

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT INFORMED CONSENT - PART I

Title of Study: *Translational Investigation of Growth and Everyday Routine in Kids (TIGER Kids)*

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help people in the future.
- You have the right to refuse to take part, or agree to take part now and change your mind later on.
- Please review this consent form carefully and ask any questions before you make a decision.
- Your participation is voluntary.
- By signing this consent form, you agree to participate in the study as it is described.

1- Who is doing the study?

Investigator Information:

Principal Investigator: Amanda Staiano, PhD
225-763-2729

Medical Investigator: Daniel Hsia, MD
(225) 763-2831
24-hr. Emergency Phone Nos.:
(225) 763-2672 (Weekdays 7:00 a.m.-4:30 p.m.)
(225) 765-4644 (After 4:30 p.m. and Weekends)

Co-Investigators: Peter Katzmarzyk, PhD
Robert L. Newton, Jr., PhD
Stephanie Broyles, PhD
Catherine Champagne, PhD

Dr. Amanda Staiano leads this study, which is under the medical supervision of Dr. Daniel Hsia. We expect about 340 people to be enrolled in this study. The study will last 4 years, but you will only be in the study for 2 years. This study is happening at Pennington Biomedical Research Center. LSU/Pennington Biomedical has a financial interest in the Food Craving Inventory (FCI) and Body Image Assessment Procedure for Preadolescents (BIA-P) that are used to collect data in this study.

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2- Where is the study being conducted?

This study takes place in the Translational Research Center for Children (TReCC), Outpatient Clinic, and Imaging Center at Pennington Biomedical Research Center.

3- What is the purpose of this study?

The purpose of this study is to find ways to increase your physical activity and reduce sedentary behavior (help you move more and sit less). This will lead to better health. This study will do this by using technology (like activity trackers) to find out what kinds of things keep teenagers from being active and things that help them be more active.

4- Who is eligible to participate in the study?

You may be eligible to participate in the study if you:

- Are 10 to 16 years old
- Weigh < 500 lbs
- Can understand instructions and complete all study procedures (tasks)

You may not be eligible to participate in the study if you:

- Are pregnant
- Are on a restrictive diet due to illness
- Have significant physical or mental disabilities that keep you from walking, wearing an activity monitor, or answering questions on your mobile device.

5- What will happen to you if you take part in the study?

If you agree to join and sign this consent, you will come to a clinic visit at the beginning (Year 0) and end (Year 2) of the study. Clinic visits will be held at Pennington Biomedical Research Center, in Baton Rouge, Louisiana.

The following table shows what will happen at each study visit:

	Orientation	Year 0	Year 2
Consent	X		
Height, weight, waist size measures		X	X
Blood Pressure		X	X
Blood Draw		X	X
Urine Pregnancy Test (females only)		X	X
Body Composition (DXA, MRI)		X	X
Dietary Intake (ASA-24)		X	X
Neighborhood and family environment surveys		X	X
Body image and mood surveys		X	X
Global Positioning System (GPS) tracking	7-days		7-days
Physical Activity (Actigraph GT3X+)	7-days		7-days
Ecological momentary assessment (eMA)	7-days		

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Orientation: About 1 hour (Non-fasting)

- Learn about the study and sign informed consent documents.
- Physical Activity Monitoring (7 days at home): You will be sent home with 2 devices to wear for 7 days to follow your physical activity patterns, an accelerometer and a GPS device. These devices are lightweight and will measure physical activity and where it occurs. You will wear the GPS device when awake and only take it off at bedtime or when in contact with water, such as bathing/showering or swimming. You will wear the accelerometer all day and night except when in contact with water. You will be asked to continue living your life as you normally would while wearing the devices. You will be asked to return the devices to Pennington Biomedical at the Year 0 clinic visit.
 - You will also be asked to respond to text messages over a mobile app throughout the day over 7 days. On school days, these text messages will only be sent to you after school hours. You'll answer questions about what you're doing, who you're with, and how you're feeling. These text messages will only take 2 to 3 minutes to answer. You will be provided instructions on how to safely respond to these messages.
- Dietary Recall (45 minutes): You will be asked to complete the ASA24, a 24-hour diet survey, to say what you've eaten over the past day. This will be done on a computer with an internet program. You will be asked to complete this two times from your home computer within 1 week of the Year 0 visit.

