Boston Children's Hospital

FSU RESEARCH CONSENT FORM

Use Plate or Print:

DO NOT PLACE IN MEDICAL RECORD

MRN#:

Protocol Title: Dietary Composition and Energy Expenditure during Weight-Loss Maintenance

DOB:

Subject's Name:

Principal Investigators:
Cara B. Ebbeling, PhD
David S. Ludwig, MD, PhD

Gender:

About this consent form

Please read this form carefully. It tells you important information about a nutrition research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form. If you have any questions about this research or about this form, please ask us. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

Why is this research study being conducted? What is its purpose?

Many Americans currently follow popular weight-loss diets, but we do not know which diet is best for keeping weight off. The purpose of this research study is to find out if one diet is better than the others for keeping weight off and decreasing risk for disease.

Who is conducting this research study, and where is it being conducted?

The study is being done at Framingham State University (FSU) and Boston Children's Hospital (BCH). The Nutrition Science Initiative is funding this research study. Drs. David Ludwig and Cara Ebbeling, researchers from BCH, are the Principal Investigators.

How are individuals selected for this research study? How many will participate?

We are asking you to take part in this research study because you expressed an interest in the study. You are a student, faculty member, or staff member at FSU, or a member of the greater Framingham community between the ages of 18 and 65 years. In order for you to join this study you must sign this Consent Form and meet certain criteria. You may eligible for this study because you:

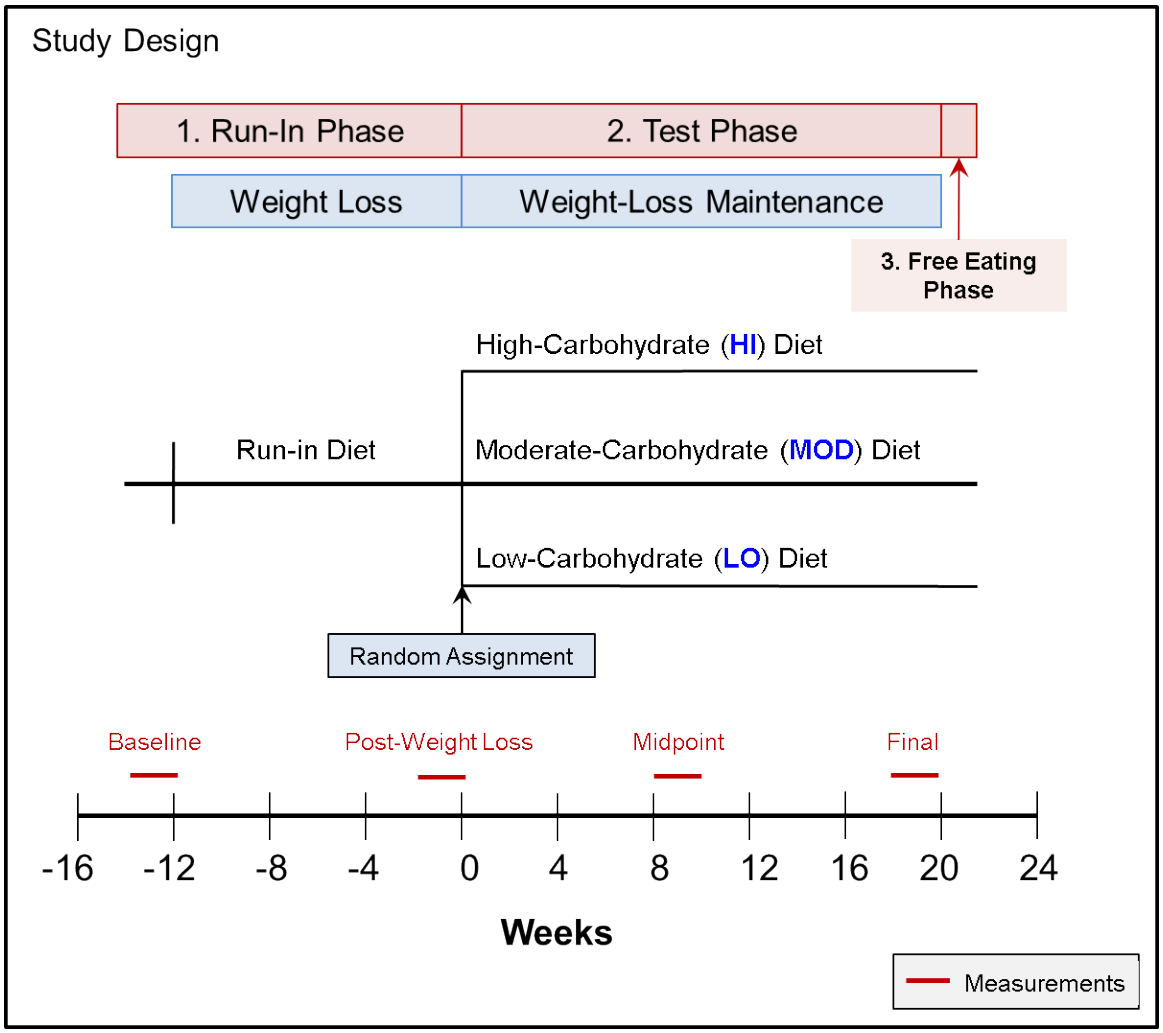
- Are willing to eat and drink only the foods and beverages on the study menus;
- Are willing not to drink alcohol during the study;
- Have medical clearance from your primary care provider to participate;
- Plan to stay at FSU for the next academic year or travel to FSU during the next academic year; and
- Successfully completed screening activities during the Spring or Summer Semester.

