Enhancing Weight Loss with Financial Incentives in Teens

NCT03137433

Parental consent, consent and assent forms dated 2021Jun07

# PARENT CONSENT FORM
## Enhancing Weight Loss with Meal Replacements in Teens

Your child is invited to participate in a research study evaluating the effect of meal replacements on weight loss in adolescents. Meal replacements are meals that have a known amount of calories so it takes the guess-work out of eating. Your child was selected as a possible participant because your child appears to meet the preliminary eligibility requirements. Please read this form and feel free to ask any questions before agreeing to participate in the study.

The primary investigator of this study is Dr. Aaron Kelly, PhD, Associate Professor in the Department of Pediatrics at the University of Minnesota. The co-investigators of this study are Drs. Claudia Fox, Kyle Rudser, Robert Jeffery, Amy Gross, Justin Ryder, Dr. Megan Oberle and Donald Dengel; these researchers work at the University of Minnesota. Additional co-investigators include Drs. M. Jennifer Abuzzahab (Children's Hospitals and Clinics of Minnesota), Seema Kumar (Mayo Clinic), and Betsy Schwartz (Park Nicollet). This study is funded by the National Institutes of Health (NIH) through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

**STUDY PURPOSE AND BACKGROUND:**
We want to see if the use of meal replacements can help with weight loss. And, we also want to figure out how much weight loss is necessary to make your child's body healthier.

**STUDY DESIGN**
This study will involve 130 adolescents (ages 13-17 years old) participating in meal replacement therapy and will last one year (12 months).

**STUDY PROCEDURES:**
A screening visit or phone call will determine if your child is eligible to participate in the study and we may also use your child's medical record to see if your child qualifies. If you agree to have your child be in this study, you will first sign this consent form and HIPAA authorization form before any study-related procedures are performed. We will ask you and your child to visit the University of Minnesota for up to eight separate visits, each lasting between 2-5 hours. For three of the visits we will ask that your child refrain from taking any medications and fast (no food or drink, water only) for 8 hours prior to your child's visit. You and your child will also be asked to participate in follow-up phone calls or emails to review safety measures and discuss lifestyle modification (making healthy changes to your lifestyle).

During the study, your child will be asked to follow a prescribed daily diet provided by Healthy for Life Meals (formerly Seattle Sutton Healthy Eating).

We will ask that you eat no additional food or calories other than what is provided during the study. The meals will be provided to you free of charge by home delivery.

Please note that you and your child may also have unscheduled visits as needed for safety. A urine pregnancy test will be conducted on all female participants at every study visit, starting at the baseline visit, and prior to any study procedures taking place. Under Minnesota state law, you will not be told the results of the pregnancy test unless a positive result would present risk of harm to your child's health. Your child will be asked to do the following things at each visit:

| | Screening (phone -or- in-person) | Baseline | Week 8 | Week 17 | Week 26 | Week 34 | Week 43 | Week 52 |
|---|---|---|---|---|---|---|---|---|
| Review Eligibility | X | | | | | | | |
| Physical exam | | X | | | | | | |
| Tanner staging (pubertal assessment) | | X | | | | | | |
| Safety labs | | X | | | | | | |
| Fasting labs and blood biomarkers | | X | | | X | | | X |
| BMI/anthropometrics | | X | X | X | X | X | X | X |
| iDXA scan (body fat assessment) | | X | | | X | | | X |
| Vascular assessment | | X | | | X | | | X |
| Blood pressure | | X | X | X | X | X | X | X |
| Questionnaires | | X | | | X | | | X |
| Safety assessment | | | X | X | X | X | X | X |
| Lifestyle counseling | | X | X | X | X | X | X | X |

**Blood and Urine for Storage**

A portion of your child's blood (approximately 2 tablespoons) will be drawn at the baseline visit for safety labs, fasting labs and blood biomarkers. Approximately 1 tablespoon will be drawn for fasting labs and blood biomarkers at week 26, and week 52. A total of approximately 4 tablespoons will be drawn throughout the course of study participation. Blood and urine samples will be stored for future study-related biomarker analysis. The additional blood and urine will be stored for no longer than five years after completion of this study and will not be used for DNA/genetic analyses. If at any time you decide you no longer want your child's blood and/or urine samples stored by the study, you may notify a study coordinator and your child's samples will be destroyed. For the visits at Baseline, Week 26 and Week 52, your child will be asked to come to the research unit after not having had anything to eat or drink for 8 hours. Your child will be asked to hold any morning medications before those visits as well. If your child takes morning medications, please feel free to bring them to the visit and your child can take them after the fasting samples are collected.

