>9</sub>
I can control my eating on the	weekends.	□₀			$\square_3$	$\square_4$	$\square_5$	□ <sub>6</sub>	$\square_{7}$	□8	
I can resist eating even when say "no" to others.	I have to				З	_4				□8	
I can resist eating when I feel run down.	physically	$\square_{\circ}$			$\square_3$	$\square_4$	$\square_5$			□,	
I can resist eating when I am	watching TV.				З	4		6		□ <sub>8</sub>	
I can resist eating when I am (or down).	depressed	$\square_{o}$			$\square_3$	$\square_4$	$\square_5$	□ <sub>6</sub>	_ <sub>7</sub>	□8	
I can resist eating when there different kinds of food availa	are many ble.				Пз			□ <sub>6</sub>		8	
		$\Box_{\circ}$			Пз						
	/eight Efficacy Lifestyle (is form describes some typical eating siwn. The following are a number of situ ting situations which you find the hard. Read each situation listed below and the difficult situations. In other words, 19 (very confident), choose ONE number sire to eat. Check this number for each time confident that:  I can resist eating when I am (nervous).  I can control my eating on the law "no" to others.  I can resist eating when I feel run down.  I can resist eating when I am (or down).  I can resist eating when I am (or down).  I can resist eating when I am (or down).	the completed:	te completed:    day	Tean resist eating when I am watching TV.  I can resist eating when I am watching Tv.  I can resist eating when I am watching Tv.  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I am depressed (or down).  I can resist eating when I feel it is	The completed:	the completed:	te completed:	te completed:	te completed:	Center Number:	Center Number:

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2 Clinician unable to obtain

Participant's Initials: first middle last

5 Not required

4 Instrument failure

3 Insufficient time

headache.

I can resist eating even when I have a

Not Done Codelist: 1 Participant refused



PAGEID = 261

	Center Number:	Partici	pant Nur	mber: _			Particip	oant's Init	ials:	midale last
Weight Efficacy Lifestyle G	Questionnaire (	WEL) (co	ontinue	d)						
I am confident that:		confide can resi			eat 4	Very confident that you can resist the desire to eat WELQ (TYPE 4)PS				
						5	6	7	8	9
10 I can resist eating when I am r	reading.			$\square_3$	$\square_{4}$	$\square_5$	$\Box_{6}$	$\square_{7}$	□ <sub>8</sub>	
11   can resist eating when I am (or irritable).	angry								□ <sub>8</sub>	
12 I can resist eating even when I a party.	am at			$\square_3$	$\square_{4}$		6		□ <sub>8</sub>	
13 I can resist eating even when a pressuring me to eat.	others are			Пз	_4		□ <sub>6</sub>		□ <sub>8</sub>	<b>□</b> ,
14 I can resist eating when I am i	n pain.			$\square_3$	$\square_{4}$	$\square_{5}$	□ <sub>6</sub>		□8	
15 I can resist eating just before g bed.	going to			Пз					□ <sub>8</sub>	
16 I can resist eating when I have experienced failure.				$\square_3$	$\Box_4$		6			
17 I can resist eating when high-care available.	alorie foods			Пз			□ <sub>6</sub>		□ <sub>8</sub>	
18 I can resist eating even when I others will be upset if I don't e		$\square_1$		$\square_3$	$\square_{4}$	$\square_{5}$	□ <sub>6</sub>		□ <sub>8</sub>	
19 I can resist eating when I feel uncomfortable.				Пз			□ <sub>6</sub>			
20 I can resist eating when I am h	парру.			Пз	$\Box_{4}$		6		□ <sub>8</sub>	

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Participant's Initials: first middle last



PAGEID = 262

AGLID - ZOZ	Center Number:			er:		first middle fast				
Date completed:/	3 <mark>6</mark> reason	(use code	elist belov	ATEHI v):	DR (1 	TYPE	4)			
MAEDS (TIPE 4)PS									·)PS	
Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)  Instructions: Using the scale shown, please rate the following items on a scale from 1 to 7. Please answer as truthfully as possible.										
	AS PAGE 65	on a sea	Never	Very	Rarely	Some-	Often	Very	Always	
1 Fasting is a good way to lose				Rarely		times		Often		
			<u></u>		3	<u></u>	5			
2 My sleep isn't as good as it u	sed to be.		i		З	□₄	5	□ <sub>6</sub>	7	
3 I avoid eating for as long as I	can.				3			□6	7	
4 Certain foods are "forbidden"	" for me to eat.		$\square_1$		$\square_3$		$\square_{5}$	□6		
5 I can't keep certain foods in my binge on them.	house because I will				Пз		5	6		
6 I can easily make myself vom	it.				$\square_3$		$\square_{5}$	□₀		
7 I can feel that being fat is terr	ible.				З			□6		
8 I avoid greasy foods.					$\square_3$	□₄		□,		
9 It's okay to binge and purge	once in a while.				$\square_3$			□6		
10 I don't eat certain foods.					$\square_3$	□₄	$\square_{5}$	□6		
11 I think I am a good person.					Пз					
12 My eating is normal.					З	□₄		□,		
13 I can't seem to concentrate la	tely.				З			□,		
14 I try to diet by fasting.					Пз			□。		
15 I vomit to control my weight.					3			□ <sub>6</sub>		
16 Lately nothing seems enjoyab	le anymore.				Пз					
17 Laxatives help keep you slim.								6		
18 I don't eat red meat.					З			□,		
19 I eat so rapidly I can't even taste my food.					3			□6		
Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required										

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: First middle last

Durham NC 27705



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MAEDS (TYPE 4)PS

Center Number: Por	ticipant N	umber: _		Pa	rticipant's	Initials: _	irst middle last
Multiaxial Assessment of Eating Disorder Sy	mpto	ms (	MAEDS)	(continue	d)		
SAME AS PAGE 66	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
20 I do everything I can to avoid being overweight.			3			□,	
21 When I feel bloated, I must do something to rid myself of that feeling.			□₃			□6	
22 I overeat too frequently.			3			□,	
23 It's okay to be overweight.			3			6	
24 Recently I have felt that I am a worthless person.			Пз			□,	
25 I would be very upset if I gained 2 pounds.			3			6	
26 I crave sweets and carbohydrates.						6	
27 I lose control when I eat.			Пз			_6	
28 Being fat would be terrible.			3			□6	
29 I have thought seriously about suicide lately.	□₁		Пз			6	
30 I don't have any energy anymore.			З			6	
31 I eat small portions to control my weight.			Пз			6	
32 l eat 3 meals a day.			З	4		6	
33 Lately I have been easily irritated.	□₁		Пз			□6	
34 Some foods should be totally avoided.			3	4		6	
35 I use laxatives to control my weight.			Пз			_6	
36 I am terrified by the thought of being overweight.			Пз			6	
37 Purging is a good way to lose weight.			Пз			□,	
38 I avoid fatty foods.						□,	

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ham NC 27705

Send to DCRI Fo



#### Month 24 Submission

MAEDS (TYPE 4)PS

PAGEID = 264

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

Multiaxial Assessment of Eating Disorder Sy	mpto	ms (	MAEDS)	continue	d)		
SAME AS PAGE 67	Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
39 Recently I have felt pretty blue.					5	G	
40 I am obsessed with becoming overweight.			_3	$\square_{4}$	$\square_{5}$		
41 I don't eat fried foods.			3	4	5		
42 I skip meals.			$\square_3$	$\square_{4}$	$\square_5$	6	
43 Fat people are unhappy.			3	4	5	6	
44 People are too concerned with the way I eat.			_3	$\square_{4}$	5	6	
45 I feel good when I skip meals.			$\square_3$	4	5	6	
46 I avoid foods with sugar.			_3	□₄	$\square_5$		
47 I hate it when I feel fat.			3	<b>□</b> ₄	5	6	
48 I am too fat.			$\square_3$	$\square_4$	$\square_5$	□,	
49 I eat until I am completely stuffed.			3	□ <sub>4</sub>	5	□6	
50 I hate to eat.			Пз	$\square_4$	$\square_5$	□,	
51 I feel guilty about a lot of things these days.			3	<b>□</b> ₄	5	6	
52 I'm very careful of what I eat.			□₃	$\square_4$	$\square_{5}$	□,	
53 I can "hold off" and not eat even if I am hungry.			3	<b>□</b> ₄	5	6	
54 I eat even when I am not hungry.			Пз	□₄	$\square_{5}$		
55 Fat people are disgusting.			3	4	5		
56 I wouldn't mind gaining a few pounds.			Пз	□₄	5		

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Participant's Initials: first middle last

ham NC 27705

CRF, page 264

02	OF	Phase 2
Gal		Phase 2

PAGEID = 265 Participant Number: Participant's Initials: OR Not done - Specify reason (use codelist below):
DATEHDR (TYPE 4) Date completed: Body Shape Questionnaire (BSQ) We would like to know how you have been feeling about your appearance over the past four weeks. BSQ (TYPE 4)PS Please read each question and check the box for the appropriate choice. Please answer all the questions. SAME AS PAGE 68 Very Over the Past Four Weeks... Rarely Often Never Always times Often Has feeling bored made you brood about your shape? Have you been so worried about your shape that you have been feeling that you ought to diet? 3 Have you thought that your thighs, hips, or bottom are too large for the rest of you? 4 Have you been afraid that you might become fat (or fatter)? 5 Have you worried about your flesh not being firm enough? 6 Has feeling full (e.g., after eating a large meal) made you feel 7 Have you felt so bad about your shape that you have 8 Have you avoided running because your flesh might wobble? 9 Has being with thin women/men made you feel self-conscious about your shape? 10 Have you worried about your thighs spreading out when sitting down? 11 Has eating even a small amount of food made you feel 12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably? 13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)? 14 Has being naked, such as when taking a bath, made you feel fat? 15 Have you avoided wearing clothes which make you particularly aware of the shape of your body? 16 Have you imagined cutting off fleshy areas of your body?