Members of the research team will ask you questions, take some measurements, and draw your blood to find out if you meet the criteria to join the study.

We will enroll about 230 subjects from the FSU campus and Framingham community.

What do I have to do if I am in this research study?

If you choose to join this research study, your participation will span one academic year – from August of one year to April of the following year (about 9 months). During these 9 months, we will give you all of your meals and snacks. Depending on the meal, you will need to eat or pick up your food in the Dining Commons at FSU. There are three (3) phases of the research study and measurements at four (4) time points as described below and in the Figure. This form first describes the study phases and then the measurements.



Three Phases of the Research Study

During each of the three (3) phases, we will provide you with all of your meals and snacks. We will ask you to eat only the foods that we give you. We will ask you to come to the FSU Dining Commons up to three (3) times per day to eat or pick up your food. Once a day, we will ask you to measure your weight using the Wi-Fi scale given to you by a member of the study team. The Wi-Fi scale will link to a Website called SetPoint Health. We will refer to this Website as the Study Portal. You can log into the Study Portal through your computer or smartphone. We will use the Study Portal to track your weight. We will ask you to record your food intake and complete a daily questionnaire in the Study Portal during the study. We will also ask for your permission to take a picture of you to post in your profile in the Study Portal. Only study staff will be able to see your profile picture. We will give you

food to take home, when necessary (during school breaks, for example). At the beginning of the study, we will ask you to attend an orientation regarding provision and consumption of study meals and snacks.

Phase 1: Weight Loss

- After the Baseline Measurements, you will start Phase 1 of the study. This phase will last about 12 weeks, from early September to early December. During the weight loss phase, we will give you a reduced amount of food so that you will lose about 12% of your body weight. For example, if you weigh 200 pounds now, you may lose about 25 pounds. Feel free to ask one of the researchers to figure out the amount of weight you might lose. The types of meals and snacks that we give you to eat will include regular foods. They will meet all of your nutrient needs.

  Before the end of Phase 1 in early December, we will ask you to come to the Study Center at 23 Salem End Road for your Post-Weight Loss Measurements.

  After the Post-Weight Loss Measurements, you will be assigned by chance (like the toss of a coin) to follow one of three diets during Phase 2 of the study. You cannot choose the diet that you are assigned to for the test phase. The study staff and investigators do not know what diet you will be assigned to. The assignment is random.

Phase 2: Test Phase

- For the next 20 weeks of the study from early December to mid-April, you will follow a diet with the intention of maintaining your weight loss. During this phase, the amount of food that we give you will not cause you to gain weight or lose weight. In other words, the study diets during this phase are designed so that you maintain weight loss. The diets provide enough calories so that you will not gain or lose weight in Phase 2 of the study. You will follow one of the diets described below, depending on random assignment. Many of the same foods are included on each diet, but portions will vary so that diets have different amounts of carbohydrate and fat.
  - The ***high-carbohydrate diet*** will include foods such as grains, fruits, vegetables, legumes (beans), nuts, dairy (milk, yogurt), protein (poultry, fish, meat, cheese), and healthful oils.
  - The ***moderate-carbohydrate diet*** will include foods such as grains, fruits, vegetables, legumes (beans), nuts, dairy (milk, yogurt), protein (poultry, fish, meat, cheese), and healthful oils.
  - The ***low-carbohydrate diet*** will include fruits, non-starchy vegetables, legumes (beans), nuts, dairy (milk, yogurt), protein (poultry, fish, meat, cheese), and healthful oils. No bread, grains, or starchy vegetables (such as potato) will be provided on this diet.