Year 0 Visit: About 3 hours (Fasting- nothing to eat or drink except water 12 hours prior to your visit)

- Body Measurements (10 minutes): A trained staff member will measure your height, weight, and waist size.
- Blood Pressure (10 minutes): You will sit quietly for 5 minutes, and a blood pressure measurement will be taken by a trained staff member using a blood pressure cuff. Your blood pressure will be measured twice.
- Blood Sample Collection (10 minutes): A trained staff member will use a small needle to take a small amount of blood (about 2 tsp) from you. A special cream called EMLA can be used to make the needle stick hurt less.
- Urine Test (10 minutes): If you're a girl, you will have a urine pregnancy test to confirm that you are not pregnant before doing the body scans (DXA and MRI). In a private bathroom, you will use a clean (sterilized) cup to pee into. You will place the cup into a private door in the bathroom where the clinic staff member will get it.
- Body Composition (45 minutes):
 - DXA –
 - This scan measures the amount of bone, muscle, and fat in your body. The scanner will measure your whole body.
 - You will wear a hospital gown, take off anything metal and lie down on the table.

- You will be placed on the table, and the staff member will place your legs together using two Velcro straps.
- A scanner with low energy X-rays and a detector will pass over your body. You will be asked to remain completely still while the scan is in progress.
- The scan takes about 10 minutes.
- MRI –
 - This scan measures the amount of fat in your belly (abdomen).
 - You will wear a hospital gown and take off anything with metal from your body. You will lie on your back on the scanner table with your arms above her head.
 - A large coil will be placed outside of your body, around your chest (upper abdomen). You will then be moved into the magnet and will hold your breath 4-5 times (once for six seconds, once for 13 seconds, and 2-3 times for about 18 seconds).
 - After the upper abdominal scans are done, you will be moved up on the table, and the coil will be placed over your lower abdomen. The same scans will be taken over this area with the same 4-5 breath holds.
 - The total scan time for this procedure is approximately 30 minutes.
 - During the scan, you will hear loud tapping noises. You will be given headphones for protection from the scanner noise and can listen to music during the scan if you'd like. You will also be given a call button in case you need the MRI Technician during the exam.
- Surveys (45-60 minutes): You will do surveys about your medical history, lifestyle including eating and physical activity habits, quality of life, friends, confidence, mood, and body image, and family and neighborhood environment. You may be asked to do these surveys on a computer. You will also be asked to select images that match your stage of development (puberty). This is a common survey done by a pediatrician as a physical exam at well child checks.
- Dietary Recall (30-45 minutes): You will be asked to complete the ASA24 Dietary Recall once more during this visit on a computer through a web based program.

Pennington Biomedical staff may contact you by phone or email approximately every 3-6 months between Year 0 and Year 2 clinic visits to check on your health status and schedule your next visit.

Year 2 Visit: About 3 hours (Fasting- nothing to eat or drink except water 12 hours prior to your visit)

The tests done during the clinic visit at Year 0 will be repeated. These include:

- Body Measurements (10 minutes)
- Blood Pressure Measurement (10 minutes)
- Blood Sample Collection (10 minutes)
- Urine Test (10 minutes)
- Body Composition (45 minutes)

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- Dietary Recall (30-45 minutes): You will be asked to complete this from your home computer two times before coming in for the Year 2 visit. You will be asked to complete the final dietary recall at the Year 2 visit.
- Surveys (45-60 minutes)
- Physical Activity Monitoring (7 days at home): The accelerometer and GPS monitor will be given to you at this visit. You will be asked to wear the devices for 7 days at home. You will be given instructions on how to return the devices to Pennington Biomedical. You will also be asked to respond to text messages over a mobile app throughout the day over 7 days.

6- Blood (Biospecimens) for Future Research

You are being asked to let us save some of your blood to use in future research. These bodily materials are called biospecimens.

Allowing blood to be taken for storage in this study is up to you (optional). No matter what you decide to do, you will still be allowed to take part in the study even if you don't want your blood to be collected and used for future research.

Some blood samples will be stored and used for this study and other blood samples will be stored for future studies. The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. If you agree to have your samples stored, you can change your mind later.

- The samples will be stored indefinitely (forever).
- If you agree to donate your samples, they may be given to other investigators for future research as well.
- The future research may take place at Pennington Biomedical and may involve Pennington Biomedical Researchers in the study.
- The future research may take place somewhere other than Pennington Biomedical Research Center and may be reviewed by another center's Institutional Review Board.
- For privacy and confidentiality, your blood samples will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your blood samples with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.
- The research done with your blood samples may help to develop new products in the future, or may be used to establish a cell line or test that could be patented or licensed. You will not be paid for any patents, inventions or licenses developed from this research.