**Measurements of Body Fat**

Body composition (muscle and fat) will be measured using dual energy x-ray absorptiometry (DXA), which is a scan requiring your child to lie still on their back for approximately fifteen minutes while an x-ray/picture is taken of your child's entire body.

**Vascular Measurements**

A small device that looks like a pen will gently be placed on your child's neck, wrist, and foot to measure blood flow. These procedures are painless but will require your child to lie still in a bed for approximately 45 minutes. The technician will give your child specific instructions during this test.

## Lifestyle Modification Counseling

You and your child will receive healthy lifestyle counseling (diet and exercise) throughout the entire study. Educational materials will be given to your child at the Baseline, Week 17, Week 26, Week 34, Week 43 and Week 52 visits, and discussed at each face-to-face visit and at seven separate follow-up phone calls or emails.

## Questionnaires

At all visits except the Screening visit, you and your child will complete a series of questionnaires to help us understand your child's eating behaviors, quality of life and mental health.

## RISKS OF STUDY PARTICIPATION:

*Blood Draw*

There is minimal risk of bruising and infection associated with the blood draw. On rare occasions, fainting may occur.

*Measurement of Body Fat*

As part of this study, your child will undergo three DXA scans. These procedures involve exposure to ionizing radiation. The average amount of radiation that the average person would receive from this procedure is less than 2% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv).

The radiation exposure is not necessary for your child's medical care, and is for research purposes only. This exposure involves minimal risk and is necessary to obtain the research information desired.

If your child is female, she will be required to take a pregnancy test prior to the DXA scan, and those participants who are pregnant will not be included in the study. Also, if your child has participated in any other study in the past twelve months, please inform the investigator for documentation of possible previous exposure to radiation.

*Meal Replacement Therapy*

There are no known risks associated with meal replacement therapy.

*Questionnaires*

There may be risks of possible loss of confidentiality and discomfort and/or embarrassment while answering questions. However, you and your child may refuse to answer any questions or stop participating at any time.

## BENEFITS OF STUDY PARTICIPATION:

Information from the tests (Dexa scan and lab results) will be available to you and to your child's doctor if you choose. The results of this study may provide new information that could be of benefit to other adolescents like your child.

## SHARING OF YOUR CHILD'S INFORMATION FOR MANDATORY REPORTING:

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;

- Communicable, infectious, or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law, or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

**ALTERNATIVES TO STUDY PARTICIPATION:**
The alternative is to not participate in the study and receive regular clinical obesity care through the University of Minnesota Masonic Children's Hospital Pediatric Weight Management Clinic or other healthcare provider. Your decision will not affect your or your child's ability to receive care or change your relationship with the doctors involved in the study.

**STUDY COSTS/COMPENSATION:**
Study procedures and meal replacements will be provided to your child at no cost. However, you will be asked to purchase your child's own fruits and vegetables during the meal replacement phase of the study. If applicable, hotel, parking, and/or meal vouchers will be provided at each visit.

Your child will also be compensated for their time, which will total $700.00 for study participation if all study visits are completed. Your child will receive $100 in the form of a gift card at visits where assessments are completed. Your child will not receive compensation for phone calls or emails. If your child receives more than $600 in one year, your child will receive a Form 1099 to complete and it will be reported to the IRS.

**RESEARCH RELATED INJURY:**
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that your child has suffered a research related injury, let the study physicians know right away.

**CONFIDENTIALITY:**
The records of this study will be kept private. Any resulting research articles will not include any information that will make it possible to identify a study participant. Your child's records for the study may be reviewed by the study sponsor and by departments at the University with appropriate regulatory oversight. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

A note will be placed in your child's medical record, along with the study doctor's contact information, indicating your child is participating in this research study. In addition, laboratory results will be placed in your child's medical record. You will be given a signed copy of this form to keep for your records.