  Around the middle of January, when you are about halfway through Phase 2, we will ask you to come to the Study Center at 23 Salem End Road for Midpoint Measurements. At the end of Phase 2 (early April), you will come back to the Study Center at 23 Salem End Road for Final Measurements.

Phase 3: Free Eating

- For the last 2 weeks of the study (mid-April to early May), we will ask you to keep following the diet to which you were randomly assigned. We will give you the same amount of food, instructing you to eat as much or as little as you like until you have had enough. If you finish the provided food and are hungry before your next meal, you will have the option of eating something of your own choosing.

Important Information about the Meal Plan
If you are a resident student, you must purchase a basic meal plan (19 meals per week) in order to participate in the study. Purchasing a meal plan is a requirement of all resident students at FSU. Compensation you receive (described below) will reimburse you for the cost of the meal plan and will cover the time required to participate in the study.

If you are a student who commutes, a member of the faculty or staff, or a member of the Framingham community your meals will be provided by the study. Compensation you receive (described below) will cover the time required to participate in the study.

Study participants will be asked to use their FSU identification badge to access the Dining Commons. Members of the faculty and staff who do not have a campus identification badge will be asked to obtain one from the Campus Police Office. Community-based study participants will be asked to use their Driver's License for identification.

Study Measurements at Four Time Points
During the study, you will be asked to complete several measurements at four (4) time points. Most of the measurements will be done at the Study Center at 23 Salem End Road. Body Composition measurements will be done at Dwight Hall, in Room G7.

You will have your Baseline Measurements taken at the beginning of August or early September before the start of Phase 1. You will have your Post-Weight Loss Measurements taken about 12 weeks later in late November. After these measurements are done, we will assign you to one of the three diets and you will start Phase 2 of the study.

Phase 2 of the study lasts 20 weeks or about 5 months. You will have your third set of measurements, the Midpoint Measurements, taken in the middle of January or early February, about 10 weeks (2.5 months) after starting the study diet. The fourth set of measurements or the Final Measurements will be taken about 10 weeks later, in late March or early April.

At each of these four (4) time points described above, we will measure your height, weight, and blood pressure. Other study measurements are described below. We will schedule several visits to complete all of these measurements during the four (4) specified time points. We will schedule visits around your class and work schedules. Some study tests must be scheduled in the morning because you will not be able to eat before the tests, but other study tests can be done in the evening or over a weekend.

Total Calories Burned

- We will measure how many calories you burn during an entire day, as you go through your usual daily routine. We will ask you to drink about a cup of water. The water will contain special tracers that are easy to see with certain tests. We will be able to measure the special tracers when they pass out of your body in your urine. We will ask you to provide a urine sample before you drink the water and then about every other day for the next two (2) weeks. It takes about two (2) weeks for all of the special tracers to leave your body completely. Drinking water with these special tracers will not expose you to any radiation or cause you any harm. You will be asked to come to the Study Center at 23 Salem End Road about every two (2) days for the next two (2) weeks to give urine samples.

- We will measure total calories burned as part of the Baseline, Post-Weight Loss, Midpoint, and Final Measurements.

Calories Burned While Resting

- We will ask you to come to the Study Center at 23 Salem End Road after an overnight fast. We will measure how many calories you burn while resting. To measure this, we will ask you to lie down on a bed, with your head and neck under a clear plastic "bubble" for about 35 minutes. You will breathe room air, and we will measure the gases in the air that you breathe out. We will measure the calories you burn while resting on two (2) days during each of the four (4) measurement periods. If the two (2) measurements differ by a lot, we will ask you to come for a third measurement on another day.
- We will measure calories burned while resting as part of the Baseline, Post-Weight Loss, Midpoint, and Final Measurements.