Blood

If you give permission, approximately 1 teaspoon of blood will be collected and stored by this study. Your stored samples may be tested at Pennington Biomedical Research

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Center or other locations used in future research. Do you give permission for your blood to be collected and used in future research by this study?

Yes, I give permission _____
Signature Date

No, I do not give permission _____
Signature Date

If you give permission, blood will be used to study genetic factors that are related to stress and health. No extra blood is necessary for this analysis. Do you give permission for your blood to be used for analysis of specific genetic factors related to stress and health?

Yes, I give permission _____
Signature Date

No, I do not give permission _____
Signature Date

If you decide you would like to withdraw your consent to use your samples, you must provide a written request to have your samples destroyed. In the event you withdraw your consent, it will not be possible to destroy samples that have already been given to researchers.

For destruction of your samples, you can contact the Principal Investigator at:

Amanda Staiano, PhD
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808

7- What are the possible risks and discomforts?

Body Measurements

- There are no anticipated risks or discomfort during these measurements.

Blood Pressure

- You may have discomfort during blood pressure recordings due to the pressure of the cuff on your arm.

Blood Sample Collection

- There is the possibility of pain and bruising at the vein on your arm where the needle goes in. Aseptic (sterile) technique and trained staff lower these risks. You may have some pain, light-headedness, infection, bleeding or bruising at the needle insertion site; however, the staff will use proper techniques while taking blood samples in order to reduce the risk of these unwanted effects. You may feel hungry or weak during the time you are required to fast before the measurement. The amount of blood drawn is about 2 teaspoons.

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- If you choose to use the EMLA cream, the treated skin may temporarily block all sensations. You should avoid scratching, rubbing, or exposure to extreme hot or cold temperatures until complete sensation has returned. If you have a history of sensitivity to local anesthetics, we do not recommend that you use the EMLA cream.

Urine Pregnancy Test (for girls)

- The urine pregnancy test may cause anxiety. You may refuse the urine pregnancy test. Because this is a required test for the study, you will no longer participate in the study if you refuse the urine pregnancy test.

Body Composition (DXA)

- The amount of radiation used for this procedure is very small. The radiation dose for this scan is similar to the radiation you are naturally exposed to in the environment in less than one day. Scans will not be performed on any subject who is pregnant, and all females must tell the DXA technologist if there is any chance that they are pregnant.

Body Composition (MRI)

- There is a small chance of claustrophobia or muscle-skeletal discomfort from lying partially in the magnet. During the imaging measurement, the noise may be somewhat unpleasant, but headphones will help with this. Although the long-term risk of exposure to a magnetic field is not known, the possibility of any long-term risk is extremely low from what we've learned about this test over the past ten years.
- **MRI/MRS Warning:** Certain implants, devices, or foreign objects implanted in the human body may interfere with the MR procedure. Volunteers who have undergone specific prior surgeries (i.e. heart, brain, gastric bypass, breast augmentation, etc) and/or have implants of specific types may be required to provide their IMPLANT CARD in order to determine implant safety/compatibility with the magnet before a scan is performed.

Surveys

- Answering these questions may cause anxiety. You may refuse to answer questions which cause you to become nervous, upset or anxious. You do not have to answer any questions you do not want to answer.

Physical Activity Assessment

- There are no known risks related to the assessment of physical activity using an accelerometer or GPS device or responding to messages.

Genetic Material

- Genetic information is unique to you and your family, even without your name or other identifiers. Pennington Biomedical Research Center follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

8- What are the possible benefits?

We cannot promise any benefits from your being in the study. If you join this study, you may help others in the future.

9- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way.

10- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Amanda Staiano, PhD at 225-763-2729. If you think you have a research-related injury or medical illness, you should call Daniel Hsia, MD at 225-763-2831 during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

11- What information will be kept private?

Every effort will be made to keep your study records private. However, someone from the Pennington Biomedical Research Center or the United States Department of Agriculture (USDA) may check and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

The Genetic Information Nondiscrimination Act (GINA) may help protect your child from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your child's information, your child may still be at risk if information about your child were to become known to people outside of this study.

12- Can your taking part in the study end early?