**PROTECTED HEALTH INFORMATION (PHI):**
Your child's PHI created or received for the purposes of this study are protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

**VOLUNTARY NATURE OF THE STUDY:**

Participation in this study is voluntary. Your decision whether or not to have your child participate will not affect your or your child's current or future relations with your doctor, clinic, the University of Minnesota Masonic Children's Hospital Pediatric Weight Management Clinic or other medical clinics. If you choose to allow your child to participate, your child is free to withdraw from the study at any time without affecting those relationships.

In addition, the study investigator may choose to withdraw your child's study participation at any time and for any reason, without your consent. Examples of reasons for study withdrawal may include failure to adhere to the study protocol.

If it is difficult for you and your child to attend the Screening visit for the study in person, let the study team know. A member of the study team has the ability to set up a meeting via Zoom to discuss the study with you and your child and to answer any questions that you may have. If you would like your child to participate in the project, you will be sent two copies of this parental consent form, two copies of an assent form and two copies of the HIPAA authorization. You will be asked to sign the two parental consent forms and HIPAA authorizations and your child will be asked to sign the two assent forms. You will be asked to return one full set to the study team via prepaid envelope. You will need to have a computer and an internet connection in order to discuss the study on Zoom. If you do not have access to a computer, consent can be discussed over the phone with you and your child. You can ask any questions that you have and, if you would like your child to participate, you will be asked to sign two copies of this form and two copies of the HIPAA authorization and your child will be asked to sign two copies of the assent. You will be asked to return a full set to the study team via a prepaid envelope.

**NEW INFORMATION:**
If during the course of this research study, there are significant new findings discovered which might influence your or your child's willingness to continue, the researchers will inform you of those developments.

**CONTACTS AND QUESTIONS:**
If you have questions about research appointments, the study, research results, or other concerns contact the researchers. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them:


| | |
|---|---|
| Aaron Kelly, PhD | Cameron Naughton |
| 612-626-3492 | 612-625-3623 |
| kelly105@umn.edu | naug0009@umn.edu |


This research has been reviewed and approved by an IRB within the Human Research Protection Program (HRPP). To share feedback privately with the HRPP about your research experience, call the, Research Participants Advocate Line: 612-625-1650 (Toll-Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**FUTURE CONTACT:**
We are requesting your permission to contact you in the future when there are studies which have been approved by our Institutional Review Board (IRB) and that may be of interest to you and your child.

**I agree to be contacted for future studies:**

☐ **YES** ☐ **NO** _____
Signature and Date

**BLOOD AND URINE SAMPLE STORAGE:**
The study would like to store some of the extra blood from your child's blood draw. These blood and urine samples will be used in the future for the sole purpose of this research and will not be used for DNA analyses. Blood and urine samples will be stored for no longer than five years after study end, in a locked freezer and identifiable by study ID only. If at any time you decide you no longer want your child's blood and urine samples stored by the study, you may notify a study coordinator and your child's samples will be destroyed. Please indicate below whether you will allow the study to store your child's blood and urine samples for future study use.

**I agree to storage of my blood and urine samples:**

☐ **YES** ☐ **NO** _____
Signature and Date

**STATEMENT OF CONSENT:**
I have read the above information. I have asked questions and have received answers. I consent to my child's participation in the study.

_____
**Participant Name (print)**

_____ _____
**Signature of Parent or Legal Guardian** **Date**

_____
**Name of Individual Conducting Consent**

_____ _____
**Signature of Individual Conducting Consent** **Date**

# CONSENT FORM
## Enhancing Weight Loss with Meal Replacements in Teens

---

You are invited to participate in a research study evaluating the effect of meal replacements on weight loss in adolescents. Meal replacements have a known amount of calories so it takes the guess-work out of eating. You were selected as a possible participant because you appear to meet the preliminary eligibility requirements. Please read this form and feel free to ask any questions before agreeing to participate in the study.

The primary investigator of this study is Dr. Aaron Kelly, PhD, Associate Professor in the Department of Pediatrics at the University of Minnesota. The co-investigators of this study are Drs. Claudia Fox, Kyle Rudser, Robert Jeffery, Amy Gross, Justin Ryder, Dr. Megan Oberle and Donald Dengel; these researchers work at the University of Minnesota. Additional co-investigators include Drs. M. Jennifer Abuzzahab (Children's Hospitals and Clinics of Minnesota), Seema Kumar (Mayo Clinic), and Betsy Schwartz (Park Nicollet). This study is funded by the National Institutes of Health (NIH) through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

**STUDY PURPOSE AND BACKGROUND:**
We want to see if the use of meal replacements can help with weight loss. And, we also want to figure out how much weight loss is necessary to make your body healthier.