Blood Draw and Oral Glucose Tolerance Test

- We will ask you to come to the Study Center at 23 Salem End Road after an overnight fast. We will place an IV (intravenous, a small plastic tube with a needle attached) line in one of your arms. The IV will be used to draw blood samples before you drink a sweet liquid and then over a 2-hour period after you drink the sweet liquid. Your blood samples will be tested for hormone levels and heart disease risk factors such as glucose (blood sugar), insulin, and fats. The total amount of blood drawn at each of these visits is a little over a half cup. During the entire 2-hour period, the arm with the IV line will be in a heated box. The box has a clear cover so that you can see all parts of your hand and arm. The hand is placed in the box that circulates air to warm your hand. A heated box is used to increase blood flow to your hand. After two (2) hours, the IV will be removed and you will be given something to eat.
- We will draw blood and conduct an oral glucose tolerance test as part of the Baseline, Post-Weight Loss, Midpoint, and Final Measurements.

Physical Activity and Sleep Patterns

- We will loan you monitors that you will use to track physical activity and sleep patterns over seven (7) days. The monitors are smaller than a cell phone and attach to a belt or a wrist strap.
- To track your physical activity, you will wear one (1) monitor on your right hip for seven (7) days in a row. You do not have to wear this monitor when you are sleeping, bathing or swimming. It can be hidden under clothing. You will need to come to the Study Center at 23 Salem End Road to drop off your physical activity monitor after wearing it for seven (7) days in a row. If we check the activity monitor and it does not contain seven (7) days of data, we will ask you to wear the monitor for a few additional days so that we obtain seven (7) days of data.
- To track your sleep patterns, you will wear the second monitor on your non-dominant wrist for seven (7) nights in a row. You can take off the monitor after waking up each morning. You will need to come to the Study Center at 23 Salem End Road to drop off your sleep monitor after wearing it for seven (7) nights in a row. If we check the sleep monitor and it does not contain seven (7) nights of data, we will ask you to wear the monitor for a few additional nights so that we obtain seven (7) nights of data.
- We will ask you to keep a physical activity and sleep diary.
- We will measure physical activity and sleep patterns as part of the Baseline, Post-Weight Loss, Midpoint, and Final Measurements.

24-Hour Urine Sample

- We will ask you to collect your urine for 24 hours. This will involve voiding into a container every time that you use the bathroom. We will measure a hormone called cortisol (a "stress" hormone) in your urine.
- We will ask you to come to the Study Center at 23 Salem End Road to drop off your 24-hour urine sample.
- We will ask you to collect a 24-hour urine sample as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not ask you to collect a 24-hour urine sample as part of the Midpoint Measurements.

Exercise Test

- You will come to the Study Center at 23 Salem End Road for the Exercise Test. We will ask you to ride a stationary cycle. The purpose of this test is to measure how many calories you burn for a given amount of work. We will ask you not to eat anything for five (5) hours before the test. The test will start with a 4-minute warm-up period. Then you will pedal at three (3) increasing levels of resistance, with each level lasting four (4) minutes. This is not a maximal test, and you will not be completely exhausted at the end of the test. You will breathe room air through a mouthpiece. We will collect and analyze the air that you breathe out. We will monitor your heart rhythm and blood pressure.
- We will do an exercise test as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not ask you to do an exercise test as part of the Midpoint Measurements.

Body Composition Tests

We will ask you to complete the two (2) body composition tests described below. The tests will be done on the same day, as part of a single study visit.

1. DXA

- You will have a special scan (x-ray) taken to measure the amount of body fat you have. The special x-ray is called "dual-energy x-ray absorptiometry" (DXA). You will report to Dwight Hall, Room G7 for the DXA Scan. We will ask you not to eat anything for five (5) hours before the test and not exercise within two (2) hours of the test. If you are female, you will be asked to take a urine pregnancy test before the scan.
- You will be asked to lie still on a table while x-ray pictures are taken of your body. The scan will take about 6 minutes.
- We will do a DXA scan as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not do a DXA scan as part of the Midpoint Measurements.

2. BodPod

- The Bod Pod is a special machine that uses changes in air volume to measure body fat. You will report to Dwight Hall, Room G7 for the BodPod test. We will ask you not to eat anything for five (5) hours before the test and not exercise or drink more than 8 ounces of water within two (2) hours of the test.
- You will be asked to wear the bathing suit or spandex we provide to you for the test.
- You will be asked to sit as still as possible inside the BodPod while breathing room air through a tube. The test will take about 5 minutes.
- We will do the BodPod test as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not do the BodPod test as part of the Midpoint Measurements.