Dr. Amanda Staiano, Dr. Daniel Hsia, or the study sponsor can take you out of the study for any reason or for no reason. You may choose to leave the study at any time without penalty; however, all data Pennington Biomedical has already been collected cannot be removed from the study. Possible reasons for leaving include injury, lack of interest, or moving out of town. The sponsor of the study may end the study early. We do not anticipate any adverse effects on your health or welfare. If you choose to leave the study, we will not follow up further with you.

13- What if information becomes available that might affect your decision to stay in the study?

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information about any such new findings will be given to you.

14- What charges will you have to pay?

Nothing.

15- What payment will you receive?

If you agree to take part, we will pay you up to \$100. You will get \$50 after completing the Year 0 clinic visit and returning activity monitor devices. You will also receive \$50 after completing the Year 2 clinic visit and returning activity monitor devices. Your check will come from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

16- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

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17- Signatures

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

Printed Name of Volunteer

Signature of Volunteer

Date

Printed Name of Person Administering Informed Consent

Signature of Person Administering Informed Consent

Date

Amanda Staiano, PhD
Principal Investigator

Daniel Hsia, MD
Medical Investigator

With this additional signature, I agree to be re-contacted for follow-up information related to this study.

Printed Name of Child

Parent/Legal Guardian Signature

Date

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR A MINOR INFORMED CONSENT - PART I

Title of Study: ***Translational Investigation of Growth and Everyday Routine in Kids (TIGER Kids)***

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help people in the future.
- You have the right to refuse to let your child take part, or agree to take part now and change your mind later on.
- Please review this consent form carefully and ask any questions before you make a decision.
- Your child's participation is voluntary.
- By signing this consent form, you agree to let your child participate in the study as it is described.

1- Who is doing the study?

Investigator Information:

Principal Investigator: Amanda Staiano, PhD
225-763-2729

Medical Investigator: Daniel Hsia, MD
(225) 763-2831
24-hr. Emergency Phone Nos.:
(225) 763-2672 (Weekdays 7:00 a.m.-4:30 p.m.)
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Co-Investigators: Peter Katzmarzyk, PhD
Robert L. Newton, Jr., PhD
Stephanie Broyles, PhD
Catherine Champagne, PhD

Dr. Amanda Staiano leads this study, which is under the medical supervision of Dr. Daniel Hsia. We expect about 340 people to be enrolled in this study. The study will last 4 years, but your child will only be in this study for 2 years. This study is happening at Pennington Biomedical Research Center. LSU/Pennington Biomedical has a financial interest in the Food Craving Inventory (FCI) and Body Image Assessment Procedure for Preadolescents (BIA-P) that are used to collect data in this study.

2- Where is the study being conducted?

This study takes place in the Translational Research Center for Children (TReCC), Outpatient Clinic, and Imaging Center at Pennington Biomedical Research Center.

3- What is the purpose of this study?

The purpose of this study is to find ways to increase your child’s physical activity and reduce sedentary behavior (help your child move more and sit less). This will lead to better health. This study will do this by using technology (like activity trackers) to find out what kinds of things keep teenagers from being active and things that help them be more active.

4- Who is eligible to participate in the study?

Your child may be eligible to participate in the study if he or she:

- is 10 to 16 years old
- weighs < 500 lbs
- can understand instructions and complete all study procedures (tasks)

Your child may not be eligible to participate in the study if he or she:

- is pregnant
- is on a restrictive diet due to illness
- has significant physical or mental disabilities that keep your child from walking, wearing an activity monitor device, or answering questions on a mobile device.

5- What will happen to you if you take part in the study?

If your child agrees to join and sign this consent, he/she will come to a clinic visit at the beginning (Year 0) and end (Year 2) of the study. Clinic visits will be held at Pennington Biomedical Research Center, in Baton Rouge, Louisiana.