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2 Clinician unable to obtain

Participant's Initials: | First middle last

5 Not required

4 Instrument failure

Send to DCR

Not Done Codelist: 1 Participant refused

3 Insufficient time



PAGEID = 266

BSQ (TYPE 4)PS Participant's Initials:

Body Shape Questionnaire (BSQ) (continued)						
Over the Past Four Weeks SAME AS PAGE 69	Never	Rarely	Some- times	Often	Very Often	Always
17 Has eating sweets, cakes or other high calorie food made you feel fat?						
18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape?			□₃	_4		□ <sub>6</sub>
19 Have you felt excessively large and rounded?			Пз	_4		6
20 Have you felt ashamed of your body?			□₃	_4		□ <sub>6</sub>
21 Has worry about your shape made you diet?				4		
22 Have you felt happiest about your shape when your stomach has been empty?			□₃	_4		
23 Have you thought that you are the shape you are because you lack self-control?			□₃	_4		6
24 Have you worried about other people seeing rolls of flesh around your waist or stomach?			□₃	□4		
25 Have you felt that it is not fair that other women/men are thinner than you?			Пз	_4		
26 Have you vomited in order to feel thinner?			□₃	□₄		6
27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)?			Пз	_4	5	6
28 Have you worried about your flesh being dimply?			□₃	□4		□ <sub>6</sub>
29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape?				4	5	6
30 Have you pinched areas of your body to see how much fat is there?			□₃	_4		□ <sub>6</sub>
31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)?						6
32 Have you taken laxatives in order to feel thinner?			□₃	_4		6
33 Have you been particularly self-conscious about your shape when in the company of other people?						
34 Has worry about your shape made you feel you ought to exercise?			□₃			

Participant's Initials: first middle last



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Handgrip Strength  Date and time of assessment:					first middle last		
Han	ndgrip Strength						
	and time of assessment:    day						
1 D)	ynometer handle position	:					
ı	Dominant hand (check only one):						
	Handgrip Strength	Zero Meter Check	Right Hand	Zero Meter Check	Left Hand		
	Test 1—peak force	□₀	kg	□₀	kg		
	Test 2—peak force	□₀	kg	$\Box_{o}$	kg		
	Test 3—peak force		kg		kg		
Not D	one Codelist: 1 Participar	nt refused 2 Clinician una	ble to obtain 3 Insufficie	nt time <b>4</b> Instrument failu	re 5 Not required		
Date and time of assessment:							



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			Center Number:	Participant N	Number: _		Particip	pant's Initials: first middle last
ls	ometric/Isokine	tic Knee	Extension and	Flexion	i			
	ate and time of assessment				-	DATEU		first middle last
01	R Not done → Specify rea	son (use cod	elist below): OAIVIL AO	FAGL 4		DATEH	JK (1	TPE 4)
1	Recent injury or pain—rig	ht knee? [		D. 05 -0				
2	Recent injury or pain—lef	t knee?	$\Box_0$ No $\Box_1$ Yes	PAGE 78	IS	OMETR	C (IY	PE 4)PS
3	Specify machine used (PE	BRC only): [	□ <sub>0</sub> Cybex □ <sub>1</sub> Biolex	MACHIN	NE <tu< th=""><th>SED&gt;</th><th></th><th></th></tu<>	SED>		
	All values corrected	for gravit	y effect torque	Right	Leg	Left L	eg	If Not Done, Specify Reason (Use codelist below)
3	60°/sec knee extension		peak torque		N.m	E 33 33 33 3	_N.m	
			total work		N.m		_N.m	
			average power		watts		_ watts	
4	$60^{\circ}/\text{sec}$ knee flexion		peak torque		N.m		_N.m	
			total work		N.m	<del></del>	_N.m	
			average power		watts		_watts	
5	180°/sec knee extension		peak torque		N.m	<del>- 2 2 -</del>	_N.m	
			total work		N.m	<del> </del>	_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	

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



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	Center Nun	nber: Participant N	lumber: Participant's Initials:	first middle las
Clinic Weight				
	day /		Staff initials: $\frac{1}{fest \ middle}$	
Clinic weight (if the two n	neasurements are more than 0.1	l kg apart, measure weight a	third time):	
Weight 1:	kg	SAME AS PA	AGE 4 WEIGHT (TYPE 4)	
Weight 2:	kg			
Weight 3:	kg			
Weight of gown:	kg			
Not Done Codelist: 1 Po	articipant refused 2 Clinician	unable to obtain 3 Insuffic	cient time 4 Instrument failure 5 Not requ	ired

Participant's Initials: first niddle last

Participant Number:

Center Number:

# Month 24 Submission Visit 2

<u>d</u>	4GEID	PAGEID = 270				Center Number:	Umber:		raniapani Number		ARHE	JR (TY	PARHDR (TYPE 4)		first middle l
é	/en-D	even-Day Physical Activity Recall (PAR)	rity Reca	II (PAR)											
B	oday's date:		Вау	Day (check only one): ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri ☐ Sat ☐ Sun OR Not done → Specify reason (use codelist below):	Mon Iu	es Wed	] Thurs	Fi.	at Sur	OR No	done →	Specify re	ason (use	codelist belo	:/w
>	Vere yo	oyed in the last sev	ın days?		° □	$\square_0 \ No \longrightarrow Skip \ to \ question \ 3 \qquad \square_1 \ Yes$	estion 3	, Yes				Intervi	Interviewer initials:		first middle last
=	f Yes: W	If Yes: Which days (check all that apply)?	٥.		Mon	Mon Tues Wed Thurs	Wed		Œ.	Sat	Sun				
_	Which d	Which days do you consider your weekend, or non-work, days?	reekend, or n	on-work, days		Mon Tues	☐ Wed ☐ Thurs	Thurs	$\Box$	] Sat   Sun	Sun				
>	ay Day of		Slee	Sleep Time	Work	Work Time	Mori	Morning (in minutes)	nutes)	Affer	Afternoon (in minutes)	inutes)	Even	Evening (in minutes)	set)
	Week	Date	In Bed	Up	Start	Stop	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard	Mod.	Hard	Very Hard
fer.		doy /	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					ARC	IT (TY	PARCHT (TYPE 4)PS	Sc	
		day /	00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59									
			00:00 to 23:59 00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59										
		day /	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 to 23:59	00:00 to 23:59		SAI	AE AS I	SAME AS PAGE 71	1				
			00:00 to 23:59	00:00 to 23:59 00:00 to 23:59	00:00 % 23:59	00:00 to 23:59									
		day / nonth year	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 % 23.59	00:00 to 23:59									

2 Glinician unable to abtain 3 Insufficient time A Instrument failure 5 Not required Not Done Codelist: 1 Participant refused

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

**Calerie** Phase 2
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**PAGEID** = **271** 

		Center Number:	Participant Number:	Participant's Initials:	first middle last
S	even-Day Physical Activ	vity Recall (PAR) (co	ontinued)		
4	Compared to your physical activity	over the past three month:	s, was last week's physical o	activity more, less,	
	or about the same (check only one)?		PAF	RQ (TYPE 4)	
	3 About the same	SAME AS PAGE 72			
In	terviewer: Please answer questions	below and note any com	ments on interview.		
5	Were there any problems with the S $\square_0$ No $\square_1$ Yes	Seven-Day PAR interview?			
6	Do you think this was a valid Seven-	-Day PAR interview?			
7	Were there any activities reported be □ No □ Yes	by the participant that you	don't know how to classify	?	
_					



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		Center Number:	Partic	ipant Number: Particip	pant's Initials:
6-D	ay Food Record				
Com	plete below OR Not done → Specify	y reason (use Codelist b	elow): _	Staff init	rials: First middle last
	SAME AS PAGE	73		Replacement Value	
Day of DLW	Date of Record	Record Quality (check only one)	Day of DLW	FOODRCD (TYPE	Record Quality (check only one)
1	/	1 Reliable 2 Unreliable 3 Missing	8	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
2	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	9	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
3	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing	10	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
4		1 Reliable 2 Unreliable 3 Missing	11	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
5	/	1 Reliable 2 Unreliable 3 Missing	12	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
6	/	1 Reliable 2 Unreliable 3 Missing	13	/	☐₁ Reliable ☐₂ Unreliable ☐₃ Missing
Not	Done Codelist: 1 Participant refused	2 Clinician unable to ob	tain 3	Insufficient time 4 Instrument failure	5 Not required



