Participant Initialization Form

Participant ID: ___**ID**_____
Date of Evaluation: __**DOEDATE**_____
Cohort: __**COHORT**____

PARTICIPANT INFORMATION

1. Date of birth *(mm/dd/yy)*: **DOBM** / **DOBD** / **DOBY**

2. Gender: 1 ☐ Male 2 ☐ Female **SEX**

3. Race *(check all that apply)*:

   RACEW ☐ Caucasian/White
   RACEB ☐ African American/Black
   RACEI ☐ American Indian/Native American
   RACEAL ☐ Alaskan Native
   RACEAS ☐ Asian
   RACEP ☐ Pacific Islander
   RACEO ☐ Other: ___**RACEOS**_____

4. Is participant Hispanic/Latino? ☐ Yes ☐ No **HISP**

5. Cellular phone number (for text messages and login): (_____) ____–_____ **PHONE**

   a. Mobile provider for this phone number: **PROVIDER**

      1 ☐ AT&T
      2 ☐ Sprint PC
      3 ☐ T-Mobile
      4 ☐ Verizon
      999 ☐ Other, specify ___**PROVIDOS**_____

6. E-mail address (for invitation to complete questionnaires): __**CEMAIL**_____

7. Do you want to send the participant an email invitation to complete the screening questionnaires? **INVIT**

   ☐ Yes ☐ No

(For coordinator use only) **RRACE**
Should the participant be randomized in the 'white' race category? ☐ W ☐ M

PARTICIPANT VISIT CHECKLIST

The participant needs to provide the following information/documentation <u>prior</u> to beginning their assessment session today. (*Items needed are marked*)

□ Informed Consent   □ Contact Screening Form

□ PAR-Q Questionnaire   □ Computer experiences and requirements

□ Physician Consent   □ Needs to meet with Principal Investigator

The assessments must be completed in the following order by the individuals listed. Under no circumstances is this protocol to be altered unless approved by the Principal Investigator for this participant.

□ Greet participant   Initial: _____

□ Blood pressure/heart rate   Initial: _____

□ Blood collection   Initial: _____

□ Height and weight   Initial: _____

□ Anthropometrics   Initial: _____

□ DXA   Initial: _____

□ Exercise Test prep   Initial: _____

□ Exercise Test   Initial: _____

□ Questionnaires completed   Initial: _____

□ DHQ completed   Initial: _____

□ Paffenbarger Questionnaire completed   Initial: _____

□ Armband given to participant   Initial: _____

□ Medications   Initial: _____

□ AEs/SAEs   Initial: _____

□ Satisfaction Survey (Month 24 only)   Initial: _____

□ Technology Use Survey (Month 24 only)   Initial: _____

Physical Assessment Form

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

SECTION I: BLOOD PRESSURE ASSESSMENT

1. Are you taking blood pressure medication?   □ Yes   □ No **BPMX**
2. Time of blood pressure measurement: **BPHR BPMIN**   □ AM   □ PM **BPTIME**
3. Arm Circumference: measured to the nearest 0.1 cm

1st Measurement	2nd Measurement	3rd Measurement*	
ARM1	ARM2	ARM3	ARM

* If the 1st and 2nd measurements differ by >1 cm, then a 3rd measurement is to be taken.

4. Select the cuff size used: **BPCUFF**

   1 □ 17.0 to <24.0 cm (Small Adult)
   2 □ 24.0 to <33.0 cm (Adult)
   3 □ 33.0 to <41.0 cm (Large Adult)
   4 □ ≥41.0 cm (Thigh or Large Adult Long)**

** If a participant's upper arm circumference would indicate use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the Large Adult Long arm cuff should be used.

5. Systolic and Diastolic Pressure:

	Systolic Pressure	Diastolic Pressure	
1st Measurement	BPSYS1	BPDIAS1	
2nd Measurement	BPSYS2	BPDIAS2	BPSYS
3rd Measurement***	BPSYS3	BPDIAS3	BPDIAS

*** If the 1st and 2nd measurements for Systolic Pressure differ by >10 mmHg or the 1st and 2nd measurements for Diastolic Pressure differ by >6 mmHg, then a 3rd measurement is to be taken.

6. Resting Heart Rate:

1st Measurement	2nd Measurement	3rd Measurement****	
HRREST1	HRREST2	HRREST3	HRREST

**** Heart rate measurements are taken from the Dinamap when blood pressure is assessed.

SECTION II: HEIGHT AND WEIGHT ASSESSMENTS

1. Body Height: measured to the nearest 0.1 cm

1st Measurement	2nd Measurement	3rd Measurement*	
HEIGHT1	HEIGHT2	HEIGHT3	HEIGHT

* If the 1st and 2nd measurements differ by >0.5 cm, then a 3rd measurement is to be taken.

2. Body Weight: measured to the nearest 0.1 kg

1st Measurement	2nd Measurement	3rd Measurement**	
WEIGHT1	WEIGHT2	WEIGHT3	WEIGHT

** If the 1st and 2nd measurements differ by >0.2 kg, then a 3rd measurement is to be taken.

BMI

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

SECTION III: INFORMATION FOR ARMBAND

1. Was the participant given the assessment armband during this visit?　□ Yes　□ No **ARMBAND**

    If 'No', date armband given to participant *(mm/dd/yy)*: **ABM** / **ABD** / **ABY**

    a. Age: **ABAGE** years

    b. Handedness: □ Right-handed　□ Left-handed **HAND**

    c. Does the participant currently smoke?　□ Yes　□ No **SMOKE**

    > Not entered in the database:
    >
    > Date of Birth *(mm/dd/yy)*: ___ / ___ / ___
    >
    > Gender: □ Male □ Female

SECTION IV: GIRTH MEASUREMENTS

1. Measured to the nearest 0.1 cm

	1st Measurement	2nd Measurement	3rd Measurement*	
Waist *(taken at the level of the umbilicus)*	**WAISTU1**	**WAISTU2**	**WAISTU3**	**WAISTU**
Waist *(taken at the level of the iliac crest)*	**WAISTC1**	**WAISTC2**	**WAISTC3**	**WAISTC**
Hip *(greatest protrusion of the buttocks)*	**HIP1**	**HIP2**	**HIP3**	**HIP**

* If the 1st and 2nd measurements differ by >1.0 cm, then a 3rd measurement is to be taken.

SECTION V: BIO-ELECTRICAL IMPEDANCE ANALYSIS (BIA)

1. Was BIA performed on the date of evaluation?　□ Yes　□ No **BIA**

    If 'No', date test performed *(mm/dd/yy)*: **BIAM** / **BIAD** / **BIAY**

	Measurement
Resistance	**RESIST**
Reactance	**REACT**

SECTION VI: DUAL-ENERGY X-RAY ABSORPTIOMETRY (DXA)

1. Urine pregnancy test completed?　□ Yes　□ No　□ N/A **PREGT**

    If 'Yes', results of urine pregnancy test:　□ Positive (do not perform DXA)　□ Negative **PREG**

2. Was DXA performed on the date of evaluation?　□ Yes　□ No **DXA**

    If 'No', date DXA performed *(mm/dd/yy)*: **DXAM** / **DXAD** / **DXAY**

SECTION VII: GRADED EXERCISE TEST

1. Was graded exercise test performed on the date of evaluation? ☐ Yes ☐ No **GETEST**

   If 'No', date test performed *(mm/dd/yy)*: __**GETESTM**__ / __**GETESTD**__ / __**GETESTY**__

Age: __**GEAGE**__ years   Height: _____ cm   Weight: _____ kg

Termination Heart Rate: __TERMHR__ bpm (85% of Age-Predicted Max Heart Rate)

Time (minutes) TIMEMIN	Speed (mph) SPEED	% Grade GRADE	Heart Rate (bpm) HR	Blood Pressure BPS/BPD	RPE RPE	GESTAGE
0:00 - 1:00	3.0	0.0%		XXXXX	XXXXX	
1:01 - 2:00	3.0	1.0%		/		
2:01 - 3:00	3.0	2.0%		XXXXX	XXXXX	
3:01 - 4:00	3.0	3.0%		/		
4:01 - 5:00	3.0	4.0%		XXXXX	XXXXX	
5:01 - 6:00	3.0	5.0%		/		
6:01 - 7:00	3.0	6.0%		XXXXX	XXXXX	
7:01 - 8:00	3.0	7.0%		/		
8:01 - 9:00	3.0	8.0%		XXXXX	XXXXX	
9:01 - 10:00	3.0	9.0%		/		
10:01 - 11:00	3.0	10.0%		XXXXX	XXXXX	
11:01 - 12:00	3.0	11.0%		/		
12:01 - 13:00	3.0	12.0%		XXXXX	XXXXX	
13:01 - 14:00	3.0	13.0%		/		
14:01 - 15:00	3.0	14.0%		XXXXX	XXXXX	
15:01 - 16:00	3.0	15.0%		/		
16:01 - 17:00	3.0	16.0%		XXXXX	XXXXX	
17:01 - 18:00	3.0	17.0%		/		
18:01 - 19:00	3.0	18.0%		XXXXX	XXXXX	
19:01 - 20:00	3.0	19.0%		/		
20:01 - 21:00	3.0	20.0%		XXXXX	XXXXX	
21:01 - 22:00	3.0	21.0%		/		
22:01 - 23:00	3.0	22.0%		XXXXX	XXXXX	
23:01 - 24:00	3.2	22.0%		/		
24:01 - 25:00	3.4	22.0%		XXXXX	XXXXX	
25:01 - 26:00	3.6	22.0%		/		
26:01 - 27:00	3.8	22.0%		XXXXX	XXXXX	
27:01 - 28:00	4.0	22.0%		/		
28:01 - 29:00	4.2	22.0%		XXXXX	XXXXX	
29:01 - 30:00	4.4	22.0%		/		
Termination Time: **GETIME**	**GESPD**	**GEGRD**	**GEHR**	**GEBPS**/**GEBPD**	**GERPE**	

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

Recovery:

Time (minutes) TIMEMIN	Speed (mph) SPEED	% Grade GRADE	Heart Rate (bpm) HR	Blood Pressure BPS/BPD	RPE RPE	GESTAGE
0:00 - 1:00	2.5	0.0%		XXXXX	XXXXX	
1:01 - 2:00	2.0	0.0%		/	XXXXX	
2:01 - 3:00	1.5	0.0%		XXXXX	XXXXX	
3:01 - 4:00	Seated	Seated		/	XXXXX	
4:01 - 5:00	Seated	Seated		XXXXX	XXXXX	
5:01 - 6:00	Seated	Seated		/	XXXXX	
6:01 - 7:00	Seated	Seated		XXXXX	XXXXX	

Reason the test was terminated: **GERSN**

1 ☐ Achieved 85% of age-predicted maximal heart rate

2 ☐ ECG abnormality prior to achieving 85% of age-predicted maximal heart rate

3 ☐ Blood pressure abnormality prior to achieving 85% of age-predicted maximal heart rate

4 ☐ Participant requested to terminate prior to achieving 85% of age-predicted maximal heart rate

5 ☐ Equipment/technical failure

6 ☐ Other: ___**GERSNOS**_____

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

SECTION VIII: MEDICATIONS

Is the participant currently taking any medications (within the past 30 days) or have they taken any prescription medications since this study's previous protocol evaluation (NOTE: For Baseline Assessment respond "Yes" if currently (within the past 30 days) taking prescription medications regularly)?