The following table shows what will happen at each study visit:

	Orientation	Year 0	Year 2
Consent	X		
Anthropometry (Height, weight, waist size)		X	X
Blood Pressure		X	X
Blood Draw		X	X
Urine Pregnancy Test (females only)		X	X
Body Composition (DXA, MRI)		X	X
Dietary Intake (ASA-24)		X	X
Neighborhood and family environment surveys		X	X
Body image and mood surveys		X	X
Global Positioning System (GPS)	7-days		7-days
Physical Activity (Actigraph GT3X+) tracking	7-days		7-days
Ecological momentary assessment (eMA)	7-days		

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Orientation: About 1 hour (Non-fasting)

- Learn about the study and sign informed consent documents.
- Physical Activity Monitoring (7 days at home): Your child will be sent home with 2 devices that he or she will be asked to wear for 7 days to monitor his or her physical activity patterns: an accelerometer and a GPS device. These devices are lightweight and will measure physical activity and where it occurs. Your child will wear the GPS device when awake and only take it off at bedtime or when in contact with water, such as bathing/showering or swimming. Your child will wear the accelerometer all day and night except when in contact with water. Your child will be asked to continue living life as he or she normally would while wearing the devices. Your child will be asked to return the devices to Pennington Biomedical at the Year 0 clinic visit.
 - Your child will also be asked to respond to text messages over a mobile app throughout the day over 7 days. On school days, these text messages will only be sent to your child after school hours. Your child will answer questions about what he or she is doing, who he or she is with, and how he or she is feeling. These text messages will only take 2 to 3 minutes to respond to. You and your child will be provided instructions on how to safely respond to these messages.
- Dietary Recall (30-45 minutes): Your child will be asked to complete the ASA24, a 24-hour diet survey, to say what he or she has eaten over the past day. This will be done on a computer with an internet program. Your child will be asked to do this two times from his or her home computer prior to the Year 0 clinic visit.

Year 0 Visit: About 3 hours (Fasting- nothing to eat or drink except water 12 hours prior to your visit)

- Body Measurements (10 minutes): A staff member will measure your child's height, weight, and waist size.
- Blood Pressure (10 minutes): Your child will sit quietly for 5 minutes, and a blood pressure measurement will be taken by a trained staff member using a blood pressure cuff. Your child's blood pressure will be measured twice.
- Blood Sample Collection (10 minutes): A trained staff member will use a small needle to take a small amount of blood (about 2 tsp) from your child. A special cream called EMLA can be used to make the needle stick hurt less.
- Urine Test (10 minutes): If your child is female and aged 12 years or older (or has had her first menstrual cycle) she will have a urine pregnancy test to confirm that she is not pregnant before doing the body scans (DXA and MRI). In a private bathroom, she will use a clean (sterilized) cup to pee into. She will place the cup into a private door in the bathroom where the clinic staff member will get it.
- Body Composition (45 minutes):
 - DXA –

- This scan measures the amount of bone, muscle, and fat in your child's body. The scanner will measure your child's whole body.
- Your child will wear a hospital gown, take off anything metal from his/her body, and lie down on the table.
- Your child will be placed on the table, and the staff member will place his or her legs together using two Velcro straps.
- A scanner with low energy X-rays and a detector will pass over your child's body. Your child will be asked to remain completely still while the scan is in progress.
- The scan takes about 10 minutes.
- MRI –
 - This scan measures the amount of fat in your child's belly (abdomen).
 - Your child will wear a hospital gown and take off anything with metal from his or her body. Your child will lie on his or her back on the scanner table with arms above his or her head.
 - A large coil will be placed over your child's body, around the chest (upper abdomen). Your child will then be moved into the magnet and will hold his or her breath 4-5 times (once for six seconds, once for 13 seconds, and 2-3 times for about 18 seconds).
 - After the upper abdominal scans are done, your child will be moved up on the table, and the coil will be placed over your child's lower abdomen. The same scans will be taken over this area with the same 4-5 breath holds.
 - The total scan time for this procedure is approximately 30 minutes.
 - During the scan, your child will hear loud tapping noises. Your child will be given headphones for protection from the scanner noise and can listen to music during the scan if desired. Your child will also be given a call button in case he or she needs the MRI Technician during the exam.
- Surveys (45-60 minutes): You and your child will be asked to do surveys about his or her medical history, lifestyle including eating and physical activity habits, quality of life, friends, confidence, mood, and body image, and family and neighborhood environment. Your child may be asked to do these surveys on a computer. Your child will be asked to select images that match his or her stage of development (puberty). This is a common survey done by a pediatrician as a physical exam at well child checks.
- Dietary Recall (30 minutes): Your child will be asked to complete the ASA24 Dietary Recall once more during this visit on a computer through a web based program.

Pennington Biomedical staff may contact you by phone or email approximately every 3-6 months between Year 0 and Year 2 clinic visits to check on your child's health status and schedule your child's next visit.