**PAGEID** = **273** 

		Center Number:	Participant Number:	Participant's Initials:
V	O <sub>2</sub> Max			
1	Date and time of test:/	SAME AS PAGE		DATEHDR (TYPE 4) Staff initials: first middle last
	OR Not done → Specify reason (use a	odelist below): — SA	ME AS PAGE 81	VOMAX (TYPE 3)
2	At what time was the participant's las	t meal/snack eaten?	00:00 to 23:59	
3	Rest ECG: Rhythm (check only one):  Ventricular conduction (che	$\square_1$ Sinus	Atrial fibrillation	□ <sub>98</sub> Other □ <sub>3</sub> RBBB
4	Heart rate (HR) data: Resting heart ra Age-predicted I Heart rate (max	neart rate:	bpm	
5		that apply: HR when	true cardiac angina occi ischemic ECG changes c	urred: bpm or NA occurred: bpm or
	Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress ii Orthopedic/extremity complaints (pai	ns/cramps)		
6	Did frequent ventricular ectopy occur  □₀ No □₁ Yes → If Yes: When did it occur (c			
7	Peak VO <sub>2</sub> : mL/kg/min	L/min		(, ), , , , , , , , , , , , , , , , , ,
8	Did the participant meet at least 2 of □ <sub>0</sub> No □ <sub>1</sub> Yes → If Yes: VO <sub>2</sub> max:	_	(see box, right)? bei	hieve a plateau in VO₂ (change ≤ 150 mL) ween the final two stages R ≥ 1.1 max ± 5 bpm of age-predicted maximum
9	Exercise time::seconds			
10	Blood pressure at VO <sub>2</sub> peak/VO <sub>2</sub> max	x:/	mm Hg	
11	Borg RPE score at VO <sub>2</sub> peak/VO <sub>2</sub> ma	<b>x:</b> (6-20)		
12	2 Peak RER:			
13	3 VE at VO <sub>2</sub> peak/VO <sub>2</sub> max:	L/min		

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\_\_\_\_

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



PAGEID = 274

Outcomes Labs  Date and time sample collection started:    No Display LMEALDT, LMEALTM					
	ple collection started:/_	/	00:00	:OUTCMELB (	(TYPE 4)PS
If a sample is not obt	Sample		lete?		OUTCMELB (TYPE 4)PS  Short Done, Reason (Use codelist below)  AS PAGE 102  First middle last  If Not Done, Reason (Use codelist below)  ADMIT (TYPE 3)  Start Time  SAME AS PAGE 87  90.00 to 23:59
	Blood		SAM	E AS PAGE 102 	first middle last
Core Tempe	rature				
			1	ection/Procedure	Reason (Use codelist below)
				Start Time	,
first middle last	·				
Inpatient Ad	lmission and Discha	rge			
	·				
Inpatient discha	arge date and time:/	month year	00:00 to	23:59	
Not Done Codelist:	1 Participant refused 2 Clinicia	n unable to obtain	3 Insufficient	time 4 Instrument failure	5 Not required



**Delayed-type Hypersensitivity (DTH)** DTHADM1 (TYPE 3) Was the DTH worksheet completed? U₀ No  $\square_1$  Yes  $\rightarrow$  If Yes: Were any Exclusion criteria met?  $\square_0$  No  $\rightarrow$  Proceed with test  $\square$ , Yes  $\rightarrow$  STOP. Do not administer test. SAME AS PAGE 85 Arm injected: \_\_\_\_, Right \_\_\_\_\_, Left DTH results: Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. DTHADM2 (TYPE 4)PS A = Largest diameter B = Second diameter perpendicular to A 24 Hour (@ Visit 4) 48 Hour (@ Visit 5) Antigen A (diameter) B (diameter) Read By: A (diameter) B (diameter) Read By: Normal saline \_\_\_\_ mm 2 Tetanus toxoid (TT) (check only one): , Tetanus toxoid (Sanofi-\_\_\_\_ mm | \_\_\_ mm Pasteur) \_\_\_<sub>98</sub> Other: \_\_ Lot #: 3 Candida (check only one): first middle last first middle last Candin (AllerMed) (initials) (initials) \_\_\_\_\_ Other: \_\_\_\_\_ Lot #: 4 Trichophyton (check only onel: Trichophyton Allergic \_\_\_\_\_ mm | \_\_\_ \_ \_\_ mm Extract (AllerMed)

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

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Send to DCR

98 Other: \_\_\_\_



**PAGEID** = 276

Clinic Weight						
Weight date and time:/						
DATEHDR (TYPE 4)						
Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time):						
Weight 1:	kg SAM	E AS PAGE 4	WEIGHT (T	YPE 4)		
Weight 2:	kg	MOVED THE RMR	PANEL TO PAGE	= 276A		
Weight 3:	kg					
Weight of gown:	kg					
Outcomes Labs						
Date and time of last me	al:/		ÇUTCMELB (T	/PE 4)PS		
Date and time sample co		year 00:00 to 23:				
	Sample	Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Са	techolamines	□₀ No □₁ Yes		first middle last		
	Blood	□₀ No □₁ Yes		first middle last		
Oral glucos	e tolerance test (OGTT)	□₀ No □₁ Yes		first middle last		
If a sample is not obtained,	indicate with a Not Done.					
24-hour Urine (	Collection					
Total Volume Collected	Date of Sample Collection	Time of Sample Collectio	If Not Don Reason (Use codelist b	Staff Initials		
	Start Date:	Start Time:	ΨRINE24 (	ΓΥΡ <b>Ε</b> 3)		
	/	00:00 to 23:59	SAME AS I	PAGE 90		
mL	Stop Date:	Stop Time:		first middle fast		
	/	00:00 to 23:59				
Not Done Codelist: 1 Par	Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required					



PAGEID = 276A

					III AIIOOIS IOSI		
Sex Hormone							
If Not Done → Specify reason (use code	list below)	SAME AS PAGE 90A	DATEH	OR (TYPE	4)		
Contraception method (females only):		None OR Check all that apply:	None OR Check all that apply:  ☐ Oral contraceptive → Specify:		•		
SAME AS PAGE 90A		☐ Other → Specify	Record on Concomitant Medications page  ☐ Other → Specify (e.g., barrier, IUD):				
Day 1		Date	Time	If Not Done, Reason (use codelist)	Staff Initials		
Day 1 of menses (formules enly)							
Date and time of last meal (males onl)	1)	/					
Hormone level blood draw 1 (males o	nly)	/	00:00 to 23:59		first middle last		
Hormone level blood draw 2 (females enty) Progesterone level							
Day 2		Date	Time	If Not Done, Reason (use codelist)	Staff Initials		
Date and time of last meel							
Hormone level blood draw 3 (females of Progesterane level	only)						
Metabolic Rate							
Sample		Date of Collection	If Not Done, Re (Use codelist be	low)	f Initials		
Resting Metabolic Rate (RMR)—Visit 4	SAME AS PAGE 153			YPE 4)PS	middle last		
Cart ID		-003 (623-002)		PBRC-016 (623 PBRC-017 (623	*		
Not Done Codelist: 1 Participant refused	2 Clinic	cian unable to obtain 3 Insufficient ti	me 4 Instrument	failure <b>5</b> Not i	required		

# bmission Visit 4

first middle last

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#### Sun OR Not done → Specify reason (use codelist below): PARHDR (TYPE 4) Interviewer initials: PARCHT ( Very Hard Afternoon (in minutes) Hard Sun Sun S PAG Mod. Participant Number: Sat Sat SAME Very Hard ☐ Tues ☐ Wed ☐ Thurs ☐ Fri Thurs Fri Morning (in minutes) Day (check only one): $\square_0 \ No \rightarrow Skip \ to \ question \ 3 \qquad \square_1 \ Yes$ Hard Mod. Wed Center Number: 00:00 to 23:59 Mon Tues Stop Work Time Won 00:00 to 23:59 Start Which days do you consider your weekend, or non-work, days? 00:00 to 23:59 ď Seven-Day Physical Activity Recall (PAR) Sleep Time calerie Phuse 2 00:00 to 23:59 In Bed Were you employed in the last seven days?

year

day

day)

Very Hard

Hard

Mod.

4)PS

TYP∄,

Evening (in minutes)

first middle last

2 C Not Done Codelist: 1 Participant refused

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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

year

nonth

day

3

00:00 to 23:59 00:00 to 23:59

year

month

day

a

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

year

month

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equired

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month

day

year

month

day

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year

month

day

PAGEID = 277

yed

Today's date: \_\_\_\_\_

If Yes: Which days (check all that apply)?

