

Month 18 Submission Month 17 Visit

	Center Number: Participant Number:	Participant's Initials	first middle last
Clinic Weight			
Weight date and time:	/	Staff initials:	ddle last
	y reason (use codelist below):		
Clinic weight (if the two	measurements are more than 0.1 kg apart, measure weight a third time):		
Weight 1:	kg		
Weight 2:	kg		
Weight 3:	kg		
Weight of gown:	kg		
Pregnancy Tes	t		
Outcomes Lab			
	collection started:/		
Sample If a sample is not obtained, indicate with a Not Done.	Sample Complete?	If Not Done, Reason	CL-II
Blood		(Use codelist below)	Staff Initials
	□₀ No □₁ Yes	(Use codelist below)	
NOTE: Be	Vaccine Administration efore any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility.	(Use codelist below) If Not Done, Reason (Use codelist below)	Initials

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

5 Not required



		Center Number: _	Participant Number:	Participant's Initials:
C	linic Weight			
W	eight date and time:/ _{month}	/	: .00:00 to 23:59	Staff initials:
	R Not done → Specify reason (use Code			first middle lost
Cli	nic weight (if the first two measurements a	re more than 0.1 kg	g apart, measure weight a third time):	
W	eight 1:	_ kg		
W	eight 2:	_ kg		
W	eight 3:	_ kg		
W	eight of gown:	_ kg		
	ital Signs			
As	sessment date and time:/	/	: - : - : - : - : - : - : - : - : -	
	If waist measurement not done → Sp	ecify reason (use c	odelist below):	
1	Natural waist measurement (if the first two measurements are more than	1.0 cm apart, measu	ure natural waist circumference a third time):	Staff initials:
	Natural waist measurement 1:			
	Natural waist measurement 2:		cm	
	Natural waist measurement 3:		cm	
2	Umbilical point waist measurement (if the umbilical point waist circumference a third tin		ments are more than 1.0 cm apart, measure	
	Umbilical point waist measurement 1	:	cm	
	Umbilical point waist measurement 2	:	cm	
	Umbilical point waist measurement 3	:	cm	
3	Pulse: bpm OR Not dor	ne → Specify reas	on (use codelist below):	Staff initials:
4	Temperature:°C C	R Not done → S	pecify reason (use codelist below):	Staff initials:
5	Respirations: per minute OR	Not done → Spe	ecify reason (use codelist below):	Staff initials:
6	Blood pressure (check only one):1	eft arm \square_{2} Righ	ht arm	Staff initials:
	6a Blood pressure 1:/	mm Hg	Time:: OR Not done = Specify rea	→ son (use codelist below):
	6b Blood pressure 2:/	mm Hg	Time:::	
	6c Blood pressure 3:/	mm Hg 1	Fime: : : : : : : : : : : : : : : : : : :	
No	ot Done Codelist: 1 Participant refused	2 Clinician unable	e to obtain 3 Insufficient time 4 Instr	ument failure 5 Not required



	Center Number:	Participant Number:	Particip	pant's Initials: first middle last		
12-Lead ECG						
Date and Time		Findin	ıgs	Staff Initials		
OR Not done → Specify reason (see codelist below): Safety Labs Date and time of last meal:	\square_1 Nor \square_2 Abr	Is ECG (check only one): \[\begin{align*} \be				
Date and time of sample collection:						
Sample	Sample		t Done, Reason e codelist below)	Staff Initials		
Blood	□ ₀ No □ ₁ Yes			first middle last		
Urine	□₀ No □₁ Yes			first middle last		
Outcomes Labs						
Date and time of last meal: Date and time sample collection started:	/ /	/				
Sample		Sample Complete?	If Not Done, Reason (Use codelist below)	Staff Initials		
Blood		□ ₀ No □ ₁ Yes		first middle last		
If a sample is not obtained, indicate with a No	t Done.					