Year 2 Visit: About 3 hours (Fasting- nothing to eat or drink except water 12 hours prior to your visit)

The tests done during the clinic visit at Year 0 will be repeated. These include:

- Body Measurements (10 minutes)
- Blood Pressure (10 minutes)
- Blood Sample Collection (10 minutes)
- Urine Test (10 minutes)
- Body Composition (45 minutes)
- Dietary Recall (30-45 minutes): Your child will be asked to complete this from his or her home computer two times before coming in for the Year 2 visit. Your child will be asked to complete the final dietary recall at the Year 2 visit.
- Surveys (45-60 minutes)
- Physical Activity Monitoring (7 days at home): The accelerometer and GPS monitor will be given to your child before this visit. Your child will be asked to wear the devices for 7 days at home. Your child will be given instructions on how to return the devices to Pennington Biomedical at the Year 2 visit.

6- Blood (Biospecimens) for Future Research

Your child is being asked to let us save some of his or her blood to use in future research. These blood materials are called biospecimens.

Allowing blood to be taken for storage in this study is up to you and your child (optional). No matter what you and your child decide to do, your child will still be allowed to take part in the study even if he or she doesn't want his or her blood to be collected and used for future research.

Some blood samples will be stored and used for this study and other blood samples will be stored for future studies. The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. If your child agrees to have his or her samples stored, your child can change his or her mind later.

- If you agree to donate your child's samples, they may be given to other investigators for future research as well.
- The future research may take place at Pennington Biomedical and may involve Pennington Biomedical Researchers in the study.
- The future research may take place at somewhere other than Pennington Biomedical Research Center and this research may be reviewed by another research center's Institutional Review Board.
- For privacy and confidentiality, your child's blood samples will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your child's blood samples with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.

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- The research done with your child's blood samples may help to develop new products in the future, or may be used to establish a cell line or test that could be patented or licensed. Your child will not be paid for any patents, inventions or licenses developed from this research. When your child reaches the age of 18, they will be asked if they wish to consent to continue use of their samples for future research. If they do not agree, the samples will be destroyed.

Blood

If you and your child give permission, approximately 1 teaspoon of blood will be collected and stored by this study. Your child's stored samples may be tested at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your child's blood to be collected and used in future research by this study?

Yes, I give permission _____
Signature Date

No, I do not give permission _____
Signature Date

If you and your child give permission, blood will be used to study genetic factors that are related to stress and health. No extra blood is necessary for this analysis. Do you give permission for your child's blood to be used for analysis of specific genetic factors related to stress and health?

Yes, I give permission _____
Signature Date

No, I do not give permission _____
Signature Date

If you decide you would like to withdraw your consent to use your child's samples, you must provide a written request to have your child's samples destroyed. In the event you withdraw your consent, it will not be possible to destroy your child's samples that have already been given to researchers.

For destruction of your samples, you can contact the Principal Investigator at:

Amanda Staiano, PhD
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808

7- What are the possible risks and discomforts?

Body Measurements

- There are no anticipated risks or discomfort during these measurements.

Blood Pressure

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- Your child may have discomfort during blood pressure recordings due to the pressure of the cuff on his or her arm.

Blood Sample Collection

- There is the possibility of pain and bruising at the vein on your child's arm where the needle goes in. Aseptic (sterile) technique and trained staff lower these risks. Your child may have some pain, light-headedness, infection, bleeding or bruising at the needle insertion site; however, the staff will use proper techniques while taking blood samples in order to reduce the risk of these unwanted effects. Your child may feel hungry or weak during the time he or she is required to fast before the measurement. The total amount of blood drawn is about 2 teaspoons.
- If your child chooses to use the EMLA cream, the treated skin may temporarily block all sensations. Your child should avoid scratching, rubbing, or exposure to extreme hot or cold temperatures until complete sensation has returned. If your child has a history of sensitivity to local anesthetics, we do not recommend that your child uses the EMLA cream.

Urine Pregnancy Test (for girls)

- The urine pregnancy test may cause anxiety. Your child may refuse the urine pregnancy test. Because this is a required test for the study, your child will no longer participate in the study if she refuses the urine pregnancy test.

Body Composition (DXA)

- The amount of radiation used for this procedure is very small. The radiation dose for this scan is similar to the radiation your child is naturally exposed to in the environment in less than one day. Scans will not be performed on any subject who is pregnant, and all females must tell the DXA technologist if there is any chance that they are pregnant.