☐ Yes ☐ No **MEDS**

If Yes, indicate medications:

	Taken Any Time Since Last Visit (Does not apply to Baseline Evaluation)	Taken Regularly for at Least 1 Month Since Last Visit (At Baseline - "taking medication regularly for past 1 month")	Currently Taking
Systemic steroids	☐ **MEDSTER2**	☐ **MEDSTER3**	☐ **MEDSTER**
Prescription weight loss drugs	☐ **MEDWL2**	☐ **MEDWL3**	☐ **MEDWL**
Diabetes medications: (check all that apply)	☐ **MEDDIAB2**	☐ **MEDDIAB3**	☐ **MEDDIAB**
Insulin	☐ **DIABINS2**	☐ **DIABINS3**	☐ **DIABINS**
Metformin	☐ **DIABMET2**	☐ **DIABMET3**	☐ **DIABMET**
Byetta	☐ **DIABBYE2**	☐ **DIABBYE3**	☐ **DIABBYE**
TZDs	☐ **DIABTZD2**	☐ **DIABTZD3**	☐ **DIABTZD**
Other, specify	☐ **DIABO2** ____**DIABOS2**____	☐ **DIABO3** ____**DIABOS3**____	☐ **DIABO** ____**DIABOS**____
Blood pressure medication	☐ **MEDBP2**	☐ **MEDBP3**	☐ **MEDBP**
Lipid-lowering medications	☐ **MEDLIP2**	☐ **MEDLIP3**	☐ **MEDLIP**
Birth control medication: (check all that apply)	☐ **MEDBC2**	☐ **MEDBC3**	☐ **MEDBC**
Combination	☐ **BCCOMBO2**	☐ **BCCOMBO3**	☐ **BCCOMBO**
Progesterone only	☐ **BCPROG2**	☐ **BCPROG3**	☐ **BCPROG**
Psychotropic medication in the following categories:	☐ **MEDPSY2**	☐ **MEDPSY3**	☐ **MEDPSY**
Antipsychotic medication	☐ **PSYPSYC2**	☐ **PSYPSYC3**	☐ **PSYPSYC**
Antidepressant	☐ **PSYDEPR2**	☐ **PSYDEPR3**	☐ **PSYDEPR**
Lithium	☐ **PSYLITH2**	☐ **PSYLITH3**	☐ **PSYLITH**
Depakote, Neurontin, or Lyrica	☐ **PSYDNL2**	☐ **PSYDNL3**	☐ **PSYDNL**
Prescription drugs for Attention Deficit-Hyperactivity Disorder (ADHD)	☐ **PSYADHD2**	☐ **PSYADHD3**	☐ **PSYADHD**

Physical Assessment Form

Participant ID: ____**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

SECTION IX: ADVERSE EVENTS/SERIOUS ADVERSE EVENTS

1. Since the last study visit:

SAE a. Was the participant hospitalized overnight for any reason? ☐ Yes ☐ No

AE b. Did the participant experience any Adverse Events? ☐ Yes ☐ No

> If 'Yes' to **a** or **b**, complete the appropriate AE/SAE forms.

SECTION X: COMPLETION OF ASSESSMENTS

1. Did the participant complete all assessments <u>required</u> for the protocol visit? ☐ Yes ☐ No **COMPLETE**

   If 'No', indicate the assessments that were not completed or were partially completed:

	Assessment	Not Completed	Partially Completed	Reason (If "other", specify reason)	
CBPHR	☐ Blood Pressure/Heart Rate	☐ **CBPHRC**	☐	_**CBPHRR**_	**CBPHRROS**
CBLD	☐ Blood Collection	☐ **CBLDC**	☐	_**CBLDR**_	**CBLDROS**
CHTWT	☐ Height and Weight	☐ **CHTWTC**	☐	**CHTWTR**	**CHTWTROS**
CANTH	☐ Anthropometrics	☐ **CANTHC**	☐	**CANTHR**	**CANTHROS**
CDXA	☐ DXA	☐ **CDXAC**	☐	**CDXAR**	**CDXAROS**
CXTST	☐ Exercise Test	☐ **CXTSTC**	☐	**CXTSTR**	**CXTSTROS**
CQST	☐ Questionnaires	☐ **CQSTC**	☐	**CQSTR**	**CQSTROS**
CDHQ	☐ DHQ	☐ **CDHQC**	☐	**CDHQR**	**CDHQROS**
CPAFF	☐ Paffenbarger	☐ **CPAFFC**	☐	**CPAFFR**	**CPAFFROS**
CARMB	☐ Assessment Armband	☐ **CARMBC**	☐	**CARMBR**	**CARMBROS**
CSAT	☐ Satisfaction Survey (24M only)	☐ **CSATC**	☐	**CSATR**	**CSATROS**
CTECH	☐ Technology Use (24M only)	☐ **CTECHC**	☐	**CTECHR**	**CTECHROS**

Reasons:
1 = Agreed to "mini" evaluation   4 = Participant concern regarding pain/discomfort   7 = Other, specify
2 = Safety/medical issue   5 = Refused, no reason provided
3 = Time constraint   6 = Unknown

SECTION XI: SATISFACTION SURVEY (Month 24 only)

Date of Assessment *(mm/dd/yy)*: **SATM** / **SATD** / **SATY**
(If not the same as Date of Evaluation)

1. How satisfied overall with the weight management program received from the IDEA Study? **SATOVER**
   - 1 ☐ very dissatisfied
   - 2 ☐ somewhat dissatisfied
   - 3 ☐ somewhat satisfied
   - 4 ☐ very satisfied

2. Would recommend the weight management program received from the IDEA Study to others? **SATREC**
   - 1 ☐ definitely not
   - 2 ☐ probably not
   - 3 ☐ probably would
   - 4 ☐ definitely would

3. Given the effort put into following the weight management program received from the IDEA Study, how satisfied with <u>progress</u> over the past 2 years? (-4 to 4): _____ **SATPROG**

Physical Activity Stages of Change

SECTION I: STAGES OF CHANGE – PHYSICAL ACTIVITY

*Directions: For each question below, please mark **"Yes"** or **"No"**. Please be sure to follow the instructions carefully.*

1. Physical activity or exercise includes such activities as walking briskly, digging in the garden, jogging, climbing stairs, heavy housecleaning or any other activity where the exertion is similar to these activities.

			Yes	No
a.	I am currently <u>physically active</u>	**ACTCUR**	☐	☐
b.	I intend to become more <u>physically active</u> in the next 6 months	**ACTNXT6**	☐	☐

2. For activity to be **regular** it **must add up to a total of 30 or more minutes per day**, and be done **at least 5 days per week**. For example, you could take a 30 minute walk or take a 10 minute walk, rake leaves for 10 minutes, and climb up stairs for 10 minutes.

			Yes	No
a.	I currently engage in <u>regular physical activity</u>	**REGCUR**	☐	☐
b.	I have been <u>regularly physically active</u> for the past 6 months	**REGPST6**	☐	☐
c.	In the past, I have been <u>regularly physically active</u> for a period of at least 3 months	**REGPRD3**	☐	☐

SECTION II: PHYSICAL ACTIVITY SELF-EFFICACY

Directions: Select the response that best indicates how confident you are that you could be physically active in each of the following situations.

1. How confident are you that you can be physically active in each of the following situations?

			Not at all confident	Slightly confident	Moderately confident	Very confident	Extremely Confident
a.	When I am tired	**PATIRED**	1	2	3	4	5
b.	When I am in a bad mood	**PAMOOD**	1	2	3	4	5
c.	When I feel I don't have time	**PATIME**	1	2	3	4	5
d.	When I am on vacation	**PAVAC**	1	2	3	4	5
e.	When it is raining or snowing	**PAWTHR**	1	2	3	4	5

SECTION III: EXERCISE OUTCOME EXPECTATIONS AND BARRIERS

Directions: *Please indicate your level of agreement with each of the following statements.*

		Strongly Disagree				Strongly Agree
1. A major benefit of physical activity for me is *to stay in shape*.	**BENSHAPE**	1	2	3	4	5
2. A major benefit of physical activity for me is *to make me feel better in general.*	**BENFEEL**	1	2	3	4	5
3. A major benefit of physical activity for me is *good health*.	**BENHLTH**	1	2	3	4	5
4. A major benefit of physical activity for me is *to maintain proper body weight.*	**BENMAIN**	1	2	3	4	5
5. A major benefit of physical activity for me is *to improve my appearance.*	**BENAPP**	1	2	3	4	5
6. A major benefit of physical activity for me is *to enhance my self-image and confidence.*	**BENCONF**	1	2	3	4	5
7. A major benefit of physical activity for me is *its positive psychological effect.*	**BENPSYCH**	1	2	3	4	5
8. A major benefit of physical activity for me is *to reduce stress and relax.*	**BENRELAX**	1	2	3	4	5
9. A major benefit of physical activity for me is *fun and enjoyment.*	**BENFUN**	1	2	3	4	5
10. A major benefit of physical activity for me is *to help cope with life's pressures.*	**BENCOPE**	1	2	3	4	5
11. A major benefit of physical activity for me is *to lose weight*.	**BENLOSE**	1	2	3	4	5
12. A major benefit of physical activity for me is *companionship.*	**BENCOMP**	1	2	3	4	5
13. The major reason when I do not exercise is *lack of motivation.*	**RSNMOT**	1	2	3	4	5
14. The major reason when I do not exercise is that *I am too lazy.*	**RSNLAZY**	1	2	3	4	5
15. The major reason when I do not exercise is that *I am too busy.*	**RSNBUSY**	1	2	3	4	5
16. The major reason when I do not exercise is that *I do not have enough time.*	**RSNTIME**	1	2	3	4	5
17. The major reason when I do not exercise is that *it interferes with school.*	**RSNSCHL**	1	2	3	4	5
18. The major reason when I do not exercise is that *I am too tired.*	**RSNTIRED**	1	2	3	4	5
19. The major reason when I do not exercise is that *it interferes with work.*	**RSNWORK**	1	2	3	4	5
20. The major reason when I do not exercise is that *it is too inconvenient.*	**RSNCONV**	1	2	3	4	5
21. The major reason when I do not exercise is that *the weather is bad.*	**RSNWTHR**	1	2	3	4	5
22. The major reason when I do not exercise is *lack of facilities.*	**RSNFAC**	1	2	3	4	5
23. The major reason when I do not exercise is that *exercise is boring.*	**RSNBORE**	1	2	3	4	5
24. The major reason when I do not exercise is that *I am too fatigued by exercise.*	**RSNFATG**	1	2	3	4	5
25. The major reason when I do not exercise is *family obligations.*	**RSNFAM**	1	2	3	4	5
26. The major reason when I do not exercise is that *I have health reasons that limit my exercise.*	**RSNHLTH**	1	2	3	4	5

Thank you for completing this questionnaire!

Weight Loss Self-Assessment

Participant ID: ____**ID**_____
Date of Evaluation: __**DOEDATE**_____
Protocol Timepoint: ___**TMPT**_____

SECTION I: STAGES OF CHANGE – WEIGHT LOSS

Directions: *For each question below, please mark* ***"Yes"*** *or* ***"No".***

		Yes	No
1. I am currently not interested in <u>engaging in diet or physical activity behaviors to lose weight</u>.	**CURNINT**	☐	☐
2. I am currently contemplating <u>engaging in diet or physical activity behaviors to lose weight,</u> but I am not sure if I am committed to doing so within the next month.	**CURCONT**	☐	☐
3. I am currently interested in <u>engaging in diet or physical activity behaviors to lose weight,</u> and I plan on initiating these changes in behavior within the next month.	**CURINTER**	☐	☐
4. I am currently <u>engaging in diet or physical activity behaviors to lose weight</u>, but I have been doing this regularly for less than 6 months.	**CURENG**	☐	☐
5. I have lost weight and I am currently <u>engaging in diet or physical activity behaviors to lose additional weight or to maintain my weight loss,</u> and I have been doing this regularly for more than 6 months.	**CURENG6**	☐	☐

SECTION II: WEIGHT LOSS SELF-EFFICACY

Directions: *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 <u>successfully resist</u> the desire to eat.*

I am confident that:

		Not confident at all								Very confident	
1. I can resist eating when I am anxious (or nervous)	**EANX**	0	1	2	3	4	5	6	7	8	9
2. I can control my eating on the weekends	**EWKEND**	0	1	2	3	4	5	6	7	8	9
3. I can resist eating even when I have to say "no" to others	**ENOTH**	0	1	2	3	4	5	6	7	8	9
4. I can resist eating when I feel physically run down	**ERUNDWN**	0	1	2	3	4	5	6	7	8	9
5. I can resist eating when I am watching TV	**ETV**	0	1	2	3	4	5	6	7	8	9
6. I can resist eating when I am depressed (or down)	**EDEP**	0	1	2	3	4	5	6	7	8	9
7. I can resist eating when there are many different kinds of foods available	**EAVAIL**	0	1	2	3	4	5	6	7	8	9
8. I can resist eating even when I feel it's impolite to refuse a second helping	**EIMPOL**	0	1	2	3	4	5	6	7	8	9
9. I can resist eating even when I have a headache	**EHDACHE**	0	1	2	3	4	5	6	7	8	9

Weight Loss Self-Assessment

		Not confident at all							Very confident		
10. I can resist eating when I am reading	EREAD	0	1	2	3	4	5	6	7	8	9
11. I can resist eating when I am angry (or irritable)	EANGRY	0	1	2	3	4	5	6	7	8	9
12. I can resist eating even when I am at a party	EPARTY	0	1	2	3	4	5	6	7	8	9
13. I can resist eating even when others are pressuring me to eat	EPRESS	0	1	2	3	4	5	6	7	8	9
14. I can resist eating when I am in pain	EPAIN	0	1	2	3	4	5	6	7	8	9
15. I can resist eating just before going to bed	EBED	0	1	2	3	4	5	6	7	8	9
16. I can resist eating when I have experienced failure	EFAIL	0	1	2	3	4	5	6	7	8	9
17. I can resist eating even when high calorie foods are available	EHCAL	0	1	2	3	4	5	6	7	8	9
18. I can resist eating even when I think others will be upset if I don't eat	EUPSET	0	1	2	3	4	5	6	7	8	9
19. I can resist eating when I feel uncomfortable	EUNCOMF	0	1	2	3	4	5	6	7	8	9
20. I can resist eating when I am happy	EHAPPY	0	1	2	3	4	5	6	7	8	9

SECTION III: WEIGHT LOSS OUTCOME EXPECTATIONS AND BARRIERS

Directions: Please indicate your level of agreement with each of the following statements.