Optional Study Measurements

All enrolled subjects are invited to take part in three (3) small data collection projects that are being conducted as part of the main research study. The three projects (genetic sample, stool sample, questionnaires) are described below.

You may decide to take part in all of the projects or in one of the projects. You may also decide not to take part in any of the projects. Your choice will not get in the way of your participation in the main study.

Genetic Sample (Optional)

- At Baseline only, we are requesting permission to save some blood cells for possible future genetic testing. Genetic material, or DNA, which is the material that is passed down or inherited from biological parents to their children can be extracted from cells. We may use the DNA to study genes to see if they may be involved in body weight, diet, and other related conditions. We may look at many genes of interest at one time, or we may perform an analysis called sequencing that gives information about all or most of your genetic information. At this time, no genetic analyses are planned. Blood cells will be saved in the Biobank Core Lab, or biorepository, located at BCH. Samples and data may be sent to other repositories in the future.

Please check one of the following:

❑ NO, I do NOT want blood cells stored for possible future genetic testing.

❑ YES, I will allow blood cells to be stored for possible future genetic testing.

Reporting of Results and Incidental Findings of Genetic Testing

We do not know for certain if genetic testing will be done on your biological sample. If genetic testing is performed, the results from the study are considered to be research, and no results will routinely be given to you.

While the purpose of any genetic analysis is to understand more about body weight, diet, and related conditions, it is also possible that we could find genes related to a different condition (also known as an "incidental finding"). Any analyses will be performed in a research laboratory and not a clinical laboratory with certified procedures for reporting patient results, therefore we cannot directly release results from this study to you. If we obtain information that we think might significantly affect your medical care (e.g., there is an available treatment), we may be able to have these results confirmed by a CLIA-certified clinical laboratory. A CLIA lab meets government-mandated requirements for quality assurance and quality control, and is certified to release results from patient tests for clinical and diagnostic purposes. There will most likely be a charge associated with this testing, which will vary depending on the laboratory. Most CLIA laboratories will ask for fresh blood samples in order to ensure the accuracy of the results. If you choose to be contacted about these results, we can only do so through your doctor. We will make every reasonable effort to get in touch with the person you specify below. If your results are confirmed, they will be reported to your physician and made available to you with proper genetic counseling.

Please check, and initial next to your choice below, relating to notification of incidental findings.

❑ NO, I do NOT want any results. Please do NOT contact my physician.

❑ YES, I want to learn about results that could significantly affect my medical care but is unrelated to body weight.

Physician's Name: _____

Address: _____

City: _____ State: _____

Phone: _____ Email: _____

Stool Sample (Optional)

- We will ask you to collect stool samples. We will use the stool samples to look at any possible changes to the bacteria that are normally in your intestines. We will also save the stool samples if we need to look at any differences between the calories you eat and drink, the calories you burn, and any weight changes that you have.
- We will ask you to collect three stool samples as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not ask you to collect a stool sample as part of the Midpoint Measurements. You will need to come to the Study Center at 23 Salem End Road to drop off each stool sample.

Please check one of the following:

❑ NO, I do NOT want to collect stool samples.

❑ YES, I will collect stool samples.

Questionnaires (Optional)

- There are two types of questionnaires (1. cognitive function, 2. feelings and eating behaviors).
- The questionnaires will be done on the same day, as part of an additional study visit. The visit will last about one (1) hour. We will ask you not to eat anything for three to five (3-5) hours before the visit.
- We will ask you to complete these questionnaires as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not ask you to complete questionnaires as part of the Midpoint Measurements.

Cognitive Function

- We will ask you to complete oral questionnaires that tell us about the effects of diet on memory, thinking abilities, and processing speed. This will involve coming to the Study Center at 23 Salem End Road and answering questions. A member of the study team will record your answers on paper forms.

Feelings and Eating Behaviors

- We will ask you to fill out several questionnaires that tell us about your emotions, your behaviors, and the way you may feel before, during, and after you eat. This will involve coming to the Study Center at 23 Salem End Road and answering questions on paper forms.

Please check one of the following:

❑ NO, I do NOT want answer questions or fill out questionnaires.

