PRINCIPAL INVESTIGATOR: Jack A. Yanovski, MD, PhD.

STUDY TITLE: **Break It Up: A study evaluating breaking up daily sedentary behavior in youth**

STUDY SITE: **NIH Clinical Center**

Cohort: Standard

Consent Version: 01/28/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Jack A. Yanovski, M.D., Ph.D.; Building 10, Room 1-1330, Bethesda, MD, 20892, Telephone 301-496-0858; email: jy15i@nih.gov or Sheila M. Brady, NP, Building 10, Room 1-1330, Bethesda, MD 20892, Telephone 301-451-3783; email: Sheila.Brady@nih.gov

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this project is to find out if breaking up sedentary (low activity) time with short walking breaks over the course of 6 days will affect how children use sugar in the body (metabolism), as well as find out if breaking up sedentary time changes children's attention, memory, feelings, physical activity or eating behavior.

FACTS THAT LED US TO THIS STUDY

Some short (single day) studies in adults have found that insulin and glucose blood levels are lower when a long period of sitting is broken up with walking compared to sitting without breaks. This means that the body can better process sugars from the diet when there are walking breaks during the day. There are also studies that show this in children.

Additionally, some studies in children have found that children's attention and working memory may be improved after exercise. This means that skills that affect academic performance are increased after exercise. It is not known if short walking breaks have the same effects. This study will help us understand if breaking up sitting with walking for 6 consecutive days will help children's bodies use sugars and improve children's concentration.

STUDY POPULATION

We will study up to 120 children, age 7 to 11 years, who are in general good health.

PROCEDURES

Study Overview: If you and your child agree to participate, your child will be seen once as an outpatient for about 6 hours at a screening visit to determine if your child is eligible for the study. If your child is found to be eligible for the study, your child will be one of 120 children seen as outpatients at the NIH Clinical Center for 6 consecutive-day visits. The first 5 visits will take place after school and will take about 3 hours. The last visit will be in the morning and take about 5 hours. These visits must be completed within 3 months of the outpatient screening visit.

Your child will either be sitting for 3 hours (the "sitting only" test) for their 5 after-school visits and final visit or they will be sitting for 3 hours with 3-minute walking breaks every 30 minutes (the "sitting breaks" test) for these visits.

This study uses a randomized, parallel design. In this type of study, all children who participate will be assigned to do either one week of sedentary activities or one week of sedentary activities with 3-minute walking breaks on a treadmill every 30 minutes at a moderate activity rate that will be selected according to your child's fitness level.

There are a total of 7 study visits:

A. Outpatient screening visit

To find out if your child can take part in this study, your child will be seen on a weekday in the Pediatric Day-Hospital of the Clinical Center at the National Institutes of Health. A parent or guardian will need to accompany your child. Your child will need to come to this visit fasting, which means he/she cannot eat or drink anything after 10 PM the night before the visit, or the morning of the visit (although water is permitted). Your child will be able to eat after we complete study blood tests. During this visit, we will do the following 10 things over approximately 6 hours:

1. We will go over this **consent form** in detail, review all parts of the study, and ask you and your child to sign the consent (this is what you sign) and the assent (what your child signs).
2. **History and physical exam**. A doctor or nurse practitioner will ask you and your child some questions about your child's medical history, and will weigh and examine your child, similar to what your child may have done during a typical physician office visit. Because puberty affects metabolism, this session will include a genital exam to determine pubertal status, like the exam your child normally has at yearly visits to the pediatrician. Your child may find this embarrassing.
3. **Body measurements.** A research team member will measure your child's body fat by body circumference. Measuring body fat by body part circumference measures will be done with a tape measure, while your child wears only underwear. Such measurements are not painful, although some children may feel uncomfortable standing in underwear.
4. **Fasting blood tests.** Fasting means your child will not eat anything (but may drink water) after 10 PM the previous evening and these tests will be drawn in the morning before your child has anything to eat. After putting a special cream on called ELA MAX, which will help numb the skin and lessen the discomfort of the needle stick, we will draw blood (at most 3 tablespoons) for triglycerides, hemoglobin, kidney and liver tests, blood sugar, hormone levels and cholesterol. If we find anything unusual on these tests, we will inform you as well as your doctor. We will also collect **research samples** to look for differences between people.
5. **DXA X-ray.** This is an x-ray test that looks at how much body fat and muscle your child has. The test involves lying still on a table while a small camera passes over your child's body. You can stay with your child in the room during the x-ray. Your child will be able to see you at all times. The dose of the x-ray is much less than the amount your child would get from a normal chest x-ray. The total amount of time to do this test will be about 20- 30 minutes. This study is done in the Metabolic Clinical Research Unit within the NIH Clinical Center.