		Strongly Disagree				Strongly Agree
1. A major benefit of weight loss for me is *to stay in shape*.	WBENSH	1	2	3	4	5
2. A major benefit of weight loss for me is *to make me feel better in general.*	WBENFEEL	1	2	3	4	5
3. A major benefit of weight loss for me is *good health.*	WBENHLTH	1	2	3	4	5
4. A major benefit of weight loss for me is *to improve my appearance.*	WBENAPP	1	2	3	4	5
5. A major benefit of weight loss for me is *to enhance my self-image and confidence.*	WBENCONF	1	2	3	4	5
6. A major benefit of weight loss for me is *its positive psychological effect.*	WBENPSYC	1	2	3	4	5
7. A major benefit of weight loss for me is *to reduce stress and relax.*	WBENRELX	1	2	3	4	5
8. A major benefit of weight loss for me is *it enhances opportunities for fun and enjoyment.*	WBENFUN	1	2	3	4	5
9. A major benefit of weight loss for me is *it helps me cope with life's pressures.*	WBENCOPE	1	2	3	4	5

Weight Loss Self-Assessment

		Strongly Disagree				Strongly Agree
10. A major benefit of weight loss for me is *it enhances opportunities for companionship and social interactions.*	**WBENCOMP**	1	2	3	4	5
11. A major reason I have difficulty losing weight is *lack of motivation.*	**WRSNMOT**	1	2	3	4	5
12. A major reason I have difficulty losing weight is that *I am too lazy.*	**WRSNLAZY**	1	2	3	4	5
13. A major reason I have difficulty losing weight is that *I am too busy.*	**WRSNBUSY**	1	2	3	4	5
14. A major reason I have difficulty losing weight is that *I do not have enough time to focus on the appropriate weight loss behaviors.*	**WRSNTIME**	1	2	3	4	5
15. A major reason I have difficulty losing weight is *school commitments.*	**WRSNSCHL**	1	2	3	4	5
16. A major reason I have difficulty losing weight is *work commitments.*	**WRSNWORK**	1	2	3	4	5
17. A major reason I have difficulty losing weight is *family obligations.*	**WRSNFAM**	1	2	3	4	5
18. A major reason I have difficulty losing weight is that *I am not sure how to eat appropriately.*	**WRSNKNOW**	1	2	3	4	5
19. A major reason I have difficulty losing weight is that *eating appropriately is too expensive.*	**WRSNFEXP**	1	2	3	4	5
20. A major reason I have difficulty losing weight is that *eating appropriately is inconvenient.*	**WRSNFCON**	1	2	3	4	5
21. A major reason I have difficulty losing weight is that *I am not able to make the necessary changes in my eating behaviors.*	**WRSNFCHG**	1	2	3	4	5
22. A major reason I have difficulty losing weight is that *I am not sure how to exercise appropriately.*	**WRSNEXER**	1	2	3	4	5
23. A major reason I have difficulty losing weight is that *exercise is too expensive.*	**WRSNEEXP**	1	2	3	4	5
24. A major reason I have difficulty losing weight is that *exercise is inconvenient.*	**WRSNECON**	1	2	3	4	5
25. A major reason I have difficulty losing weight is that *I am not able to make the necessary changes in my exercise behaviors.*	**WRSNECHG**	1	2	3	4	5

Thank you for completing this questionnaire!

Weight History Form

Participant ID: ___**ID**_____

Date of Evaluation: __**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

Directions: This questionnaire asks about you and your weight history. Please read each question carefully and then answer each question as completely and honestly as possible.

1. What is the most you have weighed (women not counting pregnancies)? __**MAXWGT**__ lbs
   How old were you then? __**MAXWAGE**__ years

2. What is the least you have weighed since age 18? __**MINWGT**__ lbs
   How old were you then? __**MINWAGE**__ years

3. How much would you like to weigh? __**DESWGT**__ lbs

4. Have you ever dieted to lose weight? ☐ Yes ☐ No **DIET**

5. Have you ever participated in an organized weight loss program
   (e.g., Weight Watchers, TOPS, etc.)? ☐ Yes ☐ No **DIETORG**

6. Are you currently dieting to lose weight? ☐ Yes ☐ No **DIETCURL**

7. Are you currently dieting to maintain your weight? ☐ Yes ☐ No **DIETCURM**

8. Put a check to indicate whether you were extremely underweight, underweight, normal weight, overweight, or extremely overweight at each of the following ages:

	Extremely Underweight	Underweight	Normal Weight	Overweight	Extremely Overweight	Not Applicable
a. Pre-School **PRESCH**	1	2	3	4	5	6
b. Elementary School **ELEMSCH**	1	2	3	4	5	6
c. Junior High (12-14 yrs) **JRHIGH**	1	2	3	4	5	6
d. High School (15-18 yrs) **HIGHSCH**	1	2	3	4	5	6
e. 19-25 yrs **ADULTYNG**	1	2	3	4	5	6
f. 26-35 yrs **ADULT**	1	2	3	4	5	6

9. Check the number of times in your life you have **intentionally** lost the number of pounds shown below (e.g., through diet, exercise, a formal weight control program, etc.)

	NEVER	1-2	3-5	6-10	More than 10
a. How often have you lost 10-19 pounds? **ILOST10**	1	2	3	4	5
b. How often have you lost 20-49 pounds? **ILOST20**	1	2	3	4	5
c. How often have you lost 50-79 pounds? **ILOST50**	1	2	3	4	5
d. How often have you lost 80-99 pounds? **ILOST80**	1	2	3	4	5
e. How often have you lost 100+ pounds? **ILOST100**	1	2	3	4	5

Weight History Form

10. Check the number of times in your life you have **<u>unintentionally</u>** lost the number of pounds shown below (e.g., because of illness, injury, etc.)

			NEVER	1-2	3-5	6-10	More than 10
a.	How often have you lost 10-19 pounds?	**ULOST10**	1	2	3	4	5
b.	How often have you lost 20-49 pounds?	**ULOST20**	1	2	3	4	5
c.	How often have you lost 50-79 pounds?	**ULOST50**	1	2	3	4	5
d.	How often have you lost 80-99 pounds?	**ULOST80**	1	2	3	4	5
e.	How often have you lost 100+ pounds?	**ULOST100**	1	2	3	4	5

11. If you gained weight, how much would your weight have to increase before you considered this weight gain to be significant? **SIGGAIN**
    - 1 ☐ < 5 pounds
    - 2 ☐ 5-10 pounds
    - 3 ☐ 11-15 pounds
    - 4 ☐ 16-20 pounds
    - 5 ☐ > 20 pounds

12. Family Weight History

MOBESE a. Was your biological mother overweight or obese? ☐ Yes ☐ No ☐ Unknown
FOBESE b. Was your biological father overweight or obese? ☐ Yes ☐ No ☐ Unknown

Thank you for completing this questionnaire!

Directions: *Please select the response that best describes your answer to the following items.*

		Never	Seldom	Occasionally	Often	Repeatedly
1. Before going out in public, I always notice how I look	**PUBLOOK**	0	1	2	3	4
2. I am careful to buy clothes that will make me look my best	**CLOTHES**	0	1	2	3	4
3. I would pass most physical-fitness tests	**FITTEST**	0	1	2	3	4
4. It is important that I have enough superior physical strength	**STRONG**	0	1	2	3	4
5. My body is sexually appealing	**SEXAPP**	0	1	2	3	4
6. I am not involved in a regular physical exercise program	**NOEXPRO**	0	1	2	3	4
7. I am in control of my health	**CONTHLTH**	0	1	2	3	4
8. I know a lot about things that affect my physical health	**KNOWHLTH**	0	1	2	3	4
9. I have deliberately developed a healthy lifestyle	**HLTHLIFE**	0	1	2	3	4
10. I constantly worry about being or becoming fat	**WORRY**	0	1	2	3	4
11. I like my looks just the way they are	**LOOKS**	0	1	2	3	4
12. I check my appearance in a mirror whenever I can	**CHKAPP**	0	1	2	3	4
13. Before going out, I usually spend a lot of time getting ready	**PREPTIME**	0	1	2	3	4
14. My physical endurance is good	**PHENDUR**	0	1	2	3	4
15. Participating in sports is unimportant to me	**SPORTIMP**	0	1	2	3	4
16. I do not actively do things to keep physically fit	**KEEPFIT**	0	1	2	3	4
17. My health is a matter of unexpected ups and downs	**UPDOWN**	0	1	2	3	4
18. Good health is one of the most important things in my life	**HLTHIMP**	0	1	2	3	4
19. I don't do anything that I know might threaten my health	**THREAT**	0	1	2	3	4

Body Image Scale

		Never	Seldom	Occasionally	Often	Repeatedly
20. I am very conscious of even small changes in my weight	**SMCHNG**	0	1	2	3	4
21. Most people would consider me good looking	**GOODLOOK**	0	1	2	3	4
22. It is important that I always look good	**LOOKIMP**	0	1	2	3	4
23. I use very few grooming products	**GRMPROD**	0	1	2	3	4
24. I easily learn physical skills	**LEARNEZ**	0	1	2	3	4
25. Being physically fit is not a strong priority in my life	**PRIORITY**	0	1	2	3	4
26. I do things to increase my physical strength	**INCSTRNG**	0	1	2	3	4
27. I am seldom physically ill	**SELDMILL**	0	1	2	3	4
28. I take my health for granted	**GRANTED**	0	1	2	3	4
29. I often read books and magazines that pertain to health	**READHLTH**	0	1	2	3	4
30. I like the way I look without my clothes	**NOCLOTH**	0	1	2	3	4
31. I am self-conscious if my grooming isn't right	**GRMSC**	0	1	2	3	4
32. I usually wear whatever is handy without caring how it looks	**HANDY**	0	1	2	3	4
33. I do poorly in physical sports or games	**SPORTBAD**	0	1	2	3	4
34. I seldom think about my athletic skills	**ATHSKLS**	0	1	2	3	4
35. I work to improve my physical stamina	**STAMINA**	0	1	2	3	4
36. From day to day I never know how my body will feel	**DAILY**	0	1	2	3	4
37. If I am sick, I don't pay much attention to my symptoms	**SICKSYMP**	0	1	2	3	4
38. I make no special effort to eat a balanced and nutritious diet	**BALDIET**	0	1	2	3	4

Body Image Scale

		Never	Seldom	Occasionally	Often	Repeatedly
39. I like the way my clothes fit me	CLTHFIT	0	1	2	3	4
40. I don't care what people think about my appearance	PPLTHAPP	0	1	2	3	4
41. I take special care with my hair grooming	GRMHAIR	0	1	2	3	4
42. I dislike my physique	PHYSIQ	0	1	2	3	4
43. I don't care to improve my abilities in physical activities	PHABLTY	0	1	2	3	4
44. I try to be physically active	PHYSACT	0	1	2	3	4
45. I often feel vulnerable to sickness	VULNSICK	0	1	2	3	4
46. I pay close attention to my body for signs of illness	ATTNILL	0	1	2	3	4
47. If I'm coming down with a cold or flu, I just ignore it and go on as usual	IGNRFLU	0	1	2	3	4
48. I am physically unattractive	UNATTR	0	1	2	3	4
49. I never think about my appearance	INTHAPP	0	1	2	3	4
50. I am always trying to improve my physical appearance	IMPAPP	0	1	2	3	4
51. I am very well coordinated	WELLCOOR	0	1	2	3	4
52. I know a lot about physical fitness	KNOWFIT	0	1	2	3	4
53. I play a sport regularly throughout the year	PLAYREG	0	1	2	3	4
54. I am a physically healthy person	PHYSHLTH	0	1	2	3	4
55. I am very aware of small changes in my physical health	AWARECHG	0	1	2	3	4
56. At the first sign of illness, I seek medical advice	ILLMED	0	1	2	3	4
57. I am on a weight-loss diet	WLDIET	0	1	2	3	4

Body Image Scale

		Never	Rarely	Sometimes	Often	Very Often
58. I have tried to lose weight by fasting or going on crash diets	**WLFAST**	0	1	2	3	4

		Very Underweight	Somewhat Underweight	Normal Weight	Somewhat Overweight	Very Overweight
59. I think I am…:	**ITHINK**	1	2	3	4	5
60. From looking at me, most other people would think I am…:	**PPLTHINK**	1	2	3	4	5

Directions: *Indicate how satisfied you are with each of the following areas of your body:*

		Very Dissatisfied	Mostly Dissatisfied	Neither Satisfied nor Dissatisfied	Mostly Satisfied	Very Satisfied
61. Face (facial features, complexion)	**SATFACE**	1	2	3	4	5
62. Hair (color, thickness, texture)	**SATHAIR**	1	2	3	4	5
63. Lower torso (buttocks, hips, thighs, legs)	**SATLTORS**	1	2	3	4	5
64. Mid torso (waist, stomach)	**SATMTORS**	1	2	3	4	5
65. Upper torso (chest or breasts, shoulders, arms)	**SATUTORS**	1	2	3	4	5
66. Muscle tone	**SATMUSC**	1	2	3	4	5
67. Weight	**SATWGHT**	1	2	3	4	5
68. Height	**SATHGHT**	1	2	3	4	5
69. Overall appearance	**SATAPP**	1	2	3	4	5

Thank you for completing this questionnaire!