Date

Day of Week

Day #

e

ø



**PAGEID** = **278** 

	Center Number: Participant Number: Participant's Initials: first_middle_lo
S	even-Day Physical Activity Recall (PAR) (continued)
4	or about the same (check only one)?  PARQ (TYPE 4)
	Less SAME AS PAGE 72  3 About the same
In	terviewer: Please answer questions below and note any comments on interview.
5	Were there any problems with the Seven-Day PAR interview?
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



**PAGEID = 279** 

	Center Number: Participant Number: _	Particip	oant'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

SAME AS PAGE 90

**BIOPSY (TYPE 4)** 

# FORM/BLOCK = ADVERSE EVENTS Signs, Symptoms and Adverse Events Log

**AELOG (TYPE 4)R** Participant's Initials:

> Center Number: THIS IS A REPEATING PAGE

Month 12 Month 18

Month 6 Month 9

Month 3

Baseline 2 Month 1

Baseline 1

Causality

Participant Number:

middle last

first

OR Check if Continuing Start/End Date attached page for codelist Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline; TIMEPT<TUTMPT> See Start Date: AESTRDT AESTPDT AEOUTCME<TUOCME , Still present and unchanged A Resolved with sequelae Outcome Month 24

\_2 Improving ], Death Action Taken Due to AE 3 Medical therapy required (check all that apply) Intervention temporarily

discontinued

□, None

AEINTEN<TÚTENScheck only one)

Intensity

Serious

Adverse Event

AE#

AENUM<1:4>

4 Intervention permanently

discontinued

ISE<TUCAUS>

AECAL

J<sub>s</sub> Very likely

AESER XYESNO

Probably

\_\_\_\_\_\_ Severe

J Doubtful

2 Moderate

Ü. Kiid Biik

AESPEC<V:100>

, None

], Still present and unchanged ACNONE

**VECONTAXYES** OR | Continuing

End Date:

Start Date:

End Date:

¬
Resolved with sequelae

S Death

day

Medical therapy redAGMEDRE ]2 Intervention temporque TEMPD ☐ 38 Other (specify):

discontinued

J None

] Doubtful

2 Moderate

, None

, Mild

, kes \*

2 Improving

3 Resolved

Intervention permane<mark>政像PERMD</mark> **ACOTHR** discontinued

☐s Very likely

Probably

3 Possibly

3 Severe

, Continuing

ő

Start Date:

], Still present and unchanged

\_\_ Improving

3 Resolved

End Date:

day

98 Other (specify):

\_l None

2 Intervention temporarily discontinued

], Doubfful

2 Moderate

∭. Kild

4EDRTEXT

**MEDRA** 

, None

3 Medical therapy required

Intervention permanently

Resolved with sequelae

S Death

Jog Other (specify): discontinued

J₅ Very likely

A Probably

J<sub>3</sub> Possibly

☐<sub>3</sub> Severe

SODETM<DATETIME

MATCHES<V:4> CONFLVL<V:2>

30DER<V:20>

**NORKFLOW<V:5> /EDRCODE<V:8>** 

□, Continuing

ő

Start Date:

, Still present and unchanged

2 Improving

3 Resolved

J, None

], Intervention temporarily discontinued

]<sub>2</sub> Doubiful

, None

Mild □

3. Possibly

☐<sub>2</sub> Moderate ☐<sub>3</sub> Severe

Resolved with sequelae

Js Death

3 Medical therapy required 1 Intervention permanently ☐% Other (specify): discontinued

☐s Very likely

→ Probably

Congenital anomaly or birth defect Other significant medical event

> Hity/incapacity ılization

□, Continuing

8

End Date:

day

CAE Bonaubina Cuibouias I Das

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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Signs, Symptoms and Adverse Events

calerie Phase 2

PAGEID = 280

'If Serious is Yes, submit expedited SAE form.

#### **TUTMPT Codelist**

- 1 = Baseline 1
- 2 = Baseline 2
- 3 = Month 1
- 4 = Month 3
- 5 = Month 6
- 6 = Month 9
- 7 = Month 12
- 8 = Month 18
- 9 = Month 24

Participant Number: \_\_\_ \_\_ \_\_

PAGEID = 281

#### **Concomitant Medications Log**

Participant's Initials: \_\_\_\_\_\_

Medication	Start Date or ☑ if Pre-study	6  Month 9  Month 12  Stop Date or ✓ if Continuing	Indication
STUDYSUP <tumed>  Study vitamin-mineral supplement</tumed>	SUPSTRDT	SUPSTPDT CONME	
2 Study calcium supplement	Derivation for CONMED1	Vitamins 90  day morth year  Calcium 00	HOCODE 0005301001 0751501001
SEE PAGE 281A	or	day morth year  OR 1 Continuing	IED2 (TYPE 4)R
DNUM <i:2> 4 CMED<v:110></v:110></i:2>	CMSTRDT  day month year  OR 1 Pre-study	CMSTPDT	MEDIND <v:110< td=""></v:110<>
5	CMPSTDY <xyes>  day / morth / year  OR 1 Pre-study</xyes>	CMEDCONT < XYES:  day / morth / year  OR	
WHODRUG_B2 WHONAME <v:80></v:80>	or D <sub>1</sub> Pre-study	or $\prod_1$ Continuing	
WHOCODE <v:32> WORKFLOW <v:5> CODER <v:20></v:20></v:5></v:32>	or D <sub>1</sub> Pre-study	or $\prod_1$ Continuing	
CODETM <datetime CONFLVL <v:2> MATCHES <v:4></v:4></v:2></datetime 	or 1 Pre-study	or la Continuing	
WHODRUG_ATC_B2	or the property of the state of	day morth year  OR 1 Continuing	
ATCTERM <v:110> 10 ATCCODE<v:40> WORKFLO2<v:5></v:5></v:40></v:110>	day /_ morth /_ year OR  1 Pre-study	or	
CODETM2 < DATETIME CONFLVL2 < V:2 > MATCHES2 < V:4 > CODER2 < V:20 >	or 1 Pre-study	day / morth year  OR 1 Continuing	

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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#### THIS IS A REPEATING PAGE

#### **Concomitant Medications Log**

PAGEID = 281+

Center Number:	Participant Number:	Participant's Initials:	
	1 of 11 of 10 of 1	i or noponii a minora.	Cont. or Infall or June

Concomitant Medications Log						
Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box.  Send copies of this form with each submission starting with baseline:  Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24						
Medication	Start Date or ☑ if Pre-study	Stop Date or ☑ if Continuing	Indication			
1	or The Study	CON  day //	MED2 (TYPE 4)R			
2	or Pre-study	day / morth / year  OR 1 Continuing	SAME AS PAGE 281			
3	or north year	or				
4	or D <sub>1</sub> Pre-study	day / morth / year —  OR □₁ Continuing				
5	or north year	or _1 Continuing				
6	or	or $\prod_1$ Continuing				
7	or 1 Pre-study	day / morth year  OR 1 Continuing				
8	or 1 Pre-study	day / morth / year  OR  1 Continuing				
9	or 1 Pre-study	day morth year  OR 1 Continuing				
10	or	day //				
11	or $\frac{1}{1}$ Pre-study	doy /— morth /— year — OR □₁ Continuing				
12	or Pre-study	day /- morth /- year				

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



#### **Concomitant Medications Log**

PAGEID = 281

CONMED1 (TYPE 4)PS

	Study Calcium Supplement 1000 mg								
	Medication STUDYSUP <tumed></tumed>	Start Date	Stop Date						
3	= Study calcium supplement, 1000 mg	SUPSTRDT	⊸SÚPSHPDT <sub>year</sub> —						

SAME AS PAGE 281

Derivation for CONMED1

<u>WHOTERM</u> Calcium

WHOCODE 00751501001

CRF, page 281A



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#### THIS IS A REPEATING PAGE

Date received at DCRI Safety Surveillance

FORM/BLOCK = ADVERSE EVENTS Serious Adverse Fvent Form

Report type: Initial SAETYPE <turptp> Follow-up #: Center Num</turptp>	ber:	Participant Number: _		Participant's Initials:
SAE Details:		Participant's	Details:	
SAE Term (Medical Diagnosis):  SAEDIAG <v:100>  SAESTRDT  SAE Onset Date:/</v:100>	Date of birth:/			
Serious Reporting Criteria: (check all that apply)  Death DEATH ALL <xyes> Life-threatening LIFETHRT DISINCAP Persistent or significant disability or incapacity Prolonged or required hospitalization PRLGHOSF Congenital anomaly or birth defect CONGDEF Other significant event requiring medical and/or surgical intervention OTHRSIG</xyes>	Serious Reporting Criteria:  (check all that apply)  th DEATH ALL <xyes> hreatening LIFETHRT DISINCAP stent or significant disability or incapacity onged or required hospitalization PRLGHOSP genital anomaly or birth defect CONGDEF ar significant event requiring medical and/or ical intervention OTHRSIG  SAE  Causality:  1 N  2 D  3 PC  4 PI  5 VI  Intensity:</xyes>		publiful  ssibly  bably  bably  ry likely   SAEINTEN <tuten>  Id  baderate  vere  Death → If Death: Date of death:  DEATHDT/  day  month  MEDRA  MEDRA  MEDRTEXT<v:100>  MEDRCODE<v:8>  WORKFLOW<v:5>  CODETM<datetime></datetime></v:5></v:8></v:100></tuten>	
Action Taken with Study Intervention: (check all that approximately accepted and the property of the property	d fax the To	Permanent Discontinua	MA CO	

ADDITIONAL PANEL ITEM ON PAGE 284.