**STUDY DESIGN**
This study will involve 130 adolescents (ages 13-17 years old) participating in meal replacement therapy and will last one year (12 months).

**STUDY PROCEDURES:**
A screening visit or phone call will determine if you are eligible to participate in the study and we may also use your medical record to see if you qualify. If you agree to be in this study, you will first sign this consent form and HIPAA authorization form before any study-related procedures are performed. We will ask you to visit the University of Minnesota for up to eight separate visits, each lasting between 2-5 hours. For three of the visits we will ask that you refrain from taking any medications and fast (no food or drink, water only) for 8 hours prior to your visit.

During the study, you will be asked to follow a prescribed daily diet provided by Healthy for Life Meals (formerly Seattle Sutton Healthy Eating).

We will ask that you eat no additional food or calories other than what is provided during the study. The meals will be provided to you free of charge by home delivery.

You will also be asked to participate in follow-up phone calls or emails to review safety measures and discuss lifestyle modification (making healthy changes to your lifestyle). Please note that you may also have unscheduled visits as needed for safety. A urine pregnancy test will be conducted on all female participants at every study visit, starting at the baseline visit, and prior to any study procedures taking place. You will be asked to do the following things at each visit:



Study Code: 1703M10321
Version Date: 07Jun202
Consent Form

## STUDY PROCEDURES (CONT.):

| | Screening (phone -or- in-person) | Baseline | Week 8 | Week 17 | Week 26 | Week 34 | Week 43 | Week 52 |
|---|---|---|---|---|---|---|---|---|
| Review Eligibility | X | | | | | | | |
| Physical exam | | X | | | | | | |
| Tanner staging (pubertal assessment) | | X | | | | | | |
| Safety labs | | X | | | | | | |
| Fasting labs and blood biomarkers | | X | | | X | | | X |
| BMI/anthropometrics | | X | X | X | X | X | X | X |
| iDXA scan (body fat assessment) | | X | | | X | | | X |
| Vascular assessment | | X | | | X | | | X |
| Blood pressure | | X | X | X | X | X | X | X |
| Questionnaires | | X | | | X | | | X |
| Safety assessment | | | X | X | X | X | X | X |
| Lifestyle counseling | | X | X | X | X | X | X | X |

### Blood and Urine for Storage

A portion of your blood (approximately 2 tablespoons) will be drawn at the baseline visit for safety labs, fasting labs and blood biomarkers. Approximately 1 tablespoon will be drawn for fasting labs and blood biomarkers at week 26, and week 52. A total of approximately 4 tablespoons will be drawn throughout the course of study participation. Blood and urine samples will be stored for future study-related biomarker analysis. The additional blood and urine will be stored for no longer than five years after completion of this study and will not be used for DNA/genetic analyses. If at any time you decide you no longer want your blood and/or urine samples stored by the study, you may notify a study coordinator and your samples will be destroyed. For the visits at Baseline, Week 26, and Week 52, you will be asked to come to the research unit after not having had anything to eat or drink for 8 hours. You will be asked to hold any morning medications before those visits as well. If you take morning medications, please feel free to bring them to the visit and you can take them after the fasting samples are collected.

### Measurements of Body Fat

Body composition (muscle and fat) will be measured using dual energy x-ray absorptiometry (DXA), which is a scan requiring you to lie still on your back for approximately fifteen minutes while an x-ray/picture is taken of your entire body.

### Vascular Measurements

A small device that looks like a pen will gently be placed on your neck, wrist, and foot to measure blood flow. These procedures are painless but will require you to lie still in a bed for approximately 45 minutes. The technician will give you specific instructions during this test.

### Lifestyle Modification Counseling

You will receive healthy lifestyle counseling (diet and exercise) throughout the entire study. Educational materials will be given to you at the Baseline, Week 17, Week 26, Week 34, Week 43 and Week 52 visits, and discussed at each face-to-face visit and at seven separate follow-up phone calls or emails.

### Questionnaires

At all visits except the Screening visit, you will complete a series of questionnaires to help us understand your eating behaviors, quality of life and mental health.