![idea logo](Innovative Diet Exercise & Activity)

Participant ID: ___**ID**_____

Date of Evaluation: __**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

Directions: *Read each of the following 36 statements carefully. If you agree with the statement, or feel that it is true as applied to you, mark the box in the* **"True"** *column. If you disagree with the statement, or feel that it is false as applied to you, mark the box in the* **"False"** *column. Be certain to answer every question.*

		True	False
1. When I smell a sizzling steak or see a juicy piece of meat, I find it difficult to keep from eating, even if I have just finished a meal.	**STEAK**	☐	☐
2. I usually eat too much at social occasions, like parties and picnics.	**SOCOCC**	☐	☐
3. I am usually so hungry that I eat more than three times a day.	**MORETHN3**	☐	☐
4. When I have eaten my quota of calories, I am usually good about not eating any more.	**QUOTA**	☐	☐
5. Dieting is so hard for me because I just get too hungry.	**TOOHNGRY**	☐	☐
6. I deliberately take small helpings as a means of controlling my weight.	**SMHELP**	☐	☐
7. Sometimes things just taste so good that I keep on eating even when I am no longer hungry.	**TASTEGD**	☐	☐
8. Since I am often hungry, I sometimes wish that while I am eating, an expert would tell me that I have had enough or that I can have something more to eat.	**EXPERT**	☐	☐
9. When I feel anxious, I find myself eating.	**ANXS**	☐	☐
10. Life is too short to worry about dieting.	**LFSHORT**	☐	☐
11. Since my weight goes up and down, I have gone on reducing diets more than once.	**REDUCE**	☐	☐
12. I often feel so hungry that I just have to eat something.	**HUNGRY**	☐	☐
13. When I am with someone who is overeating, I usually overeat too.	**OVEREAT**	☐	☐
14. I have a pretty good idea of the number of calories in common foods.	**CALCOM**	☐	☐
15. Sometimes when I start eating, I just can't seem to stop.	**NOTSTOP**	☐	☐
16. It is not difficult for me to leave something on my plate.	**PLATE**	☐	☐
17. At certain times of the day, I get hungry because I have gotten used to eating then.	**CERTIME**	☐	☐
18. While on a diet, if I eat a food that is not allowed, I consciously eat less for a period of time to make up for it.	**MAKEUP**	☐	☐
19. Being with someone who is eating often makes me hungry enough to eat also.	**EATWTH**	☐	☐
20. When I feel blue, I often overeat.	**BLUE**	☐	☐

Participant ID: ___ID_____

Date of Evaluation: __DOEDATE_____

Protocol Timepoint: ___TMPT_____

		True	False
21. I enjoy eating too much to spoil it by counting calories or watching my weight.	**ENJOY**	☐	☐
22. When I see a real delicacy, I often get so hungry that I have to eat right away.	**DELIC**	☐	☐
23. I often stop eating when I am not really full as a conscious means of limiting the amount that I eat.	**NOTFULL**	☐	☐
24. I get so hungry that my stomach often seems like a bottomless pit.	**BTMLSPIT**	☐	☐
25. My weight has hardly changed at all in the last ten years.	**NOCHNG**	☐	☐
26. I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	**FINISH**	☐	☐
27. When I feel lonely, I console myself by eating.	**LNLY**	☐	☐
28. I consciously hold back at meals in order not to gain weight.	**HOLDBACK**	☐	☐
29. I sometimes get very hungry late in the evening or at night.	**LATE**	☐	☐
30. I eat anything I want, any time I want.	**EATANY**	☐	☐
31. Without even thinking about it, I take a long time to eat.	**LONGTIME**	☐	☐
32. I count calories as a conscious means of controlling my weight.	**CNTCAL**	☐	☐
33. I do not eat some foods because they make me fat.	**FAT**	☐	☐
34. I am always hungry enough to eat at any time.	**ALWAYS**	☐	☐
35. I pay a great deal of attention to changes in my figure.	**ATTNCHNG**	☐	☐
36. While on a diet, if I eat a food that is not allowed, I often then splurge and eat other high calorie foods.	**SPLRG**	☐	☐

Directions: For each of the following questions, choose the one option which most applies to you.

37. How often are you dieting in a conscious effort to control your weight? **CONSCONT**
- 1 ☐ Rarely
- 2 ☐ Sometimes
- 3 ☐ Usually
- 4 ☐ Always

38. Would a weight fluctuation of 5 pounds affect the way you live your life? **AFFLIFE5**
- 1 ☐ Not at all
- 2 ☐ Slightly
- 3 ☐ Moderately
- 4 ☐ Very much

39. How often do you feel hungry? **OFTEN**
    1 ☐ Only at meal times
    2 ☐ Sometimes between meals
    3 ☐ Often between meals
    4 ☐ Almost always

40. Do your feelings of guilt about overeating help you control your food intake? **GUILT**
    1 ☐ Never
    2 ☐ Rarely
    3 ☐ Often
    4 ☐ Always

41. How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours? **STOPHALF**
    1 ☐ Easy
    2 ☐ Slightly difficult
    3 ☐ Moderately difficult
    4 ☐ Very difficult

42. How conscious are you of what you are eating? **CONSEAT**
    1 ☐ Not at all
    2 ☐ Slightly
    3 ☐ Moderately
    4 ☐ Very much

43. How frequently do you avoid "stocking up" on tempting foods? **STOCKUP**
    1 ☐ Almost never
    2 ☐ Seldom
    3 ☐ Usually
    4 ☐ Almost always

44. How likely are you to shop for low calorie foods? **LOWCAL**
    1 ☐ Unlikely
    2 ☐ Slightly likely
    3 ☐ Moderately likely
    4 ☐ Very likely

45. Do you eat sensibly in front of others and splurge alone? **SPLRGALN**
    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? **EATSLOW**
    1 ☐ Unlikely
    2 ☐ Slightly likely
    3 ☐ Moderately likely
    4 ☐ Very likely

47. How often do you skip dessert because you are no longer hungry? **SKIPDSRT**
    - 1 ☐ Almost never
    - 2 ☐ Seldom
    - 3 ☐ At least once a week
    - 4 ☐ Almost every day

48. How likely are you to consciously eat less than you want? **EATLESS**
    - 1 ☐ Unlikely
    - 2 ☐ Slightly likely
    - 3 ☐ Moderately likely
    - 4 ☐ Very likely

49. Do you go on eating binges even though you are not hungry? **BINGE**
    - 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 to start dieting again tomorrow."* **RESTART**
    - 1 ☐ Not like me
    - 2 ☐ Little like me
    - 3 ☐ Pretty good description of me
    - 4 ☐ Describes me perfectly

51. On a scale of 1 to 6, where 1 means no restraint in eating (eat whatever you want, whenever you want it) and 6 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself? **RESTRNT**
    - ☐ 1. Eat whatever you want, whenever you want it
    - ☐ 2. Usually eat whatever you want, whenever you want it
    - ☐ 3. Often eat whatever you want, whenever you want it
    - ☐ 4. Often limit food intake, but often "give in"
    - ☐ 5. Usually limit food intake, rarely "give in"
    - ☐ 6. Constantly limiting food intake, never "giving in"

Thank you for completing this questionnaire!

Common Elements Questionnaire

Participant ID: ____**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ____**TMPT**_____

SECTION I.1: DEMOGRAPHICS *(Complete this section at Baseline visit only)*

1. Are you of Hispanic or Latino origin? **HISP**

    ☐ Yes
    ☐ No

2. Which race best describes you? *(Check all that apply)*

    ☐ African American/Black **RACEB**
    ☐ American Indian/Native American **RACEI**
    ☐ Alaskan Native **RACEAL**
    ☐ Asian **RACEAS**
    ☐ Caucasian/White **RACEW**
    ☐ Pacific Islander **RACEP**
    ☐ Other: _____**RACEOS**_____ **RACEO**

3. What is your gender? *(Check one)* **SEX**

    1 ☐ Male
    2 ☐ Female

SECTION I.2: DEMOGRAPHICS

1. What is the highest grade in school you have <u>finished</u>? *(Check one)* **EDUC**

    1 ☐ Did not finish elementary school
    2 ☐ Finished middle school (8th grade)
    3 ☐ Finished some high school
    4 ☐ High school graduate or G.E.D.
    5 ☐ Vocational or training school after high school
    6 ☐ Some college or Associate Degree
    7 ☐ College graduate or Baccalaureate Degree
    8 ☐ Masters or Doctoral Degree (PhD, MD, JD, etc.)

2. Are you currently a student?   ☐ Yes   ☐ No **STUDCUR**

    If yes, do you go to school full-time or part-time?   ☐ Full-time   ☐ Part-time **STUDFP**

3. How many children under the age of 18 live in your home? __**NCHILD**__

4. How many adults (age 18 or older, including yourself) live in your home? __**NADULT**__

5. What is your current employment status? (*Check one*) **WORK**

    1 ☐ Full-time for pay (32 or more hours per week)
    2 ☐ Part-time for pay (less than 32 hours per week)
    3 ☐ Homemaker
    4 ☐ Disabled
    5 ☐ Unemployed (not working for pay)
    6 ☐ Retired
    7 ☐ Other: _____**WORKOS**_____

6. Which of these categories best describes <u>your</u> income (not the income of your household, but your own income) for the past 12 months? This should include income (before taxes) from all sources: wages, veteran's benefits, help from relatives, rent from properties and so on. **INCOME**

- 1 ☐ Less than $5,000
- 2 ☐ $5,000 through $11,999
- 3 ☐ $12,000 through $15,999
- 4 ☐ $16,000 through $24,999
- 5 ☐ $25,000 through $34,999
- 6 ☐ $35,000 through $49,999
- 7 ☐ $50,000 through $74,999
- 8 ☐ $75,000 through $99,999
- 9 ☐ $100,000 and greater
- 10 ☐ Don't know

7. Which of these categories best describes your <u>household</u> income for the past 12 months? This should include income (before taxes) from all sources: wages, veteran's benefits, help from relatives, rent from properties and so on. **INCOMEH**

- 1 ☐ less than $25,000
- 2 ☐ $25,000 through $49,999
- 3 ☐ $50,000 through $74,999
- 4 ☐ $75,000 through $99,999
- 5 ☐ $100,000 through $199,999
- 6 ☐ $200,000 or more

8. What is your current relationship status? *(Check one)* **RELAT**

- 1 ☐ Single or casually dating
- 2 ☐ In a committed relationship or engaged
- 3 ☐ Living in a marriage-like relationship
- 4 ☐ Presently married
- 5 ☐ Separated
- 6 ☐ Divorced
- 7 ☐ Widowed

SECTION II: SUGAR-SWEETENED BEVERAGE CONSUMPTION

1. Over the <u>*past 30 days*</u>, how often did you drink soda or pop? **SODA**

- 0 ☐ Never   *If 'Never', skip to question #2 of this section*
- 1 ☐ 1 time per month or less
- 2 ☐ 2–3 times per month
- 3 ☐ 1–2 times per week
- 4 ☐ 3–4 times per week
- 5 ☐ 5–6 times per week
- 6 ☐ 1 time per day
- 7 ☐ 2–3 times per day
- 8 ☐ 4–5 times per day
- 9 ☐ 6 or more times per day