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

Fax SAE form to DCRI Safety Surveillance at 1-919-668-7138 or 1-866-668-7138

within 24 hours of initial notification



Date received at DCRI Safety Surveillance

#### **Serious Adverse Event Form**

Report type:  Initial Follow-up #:	Cent	ter Number: _		Participant Number:	Part	ticipant's Initials:	
Medical History (relevant to event):							
	TH	IS PAGE I	NOT EN	NTERED			
Concomitant Medication (do not list	medication o	administered t	to treat this	s event):			
Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date	
					□ <sub>0</sub> No □ <sub>1</sub> Yes		
				/	□₀ No □₁ Yes	day month year	
				day month year	□₀ No □₁ Yes	day month year	
					□ <sub>0</sub> No □ <sub>1</sub> Yes	/	
				day month year	□₀ No □₁ Yes	day month year	
				day	□₀ No □₁ Yes		
				/	□₀ No □₁ Yes	/	
Relevant Lab Tests:							
Test	Date		Value/Results	1	Normal Range		
	/	/	/ear				
	/	/	/eor				

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

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

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Date received at DCRI Safety Surveillance

#### **CONTINUED FROM PAGE 282**

Report type: Initial

#### **Serious Adverse Event Form**

Follow-up #: Center Number:	Participant Number: Participant's Initials:
Please provide a brief summary of the event:	
SAESUMRY <v:150></v:150>	
Please describe the sequence of events including action taken, trea	tment given, hospital dates, etc.:
NOT DATA	BASED
Information Source:	
Date level director and find of Events	Dute of this year out
Date Investigator notified of Event:/	Date of this report:/
Person completing form:	Phone number: ()
PI name:	Fax number: ()
PI signature:	Date of signature:

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

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



THIS IS A REPEATING PAGE
PAGEID = 285
Center Nu

#### **Excessive Weight Loss Episode Report**

FORM/BLOCK = SURVEILLANCE

Extessive Weight Loss Episode Report

P	AGEID = 285	Center Number:	Participant Number:	Participant's Initials: first middle last
Exc	essive Weight	Loss Episode		
when	the BMI level is first obser	as a BMI < $18.5 \text{ kg/m}^2$ . This report is a ved to be < $18.5 \text{ kg/m}^2$ , and ends whe ention as a direct result of this episode.	n the episode either resolves or	
A Id	lentifying information  Date of initial report:	-day / month / year	т	
2	Name of person mak	ing this report:	NOT DATABASED	
4	Height:	ue:	Screening)	All measurements <f:9:3></f:9:3>
lf no	who we will be with the way of the way with the way way was a way with the way way was a way was a way way was way was	rticipant is advised about the risks of ex baseline level for up to one month. discontinued and a diet plan prescri- cate the reason why it was not tem- inplete the Temporary Discontinuation	TMPDIS <xyes bed?="" cr="" discontinued:="" form<="" from="" intervention="" on="" porarily="" th=""><th>SNO&gt;  EXPLAIN<v:50></v:50></th></xyes>	SNO>  EXPLAIN <v:50></v:50>
7 4	Date of follow-up val	restarted if the BM1 increases to 18.5 k  ue:/ F  kg WEIGHT2  kg/m² CAL	LWUPDT	of treatment.
l.	II Was the participant p  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐	after one month of increased calorie in permanently discontinued from the Coate the reason CR was not perman BMI returned to 18.5 kg/m² or higher to the (specify):	CR intervention? PERM ently discontinued (check only PERMRSN<	MDIS <xyesno> one):  EXPLNOTH<v:50></v:50></xyesno>
•	imm Note that a participan	replete the Permanent Discontinuation and its permanently discontinued for was restarted. If this happens,  CALERIE PHASE2 ANNOT	rom the CR intervention it complete the Permanent	i a BMI < 18.5 kg/m² occurs at Discontinuation from CR



#### **Excessive Weight Loss Episode Report**

		Center Number:	ramapani Number:	'	rarticipant's initials	first middle last
E	xcessive Weight Loss Epi	isode (continued)				
F	Please provide a description of th	nis episode including a	ictions taken:			
	THIS	PAGE NOT ENTER	RED			
S	tudy Manager's Signatu	ıre				
Ü	ouy manager s signare					
Si	gnature:			Date:/	mosth year	_
				/	,	



#### THIS IS A REPEATING PAGE

#### **Depression Episode Report**

PAGEID = 287

	Center Number:	_ Participant Number:	Participant's Initials:
D	epression Episode		
	epression is defined as a BDI score ≥ 20. This report is completed fo DI is ≥ 20, and ends when the episode either resolves or the particij		
A	Identifying information		PRESS (TYPE 4)
	1 Date of initial report:/	ار 	
	2 Name of person making this report:	NOT DATABASED	
В	Initial Elevation in BDI Score ≥ 20		
	3 Date of initial elevation:/		
	3 Date of initial elevation://		
c	Repeat BDI Score		
	The questionnaire is repeated in <b>one week</b> .	EDRNINT	
	5 Date of follow-up questionnaire://		
	<b>6</b> BDI score: REPBDI <1:3>		
D	Temporary Discontinuation		
	If the repeat score is $\geq$ 20, the CR intervention is temporarily disco	ontinued and a participant is advised	d to seek medical help outside of the
	study.	TMPDIS <x\< th=""><th>/ESNO&gt;</th></x\<>	/ESNO>
	7 Was the participant temporarily discontinued from the C		A TMDDON TUDDI
	$\square_0$ No $\rightarrow$ If No: Indicate the reason CR was not tempor $\square_1$ BDI score returned to < 20 $\rightarrow$ If the B		
	resolve		
	Sign th	ne form on the last page and stor	re in participant's binder.
	George Other (specify):	EXPLAIN <v:< th=""><th></th></v:<>	
	☐ 1 Yes → If Yes: Complete the Temporary Discontinuation immediately.	on from CK intervention form and	a rax to safety surveillance
	out		
E	Follow-up BDI Score		
	The questionnaire is repeated in <b>one month</b> .	TO	
	8 Date of follow-up questionnaire:/	r	
	<b>9</b> BDI score: FLWUPBDI <i:3></i:3>		ANEL ITEMS NEXT



#### **Depression Episode Report**

CONTINUED FROM PAGE 287 Genter Number: Participant Number: Participant's Initials:

Depres	sion Episode	(continued)					
If BDI sci intervent 10 Was	☐ <sub>2</sub> M ☐ <sub>98</sub> C Yes → If Yes: Comp	month of treatmenthy discontinued.  The why CR was not seem of the why CR was not seem to the why CR was not seem of the was not seem of the why CR was not seem of the was not seem of the why CR was not seem of	tinued from the C ot permanently d elow 20 PI sional indicated it is	R intervention? iscontinued (chec ERMRSN <tu resume<="" s="" safe="" th="" to=""><th>PERMDIS<x\ depr="" k="" one):="" only=""> EXPLAIN2<v< th=""><th>/ESNO&gt;</th><th></th></v<></x\></th></tu>	PERMDIS <x\ depr="" k="" one):="" only=""> EXPLAIN2<v< th=""><th>/ESNO&gt;</th><th></th></v<></x\>	/ESNO>	
point after Interventi	a participant is por r the CR was resto	arted. If this ha	ppens, please o	omplete the Po	ermanent Discon		-
			NOT DATAB	ASED			
estrii 151	Manager's S				Date:	//ywar	-3

#### THIS IS A REPEATING PAGE

#### **Eating Disorder Episode Report**

PAGEID = 289

PAGEID = 289	Center Number:	Participant Number:	Participant's Initials: first middle last					
Eating Disorder Episode								
cating disorders are defined in terms of scores on the Multi-axial Assessment of Eating Disorder Symptoms (MAEDS) and the Body Acceptability Morph (BAM) and Interview for the Diagnosis of Eating Disorders—Fourth Version (IDED-IV). Reporting starts when MAEDS and/or BAM <b>indicate</b> that there is an eating disorder, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.  EDISORD (TYPE 4)								
A Identifying information								
1 Date of initial report:	193	NOT DATABASED						
Please complete Section B and/or C a BAM, or both. B Disorder Detected by the MAEDS	according to whether t							
1 1050 11/	ALL<1:3>	ore of 70 of higher on any subscale c	THE MALUS IS GUITHISIETEG					
MAEDS Domain	f-score	MAEDS Domain	f-score					
3 Binge eating BINEAT		6 Purgative behavior	PURGE					
4 Restrictive eating RESEAT		7 Avoidance of forbidden food	Is AVOID					
5 Fear of fatness FEARFAT		8 Depression	DEPRESN					
C Disorder Detected by the BAM A participant who (a) scores a t-score of 70 or (c) shows confirming acceptability of the AL 9 Was an alert issued for the current 10 Was an alert issued for the ideal but the store of the confirming acceptability. D Follow-up with IDED-IV The diagnostic criteria for anorexia nervos of its diagnostic criteria. A sub threshold esymptoms for bulimia nervosa and anorex	e extreme body size shown in LL 3 < XYESNO > Control of the contro	n the acceptability phase of the measures of t	re is administered the IDED-IV.  CBSCORE  Yes → If Yes: †-score:  IBSCORE  Yes → If Yes: †-score:  Yes  Tating of "3" or more for each					
Anorexia nervosa  Bulimia nervosa  Binge eating	symptoms for bulimia nervosa and anorexia nervosa (only).  12 Did the participant meet the following diagnostic criteria (check all that apply)?  Anorexia nervosa							

ADDITIONAL PANEL ITEMS NEXT **PAGE** 



#### **Eating Disorder Episode Report**

**CONTINUED FROM PAGE 289** 

Center Number: \_\_\_ \_ Participant Number: \_\_\_ \_ \_

Participant's Initials: first middle last

E	Eating Disorder Episode (continued)							
	E Permanent Discontinuation  If a participant meets one or more of these diagnostic criteria, the CR intervention is permanently discontinued and a participant is advised to seek medical help outside of the study.  13 Was the participant permanently discontinued from the CR intervention?  □₀ No → If No: Indicate why CR was not permanently discontinued (check only one): □₁ Did not meet diagnostic criteria for these eating disorders □₀₀ Other (specify): □₁ Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.							
F	Please provide a description of this episode including actions taken:							
	NOT BATABAGED							
	NOT DATABASED							
L								
Study Manager's Signature								
Się	gnature: Date:/							