**RISKS OF STUDY PARTICIPATION:**

*Blood Draw*
There is minimal risk of bruising and infection associated with the blood draw. On rare occasions, fainting may occur.

*Measurement of Body Fat*
As part of this study, you will undergo four DXA scans. These procedures involve exposure to ionizing radiation. The average amount of radiation that the average person would receive from this procedure is less than 2% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv).
The radiation exposure is not necessary for your medical care, and is for research purposes only. This exposure involves minimal risk and is necessary to obtain the research information desired.

If you are female, you will be required to take a pregnancy test prior to the DXA scan, and those participants who are pregnant will not be included in the study. Also, if you have participated in any other study in the past twelve months, please inform the investigator for documentation of possible previous exposure to radiation.

*Meal Replacement Therapy*
There are no known risks associated with meal replacement therapy.

*Questionnaires*
There may be risks of possible loss of confidentiality and discomfort and/or embarrassment while answering questions. However, you may refuse to answer any questions or stop participating at any time.

**BENEFITS OF STUDY PARTICIPATION:**
Information from the tests (Dexa scan and lab results) will be available to you and to your doctor if you choose. The results of this study may provide new information that could be of benefit to other adolescents like you.

**ALTERNATIVES TO STUDY PARTICIPATION:**
The alternative is to not participate in the study and receive regular clinical obesity care through the University of Minnesota Masonic Children's Hospital Pediatric Weight Management Clinic or other healthcare provider. Your decision will not affect your ability to receive care or change your relationship with the doctors involved in the study.

**STUDY COSTS/COMPENSATION:**
Study procedures and meal replacements will be provided to you at no cost. However, you will be asked to purchase your own fruits and vegetables during the meal replacement phase of the study. If applicable, hotel, parking, and/or meal vouchers will be provided at each visit.

You will also be compensated for your time, which will total $700.00 for study participation if all study visits are completed. You will receive $100 in the form of a gift card at visits where assessments are completed. You will not receive compensation for follow up phone calls/emails. If you receive more than $600 in one year, you will receive a Form 1099 to complete and it will be reported to the IRS.

**RESEARCH RELATED INJURY:**
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

**CONFIDENTIALITY:**
The records of this study will be kept private. Any resulting research articles will not include any information that will make it possible to identify a study participant. Your records for the study may be reviewed by the study sponsor and by departments at the University with appropriate regulatory oversight. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

A note will be placed in your medical record, along with the study doctor's contact information, indicating you are participating in this research study. In addition, laboratory results will be placed in your medical record. You will be given a signed copy of this form to keep for your records.

**PROTECTED HEALTH INFORMATION (PHI):**
Your PHI created or received for the purposes of this study are protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

**VOLUNTARY NATURE OF THE STUDY:**
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with your doctor, clinic, the University of Minnesota Masonic Children's Hospital Pediatric Weight Management Clinic or other medical clinics. If you choose to participate, you are free to withdraw from the study at any time without affecting those relationships.

In addition, the study investigator may choose to withdraw your study participation at any time and for any reason, without your consent. Examples of reasons for study withdrawal may include failure to adhere to the study protocol.

If it is difficult for you to attend the baseline visit of the Screening visit for the study in person, let the study team know. A member of the study team has the ability to set up a meeting via Zoom to discuss the study with you and answer any questions that you may have. If you would like to participate in the project, you will be sent two copies of this consent form and two copies of the HIPAA authorization. You will be asked to sign all of the copies and return one full set to the study team via a prepaid envelope. You will need to have a computer and an internet connection in order discuss the study on Zoom. If you do not have access to a computer, consent can be discussed over the phone. You can ask any questions that you have and, if you would like to participate, you will be asked to sign two copies

of this form and two copies of the HIPAA authorization. You will be asked to return full set to the study team via a prepaid envelope.

**NEW INFORMATION:**
If during the course of this research study, there are significant new findings discovered which might influence your willingness to continue, the researchers will inform you of those developments.

**CONTACTS AND QUESTIONS:**
If you have questions about research appointments, the study, research results, or other concerns contact the researchers. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them:


Aaron Kelly, PhD
612-626-3492
kelly105@umn.edu

Cameron Naughton
612-625-3623
naug0009@umn.edu


This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants Advocate Line: 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**FUTURE CONTACT:**
We are requesting your permission to contact you in the future when there are studies which have been approved by our Institutional Review Board (IRB) and that may be of interest to you.