1a. How often were these sodas or pop diet or sugar-free? **SODADIET**

- 1 ☐ Almost never or never
- 2 ☐ About ¼ of the time
- 3 ☐ About ½ of the time
- 4 ☐ About ¾ of the time
- 5 ☐ Almost always or always

2. Over the _past 30 days,_ how often did you drink fruit drinks? Please do not include 100% juice beverages like orange juice, but do include drinks such as cranberry cocktail, Hi-C, lemonade, or Kool-Aid, diet or regular. **FRTDRNK**

   0 ☐ Never   _If 'Never', skip to question #3 of this section_
   1 ☐ 1 time per month or less
   2 ☐ 2–3 times per month
   3 ☐ 1–2 times per week
   4 ☐ 3–4 times per week
   5 ☐ 5–6 times per week
   6 ☐ 1 time per day
   7 ☐ 2–3 times per day
   8 ☐ 4–5 times per day
   9 ☐ 6 or more times per day

2a. How often were your fruit drinks diet or sugar-free drinks? **FRTDIET**

   1 ☐ Almost never or never
   2 ☐ About ¼ of the time
   3 ☐ About ½ of the time
   4 ☐ About ¾ of the time
   5 ☐ Almost always or always

3. Over the _past 30 days_, how often did you drink sports drinks (such as Propel, PowerAde, or Gatorade)? **SPRTDRNK**

   0 ☐ Never
   1 ☐ 1 time per month or less
   2 ☐ 2–3 times per month
   3 ☐ 1–2 times per week
   4 ☐ 3–4 times per week
   5 ☐ 5–6 times per week
   6 ☐ 1 time per day
   7 ☐ 2–3 times per day
   8 ☐ 4–5 times per day
   9 ☐ 6 or more times per day

4. Over the _past 30 days_, how often did you drink energy drinks (such as Red Bull or Jolt)? **ENRGDRNK**

   0 ☐ Never
   1 ☐ 1 time per month or less
   2 ☐ 2–3 times per month
   3 ☐ 1–2 times per week
   4 ☐ 3–4 times per week
   5 ☐ 5–6 times per week
   6 ☐ 1 time per day
   7 ☐ 2–3 times per day
   8 ☐ 4–5 times per day
   9 ☐ 6 or more times per day

SECTION III: EATING AWAY FROM HOME

1. Over the _past 30 days_, how many times did you buy food at a fast food restaurant, such as McDonald's, Burger King, Arby's, Wendy's, Hardee's, Captain D's, Taco Bell, Taco John's, Chipotle, KFC, Bojangles', Pizza Hut, Panera, Quiznos? **FASTFOOD**

    1 ☐ Never or rarely
    2 ☐ 1 time per month
    3 ☐ 2-3 times per month
    4 ☐ 1-2 times per week
    5 ☐ 3-4 times per week
    6 ☐ 5-6 times per week
    7 ☐ 1 time per day
    8 ☐ 2 times per day
    9 ☐ 3 or more times per day

2. Not including the fast food restaurants listed above, in the _past 30 days_, how many times did you buy food at any other sit down (full service) restaurant and order from a waiter/waitress? **SITDOWN**

    1 ☐ Never or rarely
    2 ☐ 1 time per month
    3 ☐ 2-3 times per month
    4 ☐ 1-2 times per week
    5 ☐ 3-4 times per week
    6 ☐ 5-6 times per week
    7 ☐ 1 time per day
    8 ☐ 2 times per day
    9 ☐ 3 or more times per day

3. Over the _past 30 days_, how many times did you buy food from an all-you-can-eat buffet, such as Golden Corral, CiCi's Pizza, Sweet Tomatoes, Old Country Buffet, all-you-can-eat café at college or university dining halls? **BUFFET**

    1 ☐ Never or rarely
    2 ☐ 1 time per month
    3 ☐ 2-3 times per month
    4 ☐ 1-2 times per week
    5 ☐ 3-4 times per week
    6 ☐ 5-6 times per week
    7 ☐ 1 time per day
    8 ☐ 2 times per day
    9 ☐ 3 or more times per day

4. Over the _past week_, how many times did you eat the following meals that were prepared in your home or in the place where you live? _(Fill in the number of days for each meal)_

    Breakfast ___**HBRKFST**___ Days per week
    Lunch ___**HLUNCH**___ Days per week
    Dinner ___**HDINNER**___ Days per week

SECTION IV: WEIGHT MANAGEMENT PRACTICES

1. Over the _past 30 days_, have you done any of the following things in order to lose weight or to keep from gaining weight? *(Check all that apply)*

    ☐ Fasted   **WMFAST**
    ☐ Ate very little food   **WMLITTLE**
    ☐ Took diet pills   **WMPILLS**
    ☐ Made myself vomit (throw up)   **WMVOMIT**
    ☐ Used laxatives   **WMLAX**
    ☐ Used diuretics   **WMDIUR**
    ☐ Used food substitutes (powder/special drinks) **WMSUB**
    ☐ Skipped meals   **WMSKIP**
    ☐ Smoked cigarettes   **WMSMOKE**
    ☐ None of the above   **WMNONE**

2. How often do you weigh yourself? *(Check <u>one</u> response)* **WEIGH**

    0 ☐ Never
    1 ☐ Once a year or less
    2 ☐ Every couple of months
    3 ☐ About once a month
    4 ☐ About once a week
    5 ☐ About once a day
    6 ☐ More than once a day

3. Do you have access to a bathroom scale at home? **SCALE**

    ☐ Yes
    ☐ No

SECTION V: DAILY MEAL PATTERNS

1. In a _typical week_, how many times do you…?

		0 times	1-2 times	3-4 times	5-6 times	7 times
1. Eat breakfast	**EBRKFST**	0	1	2	3	4
2. Eat a mid-morning snack	**EMSNCK**	0	1	2	3	4
3. Eat lunch	**ELUNCH**	0	1	2	3	4
4. Eat a mid-afternoon snack	**EASNCK**	0	1	2	3	4
5. Eat dinner	**EDINNER**	0	1	2	3	4
6. Eat an evening snack	**EESNCK**	0	1	2	3	4
7. Eat within an hour of bedtime	**EBED**	0	1	2	3	4

2. In the past 30 days, were there times when you ate continuously during the day or parts of the day without planning what and how much you would eat? **EATCONT**

  1 ☐ Never or rarely
  2 ☐ 1 time per month
  3 ☐ 2-3 times per month
  4 ☐ 1-2 times per week
  5 ☐ 3-4 times per week
  6 ☐ 5-6 times per week
  7 ☐ 1 time per day
  8 ☐ 2 times per day
  9 ☐ 3 or more times per day

SECTION VI: SMOKING

1. Do you currently use chewing tobacco, snuff, snus, pipes, cigars or any other tobacco product other than cigarettes? **TOBACCO**

  ☐ Yes
  ☐ No

2. Have you smoked at least 100 cigarettes in your entire life? *NOTE: 5 packs = 100 cigarettes.* **CIGLIFE**

  ☐ Yes
  ☐ No

3. Do you now smoke cigarettes every day, some days, or not at all? **CIGFREQ**

  1 ☐ Every day
  2 ☐ Some days
  3 ☐ Not at all   *If 'Not at all', skip to question #5 of this section*

4. On average, how many cigarettes do you smoke each day? **CIGAMNT**

  0 ☐ I did not smoke cigarettes during the past 30 days
  1 ☐ 1 cigarette or less per day
  2 ☐ 2 to 5 cigarettes per day
  3 ☐ 6 to 10 cigarettes per day
  4 ☐ 11 to 20 cigarettes per day
  5 ☐ More than 20 cigarettes per day

5. During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking? **STOPSMOK**

  ☐ Yes
  ☐ No   *If 'No', skip to Section VII*

6. How long has it been since you last smoked cigarettes regularly? **LASTSMOK**

  1 ☐ Within the past month (less than 1 month ago)
  2 ☐ Within the past 3 months (1 month but less than 3 months ago)
  3 ☐ Within the past 6 months (3 months but less than 6 months ago)
  4 ☐ Within the past year (6 months but less than 1 year ago)
  5 ☐ Within the past 5 years (1 year but less than 5 years ago)
  6 ☐ Within the past 10 years (5 years but less than 10 years ago)
  7 ☐ 10 years or more

SECTION VII: ALCOHOL

1. During the *past 30 days*, have you had at least one drink of any alcoholic beverage such as beer, wine, a malt beverage or liquor? **NOTE: One drink is equivalent to a 12-ounce beer, a 5-ounce glass of wine, or a drink with one shot of liquor. ALONE**

   ☐ Yes

   ☐ No   *If 'No', skip to Section VIII*

2. During the *past 30 days*, how many days did you have at least one drink of any alcoholic beverage?

   ___**ALDAYS**___ Days in past 30 days

3. During the *past 30 days*, on the days when you drank, about how many drinks did you drink on average? **NOTE: A 40-ounce beer would count as 3 drinks, or a cocktail drink with 2 shots would count as 2 drinks.**

   __**ALDRNKS**__ Number of drinks per day

4. Considering all types of alcoholic beverages, how many times during the *past 30 days* did you have 4 or more drinks (for females) or 5 or more drinks (for males)?

   __**ALNTIMES**__ Number of times

   ☐ None

SECTION VIII: DEPRESSION   Date of Assessment: ____**DOADATE**____

(For this section, the CQ SAS load program converts the loaded values from the SQL database (ranging from 1-4) to reflect the values listed in this codebook (ranging from 0-3)).

During the *past week*:

		Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	All of the time (5-7 days)
1. I was bothered by things that don't usually bother me	**BOTHER**	0	1	2	3
2. I had trouble keeping my mind on what I was doing	**KMIND**	0	1	2	3
3. I felt depressed	**DEPRES**	0	1	2	3
4. I felt that everything I did was an effort	**EFFORT**	0	1	2	3
5. I was happy	**HAPPY**	3	2	1	0
6. I felt fearful	**FEAR**	0	1	2	3
7. My sleep was restless	**RESTLES**	0	1	2	3
8. I felt hopeful about the future	**HOPE**	3	2	1	0
9. I felt lonely	**LONELY**	0	1	2	3
10. I could not "get going"	**GETGO**	0	1	2	3
Score __**DSCORE**__		# Not completed __**NMISS**__	**CESDS**	**NMCESD**	**CESDQ**

Common Elements Questionnaire

Participant ID: ____**ID**_____
Date of Evaluation: __**DOEDATE**_____
Protocol Timepoint: ___**TMPT**_____

SECTION IX: SLEEP

During the *last month*:

1. What time do you usually go to bed in the evening (turn out the lights in order to go to sleep*)?*
    (Please also check AM or PM) Example: 07:00 PM; Midnight = AM, Noon = PM.

    a. Weekday __**BEDWDH**__ : __**BEDWDM**__ ☐ AM ☐ PM **BEDWDAP**
    b. Weekend __**BEDWEH**__ : __**BEDWEM**__ ☐ AM ☐ PM **BEDWEAP**

2. What time do you usually get out of bed in the morning? *(Please also check AM or PM)* Midnight = AM, Noon = PM.

    a. Weekday **WAKEWDH** :**WAKEWDM** ☐ AM ☐ PM **WAKEWDAP**

    b. Weekend **WAKEWEH** :**WAKEWEM** ☐ AM ☐ PM **WAKEWEAP**

3. On average, how often has it taken you more than 30 minutes to fall asleep after lights out? *(Please check the appropriate response)* **FALLASLP**

    1 ☐ 0-2 nights/week
    2 ☐ 3-5 nights/week
    3 ☐ 6-7 nights/week

4. During the *past 30 days*, for about how many days have you felt you did not get enough rest or sleep? *(Please fill in your estimate of the number of days)*

    ___**NEREST**___ Number of days

5. In the *past week*, how many days have you had trouble staying awake while driving, eating meals, in class or engaging in social activity? *(Please check the appropriate response)* **STAYAWK**

    1 ☐ 0-2 days/week
    2 ☐ 3-5 days/week
    3 ☐ 6-7 days/week

6. In the *past year*, have you been told that you snore loudly or gasp or stop breathing during sleep? **SNORE**

    ☐ Yes
    ☐ No

SECTION X: PHYSICAL ACTIVITY NEIGHBORHOOD ENVIRONMENT

1. What is the main type of housing in your neighborhood (where you currently reside most days of the week)? **HOUSING**

    1 ☐ Dormitory or residence hall
    2 ☐ Detached single-family housing
    3 ☐ Townhouses, row houses, apartments, or condos of 2-3 stories
    4 ☐ Mix of single-family residences and townhouses, row houses, apartments or condos
    5 ☐ Apartments or condos of 4-12 stories
    6 ☐ Apartments or condos of more than 12 stories
    7 ☐ Don't know/Not sure

The next items are statements about your neighborhood related to walking and bicycling.