#### **Elevated Potassium Episode Report**

PAGEID = 291

	PAGEID = 291	Center Number:	_ Participant Number	:	Participant's Initials: first	middle far
E	levated Potassium Episo	de				
re	perkalemia is defined as an initial potassiun port is completed for each episode of hyper the particular the episode either resolves or the episode either episode episode either episode either episode e	rkalemia. Reporting start	s when the initial potas	sium level is gree	ater than 5.5 mEq/L., and en	
A	1 Date of initial report:/	REPORTD	NOT DATABA	VATEK (T	YPE 4)	
В	Initial Elevation in Potassium Leve 3 Date of initial elevation:/_  4 Potassium level: mEc	INELEVD	г	All measu	rements	
c	<f:9:3></f:9:3>					
	6 Potassium level: mEd					
D	If the follow-up test is > 5.5 mEq/L, the Co to seek medical help outside of the study.  7 Was the participant temporarily d  ☐ No → If No: Indicate the reas ☐ 1 Potassium retu ☐ 98 Other (specifing 1) Yes → If Yes: Complete the Test	iscontinued from the Con CR was not tempor arned to 5.5 mEq/L or lo EXPLAIN <v:< th=""><th>R intervention?  Parily discontinued (a wer → If potassium in episode has in page, and state on from CR Intervention?</th><th>MPDIS<xye 5.5="" heck="" in="" one):="" only="" ore="" partic<="" resolved.="" returned="" stop="" th="" the="" to=""><th>SNO&gt; TMPRSN<tuelp! binder.<="" form="" here,="" ipant's="" l="" lower,="" meq="" on="" or="" sign="" th="" the="" then=""><th>VI&gt;</th></tuelp!></th></xye></th></v:<>	R intervention?  Parily discontinued (a wer → If potassium in episode has in page, and state on from CR Intervention?	MPDIS <xye 5.5="" heck="" in="" one):="" only="" ore="" partic<="" resolved.="" returned="" stop="" th="" the="" to=""><th>SNO&gt; TMPRSN<tuelp! binder.<="" form="" here,="" ipant's="" l="" lower,="" meq="" on="" or="" sign="" th="" the="" then=""><th>VI&gt;</th></tuelp!></th></xye>	SNO> TMPRSN <tuelp! binder.<="" form="" here,="" ipant's="" l="" lower,="" meq="" on="" or="" sign="" th="" the="" then=""><th>VI&gt;</th></tuelp!>	VI>
E	Follow-up Potassium Level  The CR intervention will only be restarted  8 Date of follow-up test:/		TDT		oth of treatment.	



#### **Elevated Potassium Episode Report**

CONTINUED FROM PAGE 291	enter Number:	Participant Number:	Participant's Initials:	first middle last
	•			tirst middle last

Elevated Potassium Episode (continued)								
F Permanent Discontinuation  If potassium level is still elevated above 5.0 mEq/L after one month of treatment, the CR intervention is permanently discontinued.  10 Was the participant permanently discontinued from the CR intervention? PERMDIS <xyesno>  □0 No → If No: Indicate why CR was not permanently discontinued (check only one): PERMRSN<tuelvn> □1 Potassium returned to 5.0 mEq/L or lower □2 Other (specify): EXPLAIN2<v:50> □1 Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance</v:50></tuelvn></xyesno>								
immediately.  Note that a participant is permanently discontinued from the CR intervention if a potassium level of 5.5 mEq/L or higher occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.  G Please provide a description of this episode including actions taken:								
	NOT DATABASED							
Study Manager's Signature:								
Signature:		Date:/						



#### THIS IS A REPEATING PAGE

#### **Anemia Episode Report**

**PAGEID = 293** 

	PAGEID = 293	Center Nun	ber:	Participant Number		Participant's Initials: first middle last			
A	nemia Episode								
a (	Anemia is defined as a decrease in hemoglobin and/or hematocrit level below the lower limit of normal (LLN) for the laboratory, followed by a confirmatory value satisfying the same criteria. Reporting starts when the <b>initial</b> value is observed, and ends when the episode either esolves or the participant is permanently discontinued from the CR intervention.								
A	<b>Identifying Informat</b>				EMIA1 (TYPE	4)			
	2 Name of person me ease complete Section	aking this report:  NOT  B according to whether	DATABAS	SED	All measurem <f:9:3> ematocrit was be</f:9:3>				
nc	ormal.								
В	Value(s) Below the L  3 Date of lab test:	ower Limit of Normal:	LABDT						
		Value	3	Lower Limit o	f Normal (LLN)	ABOUT THENOS			
	4 Hemoglobin:	HGLOB1	-			□ <sub>0</sub> No □ <sub>1</sub> Yes			
	5 Hematocrit:	HCRIT1			GLOBLI				
	6 RBC:	RBC1			CRITLL				
	7 Iron level:	IRON1			RBCLLN	1 $\square_0$ No $\square_1$ Yes			
c		ii torti			IRONLL	.N1			
	BLCI	RITDT		BLCRIT					
	FL	JCRITDT		FLUPCRIT	N	IOT DATABASED			
D	Repeat Test: The hematology panel is	repeated in two weeks. The i	ron level is a	DECREASE					
-	11 Date of repeat lab		year						
		Value	REPT	B <b>D</b> ower Limit o	f Normal (LLN)	Below LLN?			
	12 Hemoglobin:					ALL KXYESNQ>			
ſ	13 Hematocrit:					□₀ No □₁ Yes			
	14 RBC:	HGLOB2			GLOBLLN:	□0 140 □1 162			
Ī	15 Iron level:	HCRIT2			CRITLLN2				
	If the repeated test confir Nevertheless, s/he contin	RBC2 ms the previous findings, a p IRON2 ues the CR intervention.	articipant is c	advised to seek medic	RBCLLN2 al help outside of the IRONLLN2	study.			



#### THIS IS A REPEATING PAGE

#### **Anemia Episode Report**

PAGEID = 294Participant Number: \_\_\_ \_\_ \_\_

Anemia Episode (continued) **ANEMIA2 (TYPE 4)** E Medical Help Outside the Study: 16 Was the participant advised to seek medical help outside the study? MEDHELP<XYESNO> \_\_\_ No → If No: Indicate the reason why not: return to acceptable values, then the HELPRSN<TUHELP> episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.  $\square_{98} \text{ Other (specify): } \underline{\qquad} \text{HLPOTHSP} < \text{V}:50 > \\ \square_{1} \text{ Yes} \rightarrow \text{If Yes: Date on which patient was advised: } \underline{\qquad}_{\text{day}} / \underline{\qquad}_{\text{month}} / \underline{\qquad}_{\text{year}}$ One Month Follow-up Test If the hematology and iron levels do not return to acceptable values, the hematology panel and iron levels are repeated one month after the treatment was initiated. ALL<XYESNO> All measurements Lower Limit of Normal (LLN) <F:9:3> Value **Below LLN?** 18 Hemoglobin: □ No □, Yes **GLOBLLN3** HGLOB3 19 Hematocrit: ∏₀ No **CRITLLN3** HCRIT3 20 RBC: o No RBC3 \_\_\_\_, Yes RBCLLN3 21 Iron level: **IRON3** □<sub>o</sub> No \_\_\_, Yes **IRONLLN3** Temporary Discontinuation If anemia is not improving or worsens, the CR intervention is temporarily discontinued. 22 Was the participant temporarily discontinued from the CR intervention? TMPDIS<XYESNO>  $\square_0$  No  $\rightarrow$  If No: Indicate the reason why CR was not temporarily discontinued (check only one): Hemoglobin panel and iron levels returned to acceptable values  $\rightarrow$  If the hemoglobin and iron levels return to acceptable levels, the TMPRSN<TUANEP> episode has resolved. Stop here, sign the form on the last page, and forward to the coordinating center Other (specify): \_\_\_\_\_EXPLAIN<V:50> with the next batch of data forms. \_\_\_\_, Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section H, next page.