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



		Center Number:	Participant Number:	Participant's Initials:	rst middle las
Do	ite completed:/	/ OR Not c			
В	DI-II				
In	pick out the one weeks, including	e statement in each group tha	it best describes the way you e the statement you have pic	group of statements carefully and I have been feeling during the pas ked. Be sure that you check only o	st two
1	Sadness:	\square_0 I do not feel sad \square_1 I feel sad much of the \square_2 I am sad all of the tin \square_3 I am so sad or unhap	ne		
2	Pessimism:	 □₀ I am not discourage □₁ I feel more discourage □₂ I do not expect thing □₃ I feel my future is hop 	ed about my future than I u s to work out for me		
3	Past failure:	 □₀ I do not feel like a fa □₁ I have failed more th □₂ As I look back, I see □₃ I feel I am a total fail 	an I should have a lot of failures		
4	Loss of pleasure:	 □₀ I get as much pleasu □₁ I don't enjoy things of □₂ I get very little pleasu □₃ I can't get any pleasu 	is much as I used to ure from the things I used	to enjoy	
5	Guilty feelings:	 □₀ I don't feel particular □₁ I feel guilty over man □₂ I feel quite guilty mos □₃ I feel guilty all of the 	y things I have done or s st of the time	should have done	
6	Punishment feelings:	 □₀ I don't feel I am bein □₁ I feel I may be punish □₂ I expect to be punish □₃ I feel I am being pun 	ned ed		
7	Self-dislike:	 □₀ I feel the same about □₁ I have lost confidence □₂ I am disappointed in □₃ I dislike myself 	e in myself		
N	ot Done Codelist: 1 Participa	nt refused 2 Clinician unable	to obtain 3 Insufficient time	4 Instrument failure 5 Not require	ed



		Center Number:	Participant Number:	Participant's Initials:
В	DI-II (continued)			
8	Self-criticalness:	\Box_1 I am more critica \Box_2 I criticize myself	r blame myself more than usual I of myself than I used to be for all of my faults r everything bad that happens	
9	Suicidal thoughts or wishes:	-	•	carry them out
10	Crying:	\square_0 I don't cry any m \square_1 I cry more than I \square_2 I cry over every I \square_3 I feel like crying,	used to ittle thing	
11	Agitation:	\square_1 I feel more restles \square_2 I am so restless o	ound up or restless than usual ss or wound up than usual or agitated that it's hard to stay or agitated that I have to keep n	
12	Loss of interest:	, I am less intereste	rerest in other people or activition and in other people or things that of my interest in other people of terested in anything	ın before
13	Indecisiveness:	, I find it more diffi	about as well as ever cult to make decisions than usu ater difficulty in making decision aking my decisions	
14	Worthlessness:	-	nyself as worthwhile and useful less as compared to other peo	
15	Loss of energy:	I don't have enou	energy as ever y than I used to have ugh energy to do very much ugh energy to do anything	



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



	Center Number:	Participa	nt Numbe	er:		Partici	pant's Ini	tials:	middle last
Date completed:/	OR Not done →	Specify	reason	(use coo	lelist belo	w):			
Multiaxial Assessment of	Eating Disorder	Symp	otom	S (MAE	DS)				
Instructions: Using the scale shown, plea	ise rate the following items o	on a scal	e from 1	to 7. Ple	ease ansv	ver as tr			
			Never	Very Rarely	Rarely	Some- times	Often	Very Often	Always
1 Fasting is a good way to lose	e weight.				\square_3	4	5		7
2 My sleep isn't as good as it u	used to be.				\square_3	4	5	6	
3 I avoid eating for as long as	l can.				\square_3		5	6	
4 Certain foods are "forbidden	" for me to eat.				\square_3		5		7
5 I can't keep certain foods in my binge on them.	house because I will					4	5		
6 I can easily make myself vom	nit.				\square_3	4	5	6	
7 I can feel that being fat is term	rible.				\square_3	4	5	6	
8 I avoid greasy foods.					\square_3	4	5	6	
9 It's okay to binge and purge	once in a while.					4	5		
10 I don't eat certain foods.					\square_3				
11 I think I am a good person.					\square_3	4	5		
12 My eating is normal.							5	6	
13 I can't seem to concentrate lo	itely.					4	5	6	
14 I try to diet by fasting.					\square_3	4	5		
15 I vomit to control my weight.						4	5	6	
16 Lately nothing seems enjoyal	ole anymore.				\square_3	4	5	6	
17 Laxatives help keep you slim							5		
18 I don't eat red meat.									
19 I eat so rapidly I can't even to	aste my food.				\square_3		5		
Not Done Codelist: 1 Participant refused	2 Clinician unable to obtain	n 3 Ins	ufficient	time 4	Instrume	nt failure	5 No	t require	-d



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



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