		Strongly disagree	Disagree	Agree	Strongly agree	Don't know
2. Many shops, stores, markets or other places to buy things I need are within easy walking distance of my home.	**NSHOPS**	1	2	3	4	5
3. It is within a 10-15 minute walk to a transit stop (such as bus, train, trolley, or tram) from my home.	**NTRANS**	1	2	3	4	5
4. There are sidewalks on most of the streets in my neighborhood.	**NSIDEWLK**	1	2	3	4	5
5. There are facilities to bicycle in or near my neighborhood, such as special lanes, separate paths or trails, shared use paths for cycles and pedestrians.	**NBIKE**	1	2	3	4	5
6. My neighborhood has several free or low cost recreation facilities, such as parks, walking trails, bike paths, recreation centers, playgrounds, public swimming pools, etc.	**NRECR**	1	2	3	4	5
7. The crime rate in my neighborhood makes it unsafe to go on walks at night.	**NCRIME**	1	2	3	4	5

8. How many motor vehicles in working order (e.g., cars, trucks, motorcycles) are there at your household?

___**MVNUM**___ Motor Vehicles

☐ Don't know/Not sure

SECTION XI: GLOBAL PHYSICAL ACTIVITY QUESTIONNAIRE (GPAQ)

*Directions: Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. In answering the following questions '**vigorous**-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, '**moderate**-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.*

SECTION XI.1: Activity at Work or School (occupational or job-related)

Think first about the time you spend doing work/school. Think of work/school as the things that you have to do such as paid or unpaid work.

1. Does your work/school involve **vigorous**-intensity activity that causes large increases in breathing or heart rate *(like carrying or lifting heavy loads, digging or construction work)* for at least 10 minutes continuously? **WSAVIG**   **VAWSMIN**   **VAWSMET**

    ☐ Yes
    ☐ No   *If 'No', skip to question #4 of this section*

2. In a typical week, on how many days do you do **vigorous**-intensity activities as part of your work/school?

    __**WSAVIGD**__ Number of days

3. How much time do you spend doing **vigorous**-intensity activities at work/school on a typical day?

    __**WSAVIGH**__ : __**WSAVIGM**__ *(hours:minutes)*

4. Does your work/school involve **moderate**-intensity activity that causes small increases in breathing or heart rate *(such as brisk walking or carrying light loads)* for at least 10 minutes continuously? **WSAMOD**

    ☐ Yes   **MAWSMIN**   **MAWSMET**
    ☐ No   *If 'No', skip to Section XI.2*

5. In a typical week, on how many days do you do **moderate**-intensity activities as part of your work/school?

    __**WSAMODD**__ Number of days

6. How much time do you spend doing **moderate**-intensity activities at work/school on a typical day?

    __**WSAMODH**__ : __**WSAMODM**__ *(hours:minutes)*

SECTION XI.2: Household Activity

*Next think of household activities that you do such as house cleaning (examples: vacuuming, sweeping, mopping, etc.), yard work (examples: mowing grass, pruning shrubs, gardening, etc.), or other non-work and non-exercise related activity you do around the house (example: washing the car, etc.). Again, in answering the following questions '**vigorous**-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, '**moderate**-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.*

1. Does your household activity involve **vigorous**-intensity activity that causes large increases in breathing or heart rate for at least 10 minutes continuously? **HAVIG**

    ☐ Yes   **VAHMIN   VAHMET**
    ☐ No   *If 'No', skip to question #4 of this section*

2. In a typical week, on how many days do you do **vigorous**-intensity household activities?

    ___**HAVIGD**___ Number of days

3. How much time do you spend doing **vigorous**-intensity household activities on a typical day?

    ___**HAVIGH**___ : ___**HAVIGM**___ *(hours:minutes)*

4. Does your household work involve **moderate**-intensity activity that causes small increases in breathing or heart rate for at least 10 minutes continuously? **HAMOD**

    ☐ Yes   **MAHMIN   MAHMET**
    ☐ No   *If 'No', skip to Section XI.3*

5. In a typical week, on how many days do you do **moderate**-intensity household activities?

    ___**HAMODD**___ Number of days

6. How much time do you spend doing **moderate**-intensity household activities on a typical day?

    ___**HAMODH**___ : ___**HAMODM**___ *(hours:minutes)*

SECTION XI.3: Travel To and From Places

The next questions exclude the work/school and household activities that you have already mentioned above. Now I would like to ask you about the usual way you travel to and from places. For example: to work, for shopping, to market, to place of worship.

1. Do you walk or use a bicycle *(pedal cycle)* for at least 10 minutes continuously to get to and from places? **TRWB**   **MATRMIN   MATRMET**

    ☐ Yes
    ☐ No   *If 'No', skip to Section XI.4*

2. In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?

    ___**TRWBD**___ Number of days

3. How much time do you spend walking or bicycling for travel on a typical day?

    ___**TRWBH**___ : ___**TRWBM**___ *(hours:minutes)*

SECTION XI.4: Recreational Activities

The next questions exclude the work/school, household and transport activities that you have already mentioned. Now I would like to ask you about sports (examples: basketball, soccer, tennis, etc.), fitness (examples: weight training, fitness classes, etc.) and recreational activities (examples: hiking, canoeing, etc.).

1. Do you do any **vigorous**-intensity sports, fitness or recreational *(leisure)* activities that cause large increases in breathing or heart rate *(like jogging, a fitness class, etc.)* for at least 10 minutes continuously? **RAVIG**   **VARMIN**   **VARMET**

    ☐ Yes

    ☐ No   *If 'No', skip to question #4 of this section*

2. In a typical week, on how many days do you do **vigorous**-intensity sports, fitness or recreational *(leisure)* activities?

    ___**RAVIGD**___ Number of days

3. How much time do you spend doing **vigorous**-intensity sports, fitness or recreational *(leisure)* activities on a typical day?

    ___**RAVIGH**___ **:** ___**RAVIGM**___ *(hours:minutes)*

4. Do you do any **moderate**-intensity sports, fitness or recreational *(leisure*) activities that cause a small increase in breathing or heart rate such as brisk walking *(cycling, swimming, volleyball)* for at least 10 minutes continuously? **RAMOD**   **MARMIN**   **MARMET**

    ☐ Yes

    ☐ No   *If 'No', skip to Section XI.5*

5. In a typical week, on how many days do you do **moderate**-intensity sports, fitness or recreational (*leisure*) activities?

    ___**RAMODD**___ Number of days

6. How much time do you spend doing **moderate**-intensity sports, fitness or recreational (*leisure*) activities on a typical day?

    ___**RAMODH**___ **:** ___**RAMODM**___ *(hours:minutes)*

SECTION XI.5: Sedentary Behavior

The following question is about sitting or reclining at work/school, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping.

1. How much time do you usually spend sitting or reclining on a typical day?

    ___**SBSITH**___ **:** ___**SBSITM**___ *(hours:minutes)*   **SEDBMIN**

SECTION XII: SEDENTARY BEHAVIOR

On a typical _**weekday**_, how much time do you spend (from when you wake up until you go to bed) doing the following? Please check one answer per question.

		None	15 min. or less	30 min.	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours or more
1.	Sitting while watching television (including videos on VCR/DVD) **WDTV**	0	1	2	3	4	5	6	7	8
2.	Sitting at work / school doing computer work (email, word or data processing, web-based applications, etc.) **WDCWK**	0	1	2	3	4	5	6	7	8
3.	Sitting while using the computer for non-work / non-school activities or playing video games **WDCNWK**	0	1	2	3	4	5	6	7	8
4.	Sitting at work / school doing non-computer office / school work or paperwork **WDNCWK**	0	1	2	3	4	5	6	7	8
5.	Sitting while doing non-computer office work or paperwork <u>not</u> related to your job / school (paying bills, etc) **WDNCNWK**	0	1	2	3	4	5	6	7	8
6.	Sitting listening to music, reading a book or magazine, or doing arts and crafts **WDMRA**	0	1	2	3	4	5	6	7	8
7.	Sitting and talking on the phone or texting **WDPHONE**	0	1	2	3	4	5	6	7	8
8.	Sitting in a car, bus, train, or other mode of transportation **WDTRANS**	0	1	2	3	4	5	6	7	8

On a typical **_weekend day_**, how much time do you spend (from when you wake up until you go to bed) doing the following? Please check one answer per question.

		None	15 min. or less	30 min.	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours or more
1.	Sitting while watching television (including videos on VCR/DVD) **WETV**	0	1	2	3	4	5	6	7	8
2.	Sitting at work / school doing computer work (email, word or data processing, web-based applications, etc.) **WECWK**	0	1	2	3	4	5	6	7	8
3.	Sitting while using the computer for non-work / non-school activities or playing video games **WECNWK**	0	1	2	3	4	5	6	7	8
4.	Sitting at work / school doing non-computer office / school work or paperwork **WENCWK**	0	1	2	3	4	5	6	7	8
5.	Sitting while doing non-computer office work or paperwork <u>not</u> related to your job / school (paying bills, etc) **WENCNWK**	0	1	2	3	4	5	6	7	8
6.	Sitting listening to music, reading a book or magazine, or doing arts and crafts **WEMRA**	0	1	2	3	4	5	6	7	8
7.	Sitting and talking on the phone or texting **WEPHONE**	0	1	2	3	4	5	6	7	8
8.	Sitting in a car, bus, train, or other mode of transportation **WETRANS**	0	1	2	3	4	5	6	7	8

Thank you for completing this questionnaire!

Use of the BodyMedia System Questionnaire

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

Instructions

This questionnaire refers to the BodyMedia System that you were given to use in this program. The system includes the armband, digital display (watch or clip), and the BodyMedia website.

Past Use of the BodyMedia System

Please indicate your level of agreement or disagreement with each of the following statements relative to your **past** use of the BodyMedia System using the scale provided. If the statement does not apply to your experience, please select "Not Applicable".

Statements Regarding Past Use of the BodyMedia System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
1. The BodyMedia System made it easier to monitor my dietary intake. **PMOND**	1	2	3	4	5	0
2. The BodyMedia System made it easier to monitor my exercise. **PMONE**	1	2	3	4	5	0
3. The BodyMedia System made it easier to understand how I needed to change my eating behaviors to control my weight. **PUNDERD**	1	2	3	4	5	0
4. The BodyMedia System made it easier to understand how I needed to change my exercise behaviors to control my weight. **PUNDERE**	1	2	3	4	5	0
5. The BodyMedia System provided valuable feedback and information to help me modify my eating patterns to control my weight. **PINFOD**	1	2	3	4	5	0
6. The BodyMedia System provided valuable feedback and information to help me to modify my exercise to control my weight. **PINFOE**	1	2	3	4	5	0
7. The BodyMedia System helped me to overcome the barriers that I typically experience to eating a healthy diet. **PBARRD**	1	2	3	4	5	0
8. The BodyMedia System helped me to overcome the barriers that I typically experience to exercising. **PBARRE**	1	2	3	4	5	0
9. The BodyMedia System helped me to interact with my weight loss counselor regarding my diet. **PCOUNSD**	1	2	3	4	5	0
10. The BodyMedia System helped me to interact with my weight loss counselor regarding my exercise. **PCOUNSE**	1	2	3	4	5	0