#### THIS IS A REPEATING PAGE

## **Anemia Episode Report**

**PAGEID = 295** 

	PAGEID = 295	Center Number:	Participant Number:	Participant's Initials: First middle last
A	nemia Episode	(continued)		
Н	Two Month Follow-u	p Value	ANEMIA	43 (TYPE 4)
			on was temporarily discontinued for one mor	nth, the intervention
	is permanently discontinu	ed. follow-up lab test:/_ <sub>doy</sub> /_ <sub>month</sub> /-	FUMTH2DT	
	23 Date of two month	day month	учот	ALL <xyesno></xyesno>
[		Value	Lower Limit of Normal (LLN)	Below LLN?
Ì	24 Hemoglobin:	HGLOB4	GLOBLLN4	□₀ No □₁ Yes
Ì	25 Hematocrit:	HCRIT4	CRITLLN4	□₀ No □₁ Yes
	26 RBC:	RBC4	RBCLLN4	□₀ No □₁ Yes
	27 Iron level:	IRON4	IRONLLN4	□₀ No □₁ Yes
		All measurements		
I	Permanent Disconti	nvation <f:9:3></f:9:3>		
	28 Was the participant	t permanently discontinued from the	CR intervention? PERMDIS <xye< th=""><th>SNO&gt;</th></xye<>	SNO>
	$\square_0$ No $\rightarrow$ If No: In	dicate the reason why CR was not p	ermanently discontinued (check only one	): SN <tuaneq></tuaneq>
	L	], Hemoglobin panel and iron levels ret ] <sub>98</sub> Other (specify):	urned to acceptable values FERIVIN EXPLAIN2 <v:50></v:50>	SINCTUAINEQS
			ntinuation from CR Intervention form an	d fax to Safety
		urveillance immediately.		a rux ro outory
J	Please provide a de	scription of this episode includin	a actions taken:	
•		<b></b>		
		NOT D	ATABASED	
				———
S	tudy Manager'	s Signature:		
	gnature:		Date: /	/
J1	gd.0101		Date:/_	month year



#### THIS IS A REPEATING PAGE

### Ventricular Ischemia Episode Report

PAGEID = 296

	PAGEID = 290 Center Number: Participant Number: Participant's Initials:	last
V	entricular Ischemia Episode	
wh	ISCHEMIA (TYPE 4) is report is completed if an episode of ventricular ischemia occurs during the VO <sub>2</sub> max measurement (12 or 24 months). Reporting starts en it is first observed, and ends when the episode either resolves or the participant is permanently discontinued from the intervention.	
A	Identifying information	
	Date of initial report:/	
	2 Name of person making this report: NOT DATABASED	
В	Date when the ventricular ischemia was observed VOMAXDT  3 Date:/	
C	Temporary Discontinuation  The CR intervention is temporarily discontinued and a stress imaging study is recommended within two weeks.  4 Was CR temporarily discontinued and a stress imaging study ordered? TMPDIS <xyesno>  □₀ No → If No: Indicate the reason CR was not temporarily discontinued:  EXPLAIN<v:50></v:50></xyesno>	5
	☐ Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to Section D below.	
D	Stress Imaging Study  If a stress imaging study confirms presence of ventricular ischemia, the CR intervention will be permanently discontinued and a participant will follow all other study procedures to the study end.  5 Date of study:/	
	□ <sub>0</sub> No □ <sub>1</sub> Yes  ISCHEMIA <xyesno></xyesno>	
E	Permanent Discontinuation	
	Was the participant permanently discontinued from the CR intervention? PERMDIS <xyesno>  □ No → If No: Indicate the reason CR was not permanently discontinued: □ The study did not confirm the presence of ventricular ischemia. □ STPLAIN2<v:150> □ Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.</v:150></xyesno>	



## Ventricular Ischemia Episode Report

	Center Number: _	Participant Number:	Participant's Initials:	first middle last
Ventricular Ischemic	Episode (continued	)		
F Please provide details of	ECG findings including a	ictions taken:		
	THIS PAGE NOT E	NTERED		
Study Manager's Si	gnature:			
Signature:		D	ate://	-



## Phase 2

## Temporary Discontinuation from CR Intervention

DISCTYPE<TURPTP>

Check one:	Initial	Follow-up

mber: \_\_\_ Participant Number: \_\_\_

Participant's Initials:

first	middle	fast

Τe	emporary Discontinu	ation					
1 2	Date of temporary discontinua  Reason for discontinuation (che  ☐₁ Persistent potassium level > 5.5  ☐₂ Persistent potassium level ≥ 6.	t <b>ion:</b> —/ ck only one): mEq/L and <	//_ TE 6.0 mEq/L c	MPRSN at any point	<tutemp> during study, confirmed by re</tutemp>	peat testing at	C (TYPE 4)
	if second level is above 5.5 n  3 Treatment resistant anemia (a  4 Ventricular ischemia observed  5 Decrease in BMI to <18.5 at  6 Moderate depression (BDI ≥  7 Personal reasons (specify):  8 Other (includes any other disersurgery, or severe infections) (specifically)	nEq/L nemia has no I with exercis any time 20)	ot improved of e (stress image	after one me ge perform	onth of treatment) ed in 2 weeks)		recovery from trauma,
Pa	rticipant's Details:						
	te of birth:/ <sub>north</sub> / nder: Male Female	year		Wei	ght: cm ght: kg (if applicable):		
Rel	evant Medical History:						
Rel	evant Concomitant Medication (	do not list me	dication adn	ninistered to	o treat this event):		
	Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
						O No	day month year
					day month year	□ <sub>0</sub> No □ <sub>1</sub> Yes	day month year
					day month year	□ <sub>0</sub> No □ <sub>1</sub> Yes	day month year
Rel	evant Lab Tests:						
	Test		Date		Value/Results	ı	Normal Range
		/	month ;	yeor	ADDITIONAL P	ANEL ITE	EM NEXT
		/	month ;	учат	PAGE		
		/	month 1	учог			
		/	month	year			

Fax to Safety Surveillance at 1-866-668-7138



# Temporary Discontinuation from CR Intervention

CONTINUED FROM PAGE 298 Genter Number: \_\_\_\_\_ Participant Number: \_\_\_\_\_ Participant's Initials:

	Total	middle last
Temporary Discontin	uation (continued)	
Please describe any additional act	on taken (e.g., observation or seek medical attention outside study):	
	NOT DATABASED	
Intervention Resump	tion	
	Fill out Permanent Discontinuation from CR Intervention form	
ir res	: Date intervention was resumed:/	
Investigator's Signat	ure	
Investigator:	signature Date:/	-
1		



# Permanent Discontinuation from CR Intervention

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

PAGEID = 300

Pe	ermanent Discontinuation
1	Date of permanent discontinuation://PRMDISDT PERMRSN <tuperm>  PERMDISC (TYPE 1)</tuperm>
2	Reason(s) for discontinuation (check only one):
	<ul> <li>□ 1 Persistent potassium level &gt; 5.0 mEq/L resistant to one month of treatment</li> <li>□ 2 Persistent potassium level ≥ 5.5 mEq/L after CR was temporarily discontinued and restarted</li> </ul>
	3 Persistent anemia (anemia still not improving or worsening one month after temporary discontinuation)
	Ventricular ischemia confirmed by stress image
	$\square_5$ Decrease in BMD at the hip or spine of 5% or greater from baseline at any time during first 12 months of CR
	$\square_{\rm 6}$ Decrease in BMD at the hip or spine of 10% or greater from baseline at any time during months 12–24 of CR
	a Eating disorder (including anorexia nervosa, bulimia nervosa or binge eating OR experiencing a sub-threshold eating disorder)
	Gruther decrease in BMI after 1 month of increase calorie intake OR temporary discontinuation of CR intervention OR persistent
	decrease in BMI (< 18.5) after CR intervention restarted
	$\square_{10}$ rsychiatric disorder (including severe depression) $\square_{11}$ Reoccurrence of moderate depression (BDI still > 20) after CR intervention restarted OR moderate depression that is not improving
	or is worsening (BDI ≥ 30) after temporary discontinuation of CR intervention
	12 Major illness or disease (e.g., cancer)
	$\square_{13}$ Trauma requiring prolonged hospitalization or bed rest for more than one month
	15 Pregnancy (women only)
	PERSONAL <v:50>  Personal reasons (specify):  PERMOTHR<v:50></v:50></v:50>
Pai	ticipant's Details:
Da	re of birth: / Height: cm
Ge	nder: Male Female Weight:kg
	BMI (if applicable):
Rel	evant Medical History:
	NOT DATABASED



## Permanent Discontinuation from CR Intervention

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

						first middle fast
Permanent Discontinu	ation (	ontinued)				
Relevant Concomitant Medication (			ninistered to	o treat this event):		
Medication	Dose & Unit	Frequency	Route	Start Date	Continued	Stop Date
					□ <sub>0</sub> No □ <sub>1</sub> Yes	
				day month year	□₀ No □₁ Yes	/
				day month year	□ <sub>0</sub> No □ <sub>1</sub> Yes	
Relevant Lab Tests:	THIS	S PAGE N	IOT ENT	ΓERED		
Test		Date		Value/Results		Normal Range
	/_	month	учот			
	/	/	year			
	/	month /	учот			
	/	/	увот			
Please describe any additional action	on taken (e.	g., observatio	on or seek	medical attention outside stu	dy):	
Investigator's Signatu	Jre					
Investigator:		signature		Dat	e:/	month year

CALERIE PHASE2 ANNOTATION V4.012JUN2008

FORM/BLOCK = STUDY COMPLETION

## calerie Phase 2

## **Study Completion/ Early Discontinuation of Study Evaluation**

PAGEID = 302

PAGEID = 302	Center Number: Participant Number:	: Participant's Initials: indele tast
Completion/Early Discon	tinuation	
Did the participant complete the studion of the participant complete the studion of the prima o	ary reason for discontinuation (check only one)  REASON <tuend></tuend>	(YESNO> : STDYCOMP (TYPE 1)
□ <sub>4</sub> Death → <b>Date</b> • Co • Co • Re	→ Complete Signs, Symptoms and Adverse E  • If serious adverse event, complete Serio  • of death:///	s Log
□₁ Yes		

# HWGHLOG1 (TYPE 4)

FORM/BLOCK = HOME WEIGHT LOG

calerie Phase 2

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∍AG	
<u>6</u>	
$\equiv$	
ΣĘΑ	
REF	
A	
S IS	
Ĭ	