❑ YES, I will answer questions or fill out questionnaires.

Other Questionnaires (Optional)

- There are four types of other questionnaires (1-4. Attitudes toward body weight).
- The questionnaires will be done on the same day, as part of an additional study visit. The visit will last up to one (1) hour.
- We will ask you to complete these questionnaires as part of the Baseline, Post-Weight Loss, and Final Measurements. We will not ask you to complete questionnaires as part of the Midpoint Measurements.

Attitudes toward Body Weight

- We will ask you to fill out several questionnaires that tell us about your attitudes toward body weight. This will involve coming to the Study Center at FSU (23 Salem End Road) and answering questions using a study iPad.

Please check one of the following:

❑ NO, I do NOT want answer questions or fill out other questionnaires.

❑ YES, I will answer questions or fill out other questionnaires.

What are the risks of this research study? What could go wrong?

Diets

There may be inconvenience caused by having to come to the FSU Dining Commons at least five (5) days a week and up to seven (7) days a week to eat and pick up your meals. You may not like all of the foods that you are given to eat. There is a possibility that the dietary changes could cause or unmask an eating disorder such as anorexia nervosa or binge eating disorder.

Low Blood Sugar

Some people have low blood sugar when decreasing their food intake or after not eating for a period of time. Common symptoms of low blood sugar are light headedness, hunger, sweating, trembling, and headache. You may feel these symptoms during the weight loss phase (when we decrease the amount of food that we give you).

Calories Burned While Resting

The "bubble" used to measure how many calories you burn while you are resting is open so that you will be breathing room air. You may find it difficult to lie still and not to talk or sleep during the testing process. A researcher will oversee the proper functioning of the machine. There is no potential harm due to possible malfunction of the machine.

Total Calories Burned

Drinking the water with special tracers will not expose you to any radiation or cause you any harm. Providing a urine sample about every other day for two (2) weeks may be inconvenient.

IVs and Blood Drawing
You may feel some discomfort when the IV line is inserted into your vein. An IV line may cause a bruise or bleeding at the place where the needle is inserted. Sometimes a person feels faint when blood is drawn. Rarely, an infection may develop but can be treated.

Heated Hand Box
The heated hand box may occasionally cause your skin to redden.

Physical Activity and Sleep Monitor
It might be inconvenient for you to wear the physical activity monitor for seven (7) straight days and the sleep monitor for seven (7) straight nights. If there is not enough information on one or both of the monitors, you may be asked to wear one or both of them for several more days and/or nights.

Exercise Testing
You may have shortness of breath, abnormal heart rhythm, or high blood pressure. These symptoms usually go away when you stop exercising. Very rarely, an exercise test leads to a heart attack. We will monitor your heart rhythm and blood pressure throughout the test.

Body Composition Test (DXA)
Your participation in this research study involves exposure to radiation during the body composition scan (DXA). We are exposed to radiation every day of our lives from both natural and manmade sources. The average effective dose to a person in the U.S. from these sources is about 360 millirem per year. The radiation exposure you will receive from participating in this study from the DXA scans over the course of the entire study is equivalent to an exposure of 12 millirem (4 millirem per scan) to your whole body. This dose is well below the levels that are thought to result in a significant risk of harmful effects.

If you are female, we will ask you to take a urine pregnancy test because the DXA scan must not be performed if you are pregnant. The results of the pregnancy test are confidential and will be told to you in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. During the research, if you have a positive pregnancy test, we must withdraw you from the study. If you become pregnant, or if there is any chance that you might be pregnant, please contact the researchers immediately. The telephone call will be strictly confidential.

Body Composition Test (BodPod)
You may feel a slight pressure in your ears as air moves through the BodPod, but most people do not. There may be inconvenience or discomfort caused by having to wear a bathing suit or spandex for the test. You may find it difficult to sit still and not to talk during the testing process. A researcher will oversee the proper functioning of the machine. There is no potential harm due to possible malfunction of the machine.