11. The BodyMedia System made me more aware of my eating behaviors compared to if I did not use the BodyMedia System. **PAWARED**	1	2	3	4	5	0
12. The BodyMedia System made me more aware of my exercise compared to if I did not use the BodyMedia System. **PAWAREE**	1	2	3	4	5	0
13. The BodyMedia System made me more aware of my weight loss efforts compared to if I did not use the BodyMedia System. **PAWAREW**	1	2	3	4	5	0
14. The BodyMedia System motivated me to be adherent with my eating behaviors. **PADHERED**	1	2	3	4	5	0
15. The BodyMedia System motivated me to be adherent with my exercise. **PADHEREE**	1	2	3	4	5	0
16. The BodyMedia System motivated me to be adherent with my weight loss efforts. **PADHEREW**	1	2	3	4	5	0
17. The BodyMedia System made me more accountable for my weight loss efforts. **PACCNTW**	1	2	3	4	5	0
18. It was easy to setup the BodyMedia software on my computer. **PSETUPS**	1	2	3	4	5	0
19. The BodyMedia software was easy to use to track my eating behaviors. **PTRACKD**	1	2	3	4	5	0
20. The BodyMedia software was easy to use to track my exercise. **PTRACKE**	1	2	3	4	5	0
21. The BodyMedia software was easy to use to track my weight loss progress. **PTRACKW**	1	2	3	4	5	0
22. The armband was easy to setup. **PSETUPA**	1	2	3	4	5	0
23. The armband was comfortable to wear. **PCOMFA**	1	2	3	4	5	0
24. Wearing the armband did not interfere with my job. **PJOBA**	1	2	3	4	5	0
25. Wearing the armband did not interfere with my social life. **PSOCIALA**	1	2	3	4	5	0
26. Wearing the armband did not make me feel uncomfortable around others. **PUNCOMFA**	1	2	3	4	5	0

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
27. The digital display was comfortable to wear. **PCOMFD**	1	2	3	4	5	0
28. Wearing the digital display did not interfere with my job. **PJOBD**	1	2	3	4	5	0
29. Wearing the digital display did not interfere with my social life. **PSOCIALD**	1	2	3	4	5	0
30. Wearing the digital display did not make me feel uncomfortable around others. **PUNCOMFD**	1	2	3	4	5	0
31. Receiving immediate feedback from the armband on the display was helpful in increasing my exercise. **PFEEDE**	1	2	3	4	5	0
32. Receiving immediate feedback from the armband on the display was helpful in my weight loss efforts. **PFEEDW**	1	2	3	4	5	0

33. On average, I used the BodyMedia System to assist me with tracking my eating behaviors **PUSED**

      6 ☐ every day
      5 ☐ at least 3 days per week
      4 ☐ at least once per week
      3 ☐ at least one week per month
      2 ☐ less than one week per month
      1 ☐ only when I was struggling with my weight control efforts
      0 ☐ I did not use the BodyMedia System

34. On average, I used the software component of BodyMedia to assist me with tracking my exercise behaviors **PUSEE**

      6 ☐ every day
      5 ☐ at least 3 days per week
      4 ☐ at least once per week
      3 ☐ at least one week per month
      2 ☐ less than one week per month
      1 ☐ only when I was struggling with my weight control efforts
      0 ☐ I did not use the BodyMedia System

35. On average, I wore the armband from the BodyMedia System to assist me with tracking my exercise **PWEARA**

   6 ☐ every day
   5 ☐ at least 3 days per week
   4 ☐ at least once per week
   3 ☐ at least one week per month
   2 ☐ less than one week per month
   1 ☐ only when I was struggling with my weight control efforts
   0 ☐ I did not use the BodyMedia System

36. On average, I wore the digital display from the BodyMedia System to assist me with tracking my exercise **PWEARD**

   6 ☐ every day
   5 ☐ at least 3 days per week
   4 ☐ at least once per week
   3 ☐ at least one week per month
   2 ☐ less than one week per month
   1 ☐ only when I was struggling with my weight control efforts
   0 ☐ I did not use the BodyMedia System

37. When I did not wear the armband, the main reason that I did not wear the armband was **PNOUSE**

   1 ☐ The armband was uncomfortable.
   2 ☐ I did not find the armband provides me with helpful information.
   3 ☐ Family, friends, or coworkers questioned me about the armband.
   4 ☐ The armband was visible and I could not conceal it under my clothing.
   5 ☐ Wearing the armband made me feel uncomfortable in public situations.
   6 ☐ Other (please specify): **PNOUSEOS**

Use of the BodyMedia System Questionnaire

Participant ID: ___**ID**_____

Date of Evaluation: ___**DOEDATE**_____

Protocol Timepoint: ___**TMPT**_____

Future Use of the BodyMedia System

Please indicate your level of agreement or disagreement with each of the following statements relative to your **future** use of the BodyMedia System using the scale provided. If the statement does not apply to your experience, please select "Not Applicable".

Statements Regarding Future Use of the BodyMedia System	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
1. I would use the BodyMedia System in the future to monitor my dietary intake. **FMOND**	1	2	3	4	5	0
2. I would use the BodyMedia System in the future to monitor my exercise. **FMONE**	1	2	3	4	5	0
3. I would use the BodyMedia System in the future to help me understand how I needed to change my eating behaviors to control my weight. **FUNDERD**	1	2	3	4	5	0
4. I would use the BodyMedia System in the future to help me understand how I needed to change my exercise behaviors to control my weight. **FUNDERE**	1	2	3	4	5	0
5. I would use the BodyMedia System in the future because of the valuable feedback and information it provides to help me modify my eating patterns to control my weight. **FINFOD**	1	2	3	4	5	0
6. I would use the BodyMedia System in the future because of the valuable feedback and information it provides to help me modify my exercise to control my weight. **FINFOE**	1	2	3	4	5	0
7. I would use the BodyMedia System in the future because it helps me to overcome the barriers that I typically experience to eating a healthy diet. **FBARRD**	1	2	3	4	5	0
8. I would use the BodyMedia System in the future because it helps me to overcome the barriers that I typically experience to exercising. **FBARRE**	1	2	3	4	5	0

Participant ID: ___ID___

Date of Evaluation: ___DOEDATE___

Protocol Timepoint: ___TMPT___

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
9. I would use the BodyMedia System in the future because it helps me to interact with my weight loss counselor regarding my diet. **FCOUNSD**	1	2	3	4	5	0
10. I would use the BodyMedia System in the future because it helps me to interact with my weight loss counselor regarding my exercise. **FCOUNSE**	1	2	3	4	5	0
11. I would use the BodyMedia System in the future because it is easy to use to track my eating behaviors. **FTRACKD**	1	2	3	4	5	0
12. I would use the BodyMedia System in the future because it is easy to use to track my exercise. **FTRACKE**	1	2	3	4	5	0
13. I would use the BodyMedia System in the future because it is easy to use to track my weight loss progress. **FTRACKW**	1	2	3	4	5	0
14. I would use the BodyMedia System in the future because it made me more aware of my eating behaviors compared to if I did not use BodyMedia System. **FAWARED**	1	2	3	4	5	0
15. I would use the BodyMedia System in the future because it made me more aware of my exercise compared to if I did not use BodyMedia System. **FAWAREE**	1	2	3	4	5	0
16. I would use the BodyMedia System in the future because it made me more aware of my weight loss efforts compared to if I did not use BodyMedia System. **FAWAREW**	1	2	3	4	5	0
17. I would use the BodyMedia System in the future because it motivated me to be adherent with my eating behaviors. **FADHERED**	1	2	3	4	5	0
18. I would use the BodyMedia System in the future because it motivated me to be adherent with my exercise. **FADHEREE**	1	2	3	4	5	0
19. I would use BodyMedia in the future because it motivated me to be adherent with my weight loss efforts. **FADHEREW**	1	2	3	4	5	0
20. I would use the BodyMedia System in the future because it made me more accountable for my weight loss efforts. **FACCNTW**	1	2	3	4	5	0

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Not Applicable
21. I would use the armband in the future. **FARMB**	1	2	3	4	5	0
22. I would use the armband in the future because it is comfortable to wear. **FCOMFA**	1	2	3	4	5	0
23. I would use the armband in the future because it did not interfere with my job. **FJOBA**	1	2	3	4	5	0
24. I would use the armband in the future because it did not interfere with my social life. **FSOCIALA**	1	2	3	4	5	0
25. I would use the armband in the future because it did not make me feel uncomfortable around others. **FUNCOMFA**	1	2	3	4	5	0
26. I would use the digital display in the future. **FDISP**	1	2	3	4	5	0
27. I would use the digital display in the future because it is comfortable to wear. **FCOMFD**	1	2	3	4	5	0
28. I would use the digital display in the future because it did not interfere with my job. **FJOBD**	1	2	3	4	5	0
29. I would use the digital display in the future because it did not make me feel uncomfortable around others. **FUNCOMFD**	1	2	3	4	5	0
30. I would use the BodyMedia System in the future because it was helpful in increasing my exercise. **FHELPE**	1	2	3	4	5	0
31. I would use the BodyMedia System in the future because it was helpful in my weight loss efforts. **FHELPW**	1	2	3	4	5	0

32. If given the opportunity to use the BodyMedia System in the future to assist me with tracking my eating behaviors, I would do this **FUSED**

    6 ☐ every day

    5 ☐ at least 3 days per week

    4 ☐ at least once per week

    3 ☐ at least one week per month

    2 ☐ less than one week per month

    1 ☐ only when I am struggling with my weight control efforts

    0 ☐ I do not plan on using the BodyMedia System

33. If given the opportunity to use the BodyMedia System (software, armband, and display) in the future to assist me with tracking my exercise behaviors, I would do this **FUSEE**

    6 ☐ every day

    5 ☐ at least 3 days per week

    4 ☐ at least once per week

    3 ☐ at least one week per month

    2 ☐ less than one week per month

    1 ☐ only when I am struggling with my weight control efforts

    0 ☐ I would not use the BodyMedia System to track my exercise behaviors in the future

34. If given the opportunity to wear the armband component of the BodyMedia System in the future, I would wear it **FWEARA**

    6 ☐ every day

    5 ☐ at least 3 days per week

    4 ☐ at least once per week

    3 ☐ at least one week per month

    2 ☐ less than one week per month

    1 ☐ only when I am struggling with my weight control efforts

    0 ☐ I would not use the armband component of the BodyMedia System.

35. If you do not have a desire to use the armband feature of the BodyMedia System in the future, the main reason would be **FNOUSE**

      1 ☐ The armband is uncomfortable.

      2 ☐ The armband does not provide helpful information.

      3 ☐ Family, friends, or coworkers will question me about the armband.

      4 ☐ The armband is visible and I can not conceal it under my clothing.

      5 ☐ Wearing the armband will make me feel uncomfortable in public situations.

      6 ☐ Other (please specify): **FNOUSEOS**

Thank you for completing this questionnaire!

Paffenbarger Exercise Habits Questionnaire

Participant ID: ___**ID**___

Date of Evaluation: ___**DOEDATE**___

Protocol Timepoint: ___**TMPT**___

1. Was there anything about the past week that made exercising especially different for you in terms of extended illness, injury, or vacation? **EXERDIF**
   - ☐ Yes   *If 'Yes', please complete this questionnaire about the previous "typical" week that occurred within the past 30 days.*
   - ☐ No   *If 'No', please complete this questionnaire about this past week.*

2. First, we are interested in the number of flights of stairs you climbed on average EACH DAY in this week. We only want to know the number of flights you climb **going up** – not down.

   When answering this question, 'one flight of stairs' = 10 steps if you know the number of steps.

   ___**FLIGHTS**___ flights per day

3. We want to know how much time you spent this past week brisk walking for exercise or transportation. We are interested in bouts of walking that were at least 10 continuous minutes in duration. *This would include walking outside, at an indoor facility, or on a treadmill.*

   a. How many days this week did you walk briskly for the purpose of exercise or transportation for at least 10 continuous minutes outside, at an indoor facility, or on a treadmill?

   ___**BRWALKD**___ days in the past week

   b. On these days in which you walked briskly at least 10 continuous minutes, on average, how many minutes per day did you walk briskly?

   ___**BRWALKM**___ minutes per day

4. Were there any other sport, fitness, or recreational activities in which you participated during the past week? We are interested only in time that you were physically active while performing the activity.

   Note: Do not include "occupational" or "job related" activities as these are not considered to be sport, fitness, or recreational activity.

   Note: Household activities such as cleaning, laundry, yard work and gardening are **NOT** to be included here as they are not considered to be a sport, fitness, or recreational activity.

Sport, Fitness, or Recreational Activity SPORT	Code ACTCODE	Days per Week SPORTD	Average Time per Day SPORTM
1.	_____	_____	_____ minutes per day
2.	_____	_____	_____ minutes per day
3.	_____	_____	_____ minutes per day
4.	_____	_____	_____ minutes per day
5.	_____	_____	_____ minutes per day

5. Would you say that during the past week (the week used for questions 2-4) you were: **ACTIVE**
   - 1 ☐ less active than usual
   - 2 ☐ more active than usual
   - 3 ☐ about as active as usual

6. In general, at least once per week, do you engage in regular activity similar to brisk walking, jogging, bicycling, etc. long enough to work up a sweat, get your heart thumping, or get out of breath? **REGACT**
   - ☐ Yes   If 'Yes', please indicate the number of days per week: **REGACTD**
   - ☐ No

(Continuation of Question 4 Response)

Were there any other sport, fitness, or recreational activities in which you participated during the past week?
We are interested only in time that you were physically active while performing the activity.