**I agree to be contacted for future studies:**

☐ **YES** ☐ **NO**

_____
Signature and Date

**BLOOD AND URINE SAMPLE STORAGE:**
The study would like to store some of the extra blood from your blood draw. These blood samples will be used in the future for the sole purpose of this research and will not be used for DNA analyses. Blood and urine samples will be stored for no longer than five years after study end, in a locked freezer and identifiable by study ID only. If at any time you decide you no longer want your blood and urine samples stored by the study, you may notify a study coordinator and your samples will be destroyed. Please indicate below whether you will allow the study to store your blood and urine samples for future study use.

**I agree to storage of my blood and urine samples:**

☐ **YES** ☐ **NO** _____

Signature and Date

**STATEMENT OF CONSENT:**
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

_____
**Participant Name (print)**

_____ _____
**Signature of Participant** **Date**

_____
**Name of Individual Conducting Consent**

_____ _____
**Signature of Individual Conducting Consent** **Date**

# ASSENT FORM
## (Ages 13-17 years old)
## Enhancing Weight Loss with Meal Replacements in Teens

---

We are asking if you would like to be in a research study looking at how meal replacements help with weight loss. This study is being led by Dr. Aaron Kelly. Please read this form and ask any questions you may have before agreeing to be in the study.

The study will last for one year. We ask that you eat meal replacements provided by the study. These will delivered to your home. We ask that you only eat meals provided to you while you are in the study.

If you agree to be in this study, you will be asked to visit the University of Minnesota up to 8 times. Some visits will be long and last up to five hours, and others will be shorter than two hours. These are some of the activities we will ask you to complete if you want to be part of the study:

- Physical examination including looking at your body development: this will happen one time.
- Collection of your blood: this will happen at three visits. It may hurt at the site where the needle enters your skin and you may bleed for a bit or get a bruise. Sometimes people can faint when they have blood collected or get an infection, but this does not happen very often. When you come to these visits you will be asked not to eat for eight hours before the visit. If you take medications in the morning, you will be asked not to take them. Your parent may bring these medicines to the research unit and you could take them after the samples have been collected.
- Collection of your urine: This will happen at three visits. You will be asked to pee in a cup.
- Collection of your height, weight, and blood pressure will be done at every visit for the study.
- A measurement of your body fat will be done at three visits. You will be asked to lie on a table while the test is done. This test uses radiation to help generate its picture. The amount of radiation that you will receive from one of the tests is equivalent to spending a few hours in the sun in Minnesota.
- You will be asked to fill out questionnaires at three points during the study. These questionnaires might ask you about how you feel about your health, what kinds of activities you have been doing, and about your eating habits. Answering these questionnaires might make you feel uncomfortable.
- Lifestyle counseling: you will have these at every visit. You will be asked about the foods you are eating and the food choices that you are making and your activities.

Some of the visits will take place over the phone or Zoom while you are at home. If you decide to be in the study, we will give you a gift card each time you come to a visit.

You can decide to quit the study anytime you want. Even if we have already started, you can tell us to stop at any time. No one will be mad if you do not do the study. It is possible that we might ask you to stop the study if you are unable to follow the instructions that we give you.

**FOR GIRLS**

You will have a pregnancy test done at some of the study visits. If at any time during the study you think you might be pregnant, you must tell the study doctor or study coordinator right away. Your parent/guardian will not be told the results of the pregnancy test without your permission. However, if the study doctors believe that being pregnant may cause serious problems for your health, they may be forced to tell your parent/guardian the pregnancy results.

**PAYMENT**

You will be paid for the time it takes you to participate in this study. If you complete all the in-person visits for the study you will earn a total of $700.00. You will be given a $100 gift card at visits where assessments are completed. You will not receive compensation for phone calls or emails.

**STATEMENT OF ASSENT**

Signing here means that you have read this paper or someone read it to you and you are willing to be in this study. Remember, no one will be mad at you if you don't sign this, or if you change your mind later.

_____
Participant Name (print)

_____ _____
Signature of Participant Date

_____
Name of Individual Conducting Consent

_____ _____
Signature of Individual Conducting Consent Date