Body Composition (MRI)

- There is a small chance of claustrophobia or muscle-skeletal discomfort from lying partially in the magnet. During the imaging measurement, the noise may be somewhat unpleasant, but headphones will help with this. Although the long-term risk of exposure to a magnetic field is not known, the possibility of any long-term risk is extremely low from what we've learned about this test over the past ten years.
- **MRI/MRS Warning:** Certain implants, devices, or foreign objects implanted in the human body may interfere with the MR procedure. Volunteers who have undergone specific prior surgeries (i.e. heart, brain, gastric bypass, breast augmentation, etc) and/or have implants of specific types may be required to provide their IMPLANT CARD in order to determine implant safety/compatibility with the magnet before a scan is performed.

Surveys

- Answering these questions may cause anxiety. Your child may refuse to answer questions which cause him or her to become nervous, upset or anxious. Your child does not have to answer any questions he or she does not want to answer.

Physical Activity Assessment

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- There are no known risks related to the assessment of physical activity using an accelerometer or GPS device or responding to messages.

Genetic Material

- Genetic information is unique to your child and your family, even without your child's name or other identifiers. Pennington Biomedical Research Center follows procedures to prevent people who work with your child's DNA information from being able to discover it belongs to your child. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your child's genetic information will never be linked to your child.

In addition to the risks listed above, your child may experience a previously unknown risk or side effect.

8- What are the possible benefits?

We cannot promise any benefits from your child being in the study. If your child joins this study, he or she may help others in the future.

9- If you do not want to take part in the study, are there other choices?

You have the choice at any time to not let your child participate in this research study. If you choose to not let your child participate, any health benefits to which he or she is entitled will not be affected in any way.

10- If you have any questions or problems, whom can you call?

If you have any questions about your child's rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Amanda Staiano, PhD at 225-763-2729. If you think your child has a research-related injury or medical illness, you should call Daniel Hsia, MD at 225-763-2831 during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

11- What information will be kept private?

Every effort will be made to keep your child's study records private. However, someone from the Pennington Biomedical Research Center or the United States Department of Agriculture (USDA) may check and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your child's name and other identifying information private. Other than as set forth above, your child's identity will remain confidential unless disclosure is required by law.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify your

child. At most, the web site will include a summary of the results. You can search this web site at any time.

The Genetic Information Nondiscrimination Act (GINA) may help protect your child from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your child's information, your child may still be at risk if information about your child were to become known to people outside of this study.

12- Can your taking part in the study end early?

Dr. Amanda Staiano, Dr. Daniel Hsia, or the study sponsor can take your child out of the study for any reason or for no reason. Your child may choose to leave the study at any time without penalty; however, all data Pennington Biomedical that has already been collected cannot be removed from the study. Possible reasons for leaving the study early include injury, lack of interest, or moving out of town. The sponsor of the study may end the study early. We do not anticipate any adverse effects on your child's health or welfare. If your child chooses to leave the study, we will not follow up further with him or her.

13- What if information becomes available that might affect your decision to stay in the study?

During the course of this study there may be new findings from this or other research which may affect your child's willingness to continue participation. Information about any such new findings will be given to him or her.

14- What charges will you have to pay?

Nothing.

15- What payment will you receive?

If your child agrees to take part, we will pay your child up to \$100. Your child will get \$50 after completing the Year 0 clinic visit and returning activity monitor devices. Your child will also get \$50 after completing the Year 2 clinic visit and returning activity monitor devices. Your child's check will come from the LSU payroll department when he or she completes the study or at the appropriate milestone if he or she is compensated during

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the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

16- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which your child participates, your child will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should your child require ongoing medical treatments, they must be provided by community physicians and hospitals.

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17- Signatures

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

The study volunteer is a child. I certify that I am his/her legal guardian and legally authorized to enroll him/her in this research study. Misrepresentation of this authority could result in civil and/or criminal penalties.

Printed Name of Child

Date of Birth of Child

Printed Name of Parent/Legal Guardian

Relationship to Child

Parent/Legal Guardian Signature

Date

Printed Name of Person Administering Informed Consent

Signature of Person Administering Informed Consent

Date

Amanda Staiano, PhD

Principal Investigator

Daniel Hsia, MD

Medical Investigator

With this additional signature, I agree to be re-contacted for follow-up information related to this study.

Printed Name of Child

Parent/Legal Guardian Signature

Date