Note: Do not include "occupational" or "job related" activities as these are not considered to be sport, fitness, or recreational activity.

Note: Household activities such as cleaning, laundry, yard work and gardening are **NOT** to be included here as they are not considered to be a sport, fitness, or recreational activity.

Sport, Fitness, or Recreational Activity **SPORT**	Code **ACTCODE**	Days per Week **SPORTD**	Average Time per Day **SPORTM**
6.	_____	_____	_____ minutes per day
7.	_____	_____	_____ minutes per day
8.	_____	_____	_____ minutes per day
9.	_____	_____	_____ minutes per day
10.	_____	_____	_____ minutes per day
11.	_____	_____	_____ minutes per day
12.	_____	_____	_____ minutes per day
13.	_____	_____	_____ minutes per day
14.	_____	_____	_____ minutes per day
15.	_____	_____	_____ minutes per day
16.	_____	_____	_____ minutes per day
17.	_____	_____	_____ minutes per day
18.	_____	_____	_____ minutes per day
19.	_____	_____	_____ minutes per day
20.	_____	_____	_____ minutes per day
21.	_____	_____	_____ minutes per day
22.	_____	_____	_____ minutes per day
23.	_____	_____	_____ minutes per day
24.	_____	_____	_____ minutes per day
25.	_____	_____	_____ minutes per day
26.	_____	_____	_____ minutes per day
27.	_____	_____	_____ minutes per day
28.	_____	_____	_____ minutes per day

Participant ID: _____**ID**_____

Date of Exercise Test: ____**DETDATE**_____

Directions: *This form is to be completed when the graded exercise test is stopped for any one of the following reasons: 1) abnormal ECG response, 2) abnormal blood pressure response, 3) participant achieved 85% of age-predicted maximal heart rate.*

Reason graded exercise test was terminated *(check one)*: **TERMRSN**

1 ☐ Abnormal ECG or blood pressure response (prior to achieving 85% of age-predicted maximal heart rate)

    a. Was EMS summoned to respond? ☐ Yes ☐ No **EMS**

       If No, date participant verbally instructed to suspend exercise (*mm/dd/yy*): **VERB1M** /**VERB1D** /**VERB1Y**

    b. Date participant given written documentation to suspend exercise and to follow-up with their Primary Care Physician (*mm/dd/yy*): **WRIT1M** /**WRIT1D** /**WRIT1Y**

    c. Date review received from Primary Care Physician (*mm/dd/yy*): **PCP1M** /**PCP1D** /**PCP1Y**

    d. Response from Primary Care Physician: **PCP1RESP**

      1 ☐ Participant cleared for exercise with no restrictions

        Date participant notified to re-initiate exercise (*mm/dd/yy*): **REINIT1M** /**REINIT1D** /**REINIT1Y**

      2 ☐ Participant cleared for exercise with some modifications to exercise program

        Date participant notified to initiate modified exercise program (*mm/dd/yy*): **MOD1M** / **MOD1D** / **MOD1Y**

      3 ☐ Participant not cleared to exercise with no restrictions

        Date participant notified that they are to continue to suspend exercise (*mm/dd/yy*): **SUSP1M** / **SUSP1D** /**SUSP1Y**

2 ☐ Participant achieved 85% of age-predicted maximal heart rate

    a. Date ECG sent to Cardiologist for review (*mm/dd/yy*): **CARDSM** / **CARDSD** / **CARDSY**

    b. Date ECG returned from Cardiologist (*mm/dd/yy*): **CARDRM** /**CARDRD** /**CARDRY**

    c. Cardiologist interpretation of ECG: **CARDINT**

      1 ☐ Participant cleared for exercise (participant is to proceed with the intervention with no medical restrictions based on this exercise test)

      2 ☐ Participant not cleared for exercise

        i. Date participant verbally instructed to suspend exercise (*mm/dd/yy*): **VERB2M** /**VERB2D** /**VERB2Y**

        ii. Date participant given written documentation to suspend exercise and to follow-up with their Primary Care Physician (*mm/dd/yy*): **WRIT2M** / **WRIT2D** /**WRIT2Y**

        iii. Date review received from Primary Care Physician (*mm/dd/yy*): **PCP2M** /**PCP2D** /**PCP2Y**

        iv. Response from Primary Care Physician: **PCP2RESP**

          1 ☐ Participant cleared for exercise with no restrictions

            Date participant notified to re-initiate exercise (*mm/dd/yy*): **REINIT2M** /**REINIT2D** /**REINIT2Y**

          2 ☐ Participant cleared for exercise with some modifications to exercise program

            Date participant notified to initiate modified exercise program (*mm/dd/yy*): **MOD2M** / **MOD2D** /**MOD2Y**

          3 ☐ Participant not cleared to exercise with no restrictions

            Date participant notified that they are to continue to suspend exercise (*mm/dd/yy*): **SUSP2M** / **SUSP2D** /**SUSP2Y**

Adverse Event Form

Line	Date Participant Reported Event (mm/dd/yy)	Date of Onset (mm/dd/yy)	Event Type (code)	Was event a Serious Adverse Event?	Was event life threatening?[1]	Did event result in disability?[2]	Date of Resolution[†] (mm/dd/yy)	Brief Description of Event
LINE	**RPTM/RPTD/RPTY**	**AEM/AED/AEY**	**ETYPE**	**SAE**	**LTAE**	**RDAE**	**RESM/RESD/RESY**	**ETYPES**
1		___/___/___		Y N	Y N	Y N	___/___/___	
2		___/___/___		Y N	Y N	Y N	___/___/___	
3		___/___/___		Y N	Y N	Y N	___/___/___	
4		___/___/___		Y N	Y N	Y N	___/___/___	
5		___/___/___		Y N	Y N	Y N	___/___/___	

[†] If not resolved indicate "NA"

[1] A life-threatening event places the subject at immediate risk of death from the event as it occurred (per NHLBI)

[2] Disability that is significant or persistent (lasted at least 1 month & changed your life)

Serious Adverse Event Form

Participant ID: ___**ID**___

Date of Onset of Event: __**SAEDATE**___

Instructions: Complete one SAE form for each potential serious adverse event, based on the Adverse Event Worksheet or information received between regular data collection visits

1. Type of potential adverse event: **ETYPEII**
   - 1 ☐ Life threatening, or placed the participant at immediate risk of death
   - 2 ☐ Caused persistent or significant disability or incapacity
   - 3 ☐ Required or prolonged a hospitalization
   - 4 ☐ Pregnancy that resulted in a congenital anomaly or birth defect
   - 5 ☐ Death
   - 6 ☐ Caused other significant hazards or potentially serious harm to research subjects or others

2. How did the potential SAE come to the attention of study personnel? **ATTN**
   - 1 ☐ Reported at data study visit
   - 2 ☐ Reported at intervention visit
   - 3 ☐ Reported by participant's health care provider or through study staff review of medical records
   - 4 ☐ Reported by phone, email, letter by participant or by friend or family member
     - ☐ To clinic staff
     - ☐ To intervention staff **PHSTAFF**
   - 5 ☐ Other, specify ___**ATTNOS**___

3. Describe the event:
   ___**EDESC**___
   _____
   _____
   _____
   _____
   _____

4. Did a health professional diagnose the event?   ☐ Yes ☐ No **DXPRO**
5. Did the condition exist prior to the study?   ☐ Yes ☐ No **PRCOND**
6. What activity was the participant doing at the time of the event? __**ACT**___
7. Was the activity being performed in order to lose weight? ☐ Yes ☐ No **ACTLW**
8. Was the activity otherwise related to study participation? ☐ Yes ☐ No **ACTSP**
9. Did the participant receive treatment for the event?   ☐ Yes ☐ No **ETX**
   If Yes, briefly describe treatment: ___**ETXDESC**___

10. What is the current status of the event: **ESTAT**
    - 1 ☐ Completely recovered
    - 2 ☐ Recovered with some residual problems
    - 3 ☐ Condition improving
    - 4 ☐ Condition present and unchanged
    - 5 ☐ Condition deteriorated
    - 6 ☐ Death due to event
    - 7 ☐ Other, specify ___**ESTATOS**___

11. What was the impact of the event on study participation? **IMPACT**

   1 ☐ No impact on study participation

   2 ☐ Study participation temporarily interrupted

   3 ☐ Study participation permanently stopped

   4 ☐ Study participation modified (if intervention modified, complete <mark>Intervention Modification Form</mark>)

12. In the opinion of the investigator or safety officer, did an SAE occur?   ☐ Yes ☐ No **ESAE**

   If Yes, complete questions 13-15.

   If No, stop here.

13. In the opinion of the investigator or safety officer, was this SAE related to (caused by) participation in the study? **STDYREL**

   1 ☐ Definitely

   2 ☐ Probably

   3 ☐ Possibly

   4 ☐ Probably not

   5 ☐ Definitely not related

14. In the opinion of the investigator, was this SAE: **EXP**

   1 ☐ Expected (usually defined by whether the event has been mentioned in the protocol or consent form)

   2 ☐ Unexpected

NOTE: If an SAE is unexpected and possibly, probably, or definitely study-related, it must be reported to the NHLBI in expedited fashion.

   Expedited Reporting Rules

   All events that are fatal or life threatening or otherwise serious AND unexpected AND definitely, probably, or possibly related to the study must be reported to your IRB according to their guidelines AND to NHLBI within 7 days AND to OHRP within 30 days.

15. Category of event (choose one; if more than one applies, choose the one most likely to be study-related and/or unexpected): __**ECAT**__ if other, specify ___**ECATOS**_____

   1 Cardiovascular

   2 Musculoskeletal

   3 Diabetes

   4 Gall bladder disease

   5 Psychiatric

   6 Asthma

   7 Obstetric

   8 Weight loss-related

   9 Motor vehicle accident

   99 Other, specify

Report completed by (staff initials): __**SID**__   Date completed (*mm/dd/yy*): **DCM** / **DCD** / **DCY**

Clinician signature: _____   Date reviewed (*mm/dd/yy*):   **DRM** / **DRD** / **DRY**

Participant ID: ____**ID**_____

Date Form Completed: ___**DFCDATE**_____

Instructions: Complete this form to report a deviation from protocol, at the time that the occurrence becomes known.

1. Was the deviation related to (*check one*): **DEVIATE**

    1 ☐ Randomization (complete Section I)

    2 ☐ Study participation (complete Section II)

SECTION I: RANDOMIZATION

RINELIG ☐ Ineligible participant randomized

RPARTID ☐ Participant randomized under incorrect Participant ID

RSTRAT ☐ Participant randomized according to wrong stratum

Specify correct stratum:

Race: **STRACE**   (1=white, 2=non-white)

Gender: **STSEX**   (1=male, 2=female)

RCOHORT ☐ Participant randomized according to wrong cohort

RBEGIN ☐ Participant did not begin intervention within 7 days of randomization

Date participant began intervention (*mm/dd/yy*): **RBEGINM** / **RBEGIND** / **RBEGINY**

ROTHER ☐ Other, specify ___**ROTHERS**___   ☐ Participant never began intervention

SECTION II: STUDY PARTICIPATION

SPDISC ☐ Participant discontinued participation in study

Date participant discontinued (*mm/dd/yy*): **SPDISCM** / **SPDISCD** / **SPDISCY**

Date of last contact with participant if other than discontinuation (*mm/dd/yy*): **SPLCM** / **SPLCD** / **SPLCY**

Reason participant discontinued: **SPRSN** specify (if necessary) ___**SPRSNS**___

1. Participant refuses to continue participation
2. Participant preference (other than refusal), **specify reason**
3. Participant not compliant with study protocol
4. Participant moved from area
5. Participant lost to follow-up
6. Safety concern or adverse event
7. Pregnancy
8. Bariatric surgery
9. Limb amputation
10. Death
20. Other, **specify**

SysID	Date of Alert (mm/dd/yy)	Alert Type 1=CES-D 2=Blood pressure 3=Rapid weight loss	CES-D Score	Blood Pressure Measure	Weight Loss		Date Alert Managed (mm/dd/yy)
					kg	%	
SYSID	**ALTM/D/Y**	**ALTYPE**	**CESD**	**BPS/BPD**	**WLOSS**	**WLOSSP**	**ALMNGM/D/Y**
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___
	___/___/___	_____	_____	___/___	_____	_____	___/___/___