Genetic Testing (Optional)
We do not know if genetic testing will be done on your biological sample. Some people involved in genetic studies have felt anxious about the possibility of carrying an altered gene that places them at risk or that may be passed on to children. If these feelings arise at any time during the study, you may contact us and we will arrange for you to speak with a genetic counselor. You should also be aware that there might be social and economic disadvantages, which can be associated with the gathering of genetic information. You should understand that testing might find

an inherited altered gene, which puts you at risk for a genetic disorder in the future. Genetic information divulged to the wrong source, could affect you and your family (if an insurance company or employer acquired this genetic information). However, results from this research study will not be available to anyone and will not be placed in your medical record. Thus, it is extremely unlikely that an insurance company or employer would ever learn of such results.

Stool Collection (Optional)
It may be inconvenient or embarrassing for you to collect stool samples.

Questionnaires (Optional)

Cognitive Function
The risks of participating in tests of cognitive function are no greater than those encountered in daily life.

Feelings and Eating Behaviors
It might be uncomfortable to think about your feelings and eating behaviors. The questionnaires may bring up unpleasant feelings. There is a possibility that the questionnaires could unmask a psychological problem such as anxiety, depression, or binge eating disorder.

If you are a student who becomes upset while completing the questionnaires, we will provide the telephone number for the FSU Counseling Center or escort you to the Counseling Center if necessary. If you are a member of the faculty or staff, we will assist you in contacting the Emergency Assistance Program.

Other Questionnaires (Optional)

Attitudes toward Body Weight
It might be uncomfortable to think about your attitudes toward body weight.

What are the benefits of this research study?

You may not benefit from being in this study. However, it is likely that you will lose weight if you follow the instructions and only eat the food that we give you. Losing weight may improve your overall health. We will give you all of your food for the entire study.

A study summary letter with results of your blood tests and body composition scans will be sent to your primary care provider. This will be done at the end of the study, when all participants have completed all of the study measurements.

Are there costs associated with this research study? Will I receive any payments?

There is no charge for taking part in this research study.

All enrolled subjects will receive a study stipend totaling up to $3,280. Subjects who live on campus (resident students), who are required to purchase a full meal plan according to FSU policies, will also receive up to $3,220 as reimbursement for the cost of the meal plan. Subjects who live off campus (commuter students, faculty, staff, and community participants) will receive study meals and snacks valued at up to $3,220. The maximum total value of study compensation is $6,500. Study payments will be sent at eight specific time points during the study, as presented in the table below.

		Resident Students			Non-Resident Students, Faculty, Staff, Community Participants	
Week	Phase or Event	Monthly Meal Plan*	Monthly Stipend*	Additional Stipend†	Monthly Stipend*	Additional Stipend†
		Reimbursement	Compensation		Compensation	
-9	Run-In	$400	$100	$200	$100	$200
-4	Run-In	$400	$120		$120	
1	Test	$400	$120	$300	$120	$300
6	Test	$400	$130		$130	
11	Test	$400	$140	$400	$140	$400
16	Test	$400	$150		$150	
21	Ad libitum	$400	$170	$400	$170	$400
	Completion	$420	$550	$500	$550	$500

* Monthly payments for participating in the intervention. Each payment includes reimbursement for the meal plan (resident students only) and a stipend as compensation for time and effort to adhere to the study diets. Payments will be processed on the last business day of the month.

† Additional stipend as compensation for time and effort required for measurement of study outcomes at specified time points.

Taxes will not be taken out of study compensation. Because study compensation will be greater than the minimum reporting requirements as set by the Internal Revenue Service (>$500), FSU must report this income to the IRS and will issue you a US Form 1099 as your compensation will be considered taxable federal and state income. FSU will use your social security number to report study compensation to the IRS. You will be responsible for reporting this compensation when you file your tax return. If you withdraw from the study prior to its completion, you will be compensated for the time you have actually spent in proportion to the fraction of the study completed.

Compensation for Optional Study Measurements

- **Stool Collection (Optional)**

Subjects collecting stool samples will receive compensation, in the form of a gift card, in the amount of $25 at the Baseline Visit; $25 at the Post-Weight Loss Visit; and $50 at the Final Visit.

- **Questionnaires (Optional)**

Subjects completing the questionnaires will receive compensation, in the form of a gift card, in the amount of $10 at the Baseline Visit; $10 at the Post-Weight Loss Visit; and $30 at the Final Visit.

- **Other Questionnaires (Optional)**

Subjects completing the other questionnaires will receive compensation, in the form of a gift card, in the amount of $10 at the Baseline Visit; $10 at the Post-Weight Loss Visit; and $10 at the Final Visit.

If I do not want to take part in this research study, what are the other choices?