Center Number:

	Completed by Calerie staff:	e staff:		
	Baseline 1 5	0 Months	☐ 18 Months	
	Baseline 2	12 Months	24 Months	
	TIMEPT <tutmpt< th=""><th>TUTMPT</th><th></th><th></th></tutmpt<>	TUTMPT		
Participant Number		articipant's Initials:	itials: first midale last	

Daily Home Weight Log	eight Log					
Were you issued a new	Were you issued a new scale? $\square_0  \text{No} = \square_1  \text{Yes} -$ Please complete this loa in either blue or black ink.	Were you issued a new scale? $\square_0 \ N \circ \square_1 \ Yes \to If Yes$ : Date first used: $\square_{oop} \ \square_{oop} \ \square_{oop$	SOUPPIA GOLD TO SOUR SOUR	Serial no.:	SERIALNO <v:30></v:30>	
-						
Day of week:	Day of week:	Day of week:	Day of week:	Day of week:	Day of week HWGHLOG2 (TYPE 4)R	Day of week: DE 4)R
Date:	Date:	Date: HWLOGDT	Date:	Date:	Date:	Date:
Time: □, AM □, PM = 00000 is 17:59	Time: ☐₁ AM ☐₂ PM — ☐∞ PM = PM	Time: □1 ★M □2 PM — PM — M = M = M = M = M = M = M = M = M =	Time:	Time: ☐₁ AM ☐₂ PM —	Time:	Time: ☐1 AM ☐2 PN
Weight:	Weight:	Weight:	NOT DATABASED Weight:	Weight:	Weight: lb	Weight:
		<f:9:3></f:9:3>				
Day of week:	Day of week	Day of week:	Day of week:	<b>Day of week</b> :	Day of week:	Day of week:
Date:	Date:	Date:	Date:	Date:	Date:	Date:
month day / year	month day / year	month day / year	month day / year	month day / year	month day / year	month day / year
Time: ☐1 AM ☐2 PM	Time: ☐1 AM ☐2 PM	Time: \( \Bigcup_1 \text{ AM } \Bigcup_2 \text{ PM } \\ \Bigcup_2 \text{ PM } \\ \Bigcup_3 \text	Time: Time: Time: PM	Time:	Time:	Time: Time PM
00:00 17:59	00:00 17:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59	00:00 to 11:59

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

**During DLW Periods** 

Check scale memory

9

9

9

9

9

9

9

Weight:

Weight:

Weight:

Weight:

Weight:

Weight:

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

PAGEID = 303

Weight:



#### FORM/BLOCK = PROTOCOL DEVIATION

#### **Protocol Deviation**

THIS IS A REPEATING PAGE PAGEID = 304

PAGEID = 304	Center Number:	Participant Number:	Participant's Initials: iniddle last
Protocol Deviation			
Please indicate below any deviations fr Check all that apply (one participant per		l taken for this participant. PD	EVIATE (TYPE 4)R
Baseline 1 Baseline 2 Month	n 1		h 12 Month 18 Month 24
Date of deviation:/	DEVDT ALL <xyes></xyes>		TIMEPT <tutmpt></tutmpt>
☐ Informed Consent CONSENT		Study/laboratory procedure	LABEXPLN <v:50></v:50>
☐ Inclusion/Exclusion criteria INEXCL		Participant non-fasting NC	DNFAST
Randomization/treatment assignment R		Participant safety (specify): S	AFETY SAFEXPLN <v:50></v:50>
Concomitant Medications CONMED	)	Other (specify): OTHE	R OTHEREXP <v:50></v:50>
Brief explanation of deviation:	/EXPLN <v:150></v:150>		
Baseline 1 Baseline 2 Mont	h 1 Month 3	Month 6 Month 9 Mont	th 12 Month 18 Month 24
Date of deviation:/	year		
☐ Informed Consent		Study/laboratory procedur	es (specify):
☐ Inclusion/Exclusion criteria		Participant non-fasting	
Randomization/treatment assignment		Participant safety (specify):	
Concomitant Medications		Other (specify):	
Brief explanation of deviation:			

Submission date:	/	/	Moste	/	/	Note	/_	/_	уеаг

Participant non-fasting

Other (specify):

Study/laboratory procedures (specify): \_\_\_\_\_\_

Participant safety (specify):

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24

☐ Informed Consent

Inclusion/Exclusion criteria

Concomitant Medications

Randomization/treatment assignment

Brief explanation of deviation: \_\_\_

Date of deviation:  $\_\__{day}$  / $\_\__{month}$  / $\_\__{year}$ 

# PROTOCOL = CALERIE\_PHASE2 STUDYBOOK = END OF CR SURVEY FORM = SURVEY



<b>Center Number</b>	Participant Number		

#### **End of CR Survey**

CALSRVY (TYPE 1)

I was helped in following my CR prescription by	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
1feeling prepared by what I was told about the intervention requirements before I started the study. PRI	1 EREQ	2	ALL<	TUTOOL>	5	6	7	0
2being provided my meals during the in-feeding period MEA	1 LS	2	3	4	5	6	7	0
3trying the Mediterranean diet during the in-feeding period.	1 DIET	2	3	4	5	6	7	0
4trying the Low Glycemic diet during the in-feeding period. LO	WGLYC	2	3	4	5	6	7	0
5trying the Low-fat High fiber diet during the in-feeding period. LOW	1 /FAT	2	3	4	5	6	7	0
6being trained on portion sizes during the first few weeks of the study.	1	2	3	4	55	6	7	0
7 using a system (like HMR) to memorize estimated calories. HMR	1 SYS	2	3 CALERIE PHA	4 SE2 ANNOT	5 ATION V8.0 24	6 4FEB2012	7	0



Center Number \_\_ \_ Participant Number \_\_ \_ \_ \_

I was helped in following my CR prescription by	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
8being provided recipes by the staff. RECIP	1 ES	2	3	4	5	6	7	0
	1 EMEA	2	3	4	5	6	7	0
10changing which food groups I include in my meals and snacks.	1 ODCHG	2	3	4	5	6	7	0
11changing my eating patterns (how many times I eat a day). EATP	1 ATT	2	3	4	5	6	7	0
12trying to use a Volumetrics approach (i.e., eating low- calorie foods of high volume), in order to feel fuller on my calorie prescription.	1	2	3	4	5	6	7	0
13weighing in at my sessions.	1 GHIN	2	3	4	5	6	7	0
14weighing myself at home.	1 WGT	2	3	4	5	6	7	0



Center Number \_\_ \_ Participant Number \_\_ \_ \_ \_ \_

I was helped in following my CR prescription by	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
15using the weight zone graph. WGT	1 GRPH	2	3	4	5	6	7	0
16self- monitoring my calorie intake using a PDA. U	1 SEPDA	2	3	4	5	6	7	0
17self- monitoring my calorie intake using a computer program. COI	1 MPUTR	2	3	4	5	6	7	0
18self- monitoring my calorie intake using a paper record.	1 APEREC	2	3	4	5	6	7	0
19individual sessions with my counselors.	1 UNSLR	2	3	4	5	6	7	0
20written materials and handouts I received during individual sessions.	1 ANDOUT	2	3	4	5	6	7	0
21having extra contacts by phone with my counselors.X	1 TRPHON	2	3	4	5	6	7	0
22having extra contacts by email with my counselors.	TREMAI	2	3	4	5	6	7	0



Center Number \_\_ \_ Participant Number \_\_ \_ \_ \_

I was helped in following my CR prescription by	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
23 having extra contacts in-person with my counselors IN	1 PRSON	2	3	4	5	6	7	0
24attending group sessions.	1 PSESS	2	3	4	5	6	7	0
25written materials and handouts I received at group sessions.	1 GRPHAND	2	3	4	5	6	7	0
26using behavioral contracts with my counselors.	1 BEHAVE	2	3	4	5	6	7	0
27seeking social support of family or friends. SOC	1 CSUPP	2	3	4	5	6	7	0
28being provided meal replacements.	1 REPLACE	2	3	4	5	6	7	0
29decreasing the frequency of eating out.	1 ATOUT	2	3	4	5	6	7	0
30increasing fiber in my diet.	1 HFIB	2	3	4	5	6	7	0



Center Number \_\_ \_ Participant Number \_\_ \_ \_ \_

I was helped in following my CR prescription by	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree	Not Applicable
31returning to in-feeding later in the study (after the first in-feeding)	1 NFEED	2	3	4	5	6	7	0
32having flexible options and strategies to assist my CR (instead of one structured program for everyone).	1 FLEXOPT	2	3	4	5	6	7	0
33being given some of my results during the 2 years, such as my total calories expended and how it related to my CR goal.	CRGOAL	2	3	4	5	6	7	0



Now that you have finished the CALERIE trial, you may or may not choose to continue to follow a CR diet on your own.

Based on how you feel now, please answer these questions about your diet behavior after you finish CALERIE.

	Strongly Agree	Agree	Agree Somewhat	Neither Agree Nor Disagree	Disagree Somewhat	Disagree	Strongly Disagree
34. After leaving CALERIE, I will continue to follow a CR diet.	POSTCR	2	3	4	5	6	7

	To A Great Extent	Somewhat	Undecided	Very Little	Not At All
35. I plan to continue to follow my current level of CR	1 LEVEL <tulev></tulev>	2	3	4	5