Taking part in this research study is entirely voluntary. You do not have to participate. Your choice will not get in the way of any care that you get now or in the future at BCH.

What are my rights as a research participant?

You may drop out of the study at any time. Dropping out will not get in the way of care that you receive now or in the future at Boston Children's Hospital.

You may ask for test results. After we have looked at the data from all of the participants in the study, we will be happy to share our findings with you, if requested.

Your research records will be confidential. In all records of the study, you will be identified by a code number. Your name will be known only to the researchers. Your name will not be used in any reports or publications of the study.

Are there other things I should know about?

At the completion of this study, we would like to store any remaining samples (blood, DNA, urine, and if collected, stool) for possible future use. The remaining samples may be stored indefinitely. The samples will be stored at the Biobank Core Lab, or biorepository, located at BCH. Each of your samples will be given a unique identification number and stored without your name or other identifiers.

Only the investigators will have a list to know which sample is linked to which subject, and this list will be kept confidential in a secure location. If the investigators distribute samples to other individuals who have an interest in the causes of overweight and obesity, the samples will be released with the unique identifier without any names or medical record numbers. If at any time you would like to have the samples taken out of storage, please let us know and the samples will be moved or destroyed according to your wishes.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future.

The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Why would I be taken off the study early?

- The study is cancelled by the sponsor.
- You are not able to attend the study visits required by the study.
- You are not able to meet the study requirements.
- You need a treatment or medication that may not be taken while on the study or the Principal Investigators feel it is in your best interest to be taken off this study.
- If you are female and you become pregnant, you will be taken off the study.

Other information that may help you

BCH has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org.

BCH is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research at the hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions, or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617-355-7052 between the hours of 8:30 am and 5:00 pm.

Who may see, use or share your health information?

Your health information is protected by a law called the Health Information Portability and Accountability Act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you.

- Research staff at BCH involved in this study
- Medical staff at BCH directly involved in your care that is related to the research or arises from it
- FSU staff who prepare study meals and process study payments
- FSU students employed by the study as student research assistants and student nurses
- SetPoint Health staff who program and maintain the Study Portal used to collect and track your daily weight and food intake
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital
- People at BCH who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program
- People from agencies and organizations that provide accreditation and oversight of research
- People who oversee the study information such as data and safety monitoring boards, clinical research organizations, data coordinating centers, and others
- Sponsors or others who fund the research, including the government or private sponsors

Companies that manufacture drugs or devices used in this research

- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
- People or groups that are hired to provide services related to this research or research at BCH, including service providers, such as laboratories and others.
- Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of BCH, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the BCH Privacy Office at 857-218-4680 which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you, so identifying information will not remain with the data and will be kept separately.

Your privacy rights

If you do not want to be screened for the nutrition research study, you do not have to. If you want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care at BCH now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for BCH to use or share the protected information that was collected as part of the research; however, you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, you will need to do so in writing.

You may have the right to get some of the information that was shared with others for research, treatment, or payment. This information is available after the study analysis is done. To request the information, please contact the BCH Privacy Officer at 857-218-4680.

Contact information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Principal Investigator:	Phone: **617-355-4878**	▪ General questions about the study
David Ludwig, MD, PhD	Pager: **617-355-7243**	▪ Research-related injuries or emergencies

		[Pager #0128]	▪ Any research-related concerns or complaints
Principal Investigator: **Cara Ebbeling, PhD**	Phone: Pager:	**617-919-3457** **617-355-7243** **[Pager #0954]**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Office of Clinical Investigation	Phone:	**617-355-7052**	▪ Rights of a research subject ▪ Use of protected health information ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints ▪ If investigator/study contact cannot be reached ▪ If I want to speak with someone other than the investigator, study contact, or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this study.
- This research study has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research study is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for my participation in this research study and for the use of associated protected health information as described above (HIPAA).

Subject (18+ years)

■

_____ _____

Date (MM/DD/YEAR) Signature of **Subject** *(18+ years)*

Investigator or Associate's Statement and Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.
- I have provided a copy of the consent form signed by the subject and a copy of the hospital's privacy notification (if requested).

■

_____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the subject or legal representative, **or**

☐ The individual has certain communication impairments that limit the subject's ability to clearly express consent **or**

☐: Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the subject, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the subject or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the subject, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness and Interpreter