6. **Electrocardiogram (EKG).** Your child will have an electrocardiogram (EKG) to look at the electrical activity of the heart, and may have an echocardiogram if that test seems needed. An echocardiogram uses sound waves to take pictures of the heart muscles. These tests do not hurt and take about 30 minutes to complete.

7. **Exercise study.** Your child will be asked to exercise using a treadmill. During the exercise, we will measure your child's heart rate, blood pressure, and heart electrical activity. As your child exercises, we will monitor the amount of oxygen your child is using by having your child breathe into a mask. The incline on the treadmill will gradually increase, but the speed of the treadmill will remain stable. The incline will increase until your child reaches the point where your child cannot exercise any more. When your child says he or she can exercise no further, the incline on the treadmill will be decreased gradually to allow your child to cool down. After exercise we will ask your child to rest. The whole procedure typically takes less than 1 hour, and the exercise itself is well under 20 minutes in duration.

8. **Questionnaires.** We will ask you to complete questionnaires about your child's general health, social and psychological functioning, physical activity level and your education level and socioeconomic status. We will also practice the tests with your child that will be given on the test visit days so that your child will be familiar with everything that will happen in the study. All of this information is kept confidential, and will not be shared with you unless the results indicate your child has significant emotional concerns. If you or your child feel uncomfortable answering any question, you do not have to answer that question.

9. **Cognitive ability**. We will ask your child to complete a Picture Vocabulary Test to measure vocabulary knowledge, which is related to overall intelligence. This test is taken on a computer. Your child will be presented with an audio recording of a word and four photographic images on the computer screen and is asked to select the picture that most closely matches the meaning of the word. This test is takes about 5 minutes to complete. We will also practice the cognitive tests that will happen on the outpatient trial visits, so your child will be familiar with everything that will happen in the study.

10. **Meet with NIH Dietitians.** We will ask you and your child to meet with NIH dietitians to find out the kinds of foods your child likes to eat. You and the dietitian will plan meals that your child will enjoy eating. If your child is eligible, these meals will be given to you during the main part of the study (described below).

When we have all the lab test results from this visit, we will decide if your child can take part in the study. If your child is eligible, we will schedule the other 6 consecutive-day outpatient visits. These must be done within 3 months of the screening visit.

After-school visits (day 1-5)

Your child and one parent (or guardian) will come to the NIH Clinical Center in Bethesda, Maryland after school (at approximately 3 PM) from Monday to Friday for visits that will take approximately 3 hours. We will do the following 8 things:

1. **Brief health check.** Your child's temperature, blood pressure, resting heart rate, and resting breathing rate will be measured to make sure he/she is not sick. A research team member will also ask you and your child about sleep during the previous night, what your child ate on the previous day, and about any recent illnesses or injuries. If any of the vital signs or questions indicate that your child is sick or not able to complete the study procedures that day, testing will stop and be re-scheduled for another day.
2. **Place and Check 24 Hour Continuous Glucose Monitor (CGM).** On Day 1, a research team member will place a CGM device on the back of your child's arm. CGMs are small wearable devices that will track changes in blood sugar (glucose) throughout the week. The device is approximately the size of a quarter. The CGM is placed on the skin with a sticky, adhesive material and the small sensor rests just underneath the skin. It should stay stuck on the skin always even during bathing, showering and swimming. The research team will check it daily to make sure there is no irritation and the CGM is working properly. The device can be removed at any time if your child or you would like it removed. The goal is for your child to wear the monitor for an entire week and it will be removed at the end of your child's final visit.
3. **Place 24 Hour Continuous Activity Monitor.** On Day 1, a research team member will place a wrist activity monitor on your child's wrist. The wrist monitor is a wearable device that records physical activity and sleep activity throughout the week. It should be worn all the time except during activities with water such as bathing, showering, swimming, or washing dishes. The wrist monitor must be taken off when your child does these activities and then placed back on as soon as possible. The device will be removed and collected by the research team at the end of the study on Day 6.
4. **After School Snack and Meals for 24 hours.** Each day, we will give your child a healthy snack to eatand send you home with food for your child to eat during the next 24 hours.
5. **Activity monitors.** On all 5 days during the visit, your child will wear an accelerometer on the wrist. There are no known risks with these devices, but they may be slightly uncomfortable.
6. **Sitting tests.** Depending on which group your child is assigned, your child will sit for three hours and occupy their time with non-active pursuits (such as watching movies or reading) or have the three-hour sitting period broken up with 3-minute walking bouts on the treadmill every 30 minutes. If your child is randomized to break up sitting with walking, the treadmill will be programmed for your child's fitness level and will have

their heart rate monitored. Children randomized to the walking-breaks condition will walk for a total of 18 minutes.

7. **Cognitive tests.** Your child will complete several cognitive tests on a computer on days #1 & 5. These tests measure attention, impulse control, and working memory. These tests take about 10 minutes to complete. They will be the same kinds of tests your child practiced at the screening visit.
8. **Questionnaires.** Your child will complete some short questionnaires on days #1 & 5 that tell us about his/her mood and feelings of anxiety. These questionnaires will take about 40 minutes to complete.

FINAL STUDY VISIT

This visit will be done in the morning of day 6. This visit will take about 5 hours and involve:

1. **Fasting.** Your child will be asked not to eat or drink anything except water again on the morning of the final test visit. Your child will be able to eat at the end of the test visit.
2. **Blood draws at 9 times through a heparin lock (IV) catheter for an oral glucose tolerance test as follows:** After putting a special cream on called ELA MAX, which will help numb the skin and lessen the discomfort of the needle stick, we will draw blood through the heparin lock throughout the 3 hours of the test visit. There will be two fasting blood draws. After the fasting blood samples are taken, your child will be given some sugar water to drink (one name for this is "Glucola") and will have additional blood samples drawn at 20 minutes, and then every 30 minutes for 3 hours (approximately from 9am to 12pm). We will measure how your child's body uses sugar. The volume of blood withdrawn will be minimized (less than 4 tablespoons) so as to keep the total volume taken throughout the entire visit within the safety guidelines for blood drawing. Again, these blood draws will be done through the heparin lock which was inserted at the beginning of the final test visit and drawing blood from the heparin lock should not cause your child pain.
3. **Cognitive tests.** Just like test days #1 & 5, your child will complete several cognitive tests on a computer during this test day #6. These tests measure attention, impulse control, and working memory. These tests take about 10 minutes to complete. They will be the same kinds of tests your child practiced at the screening visit.
4. **Questionnaires.** Just like test days #1 & 5, your child will complete some short questionnaires on this test day #6 that tell us about his/her mood and feelings of anxiety. These questionnaires will take about 40 minutes to complete.
5. **Sitting test.** Your child will either be sitting for three hours or have their sitting broken up with 3-minute walking bouts every 30 minutes, just like their daily visits previously.
6. **Activity monitors.** Your child will wear a heart rate monitor around his/her chest and two

accelerometers on the wrist and right hip.

7. **Meal.** Your child will be given a meal at the end of the visit, so we can measure how much food your child eats and how long it takes until your child is full. The foods in the meal are commonly found in the supermarket and pose no risk to your child.
8. **End Study**. We will remove all devices such as the CGM, heart rate monitors and accelerometers at the end of this visit.

RISKS, INCONVENIENCES AND DISCOMFORTS

As with any research study, there may be risks, inconveniences, and discomforts that occur during the course of the study. We will try to minimize the risk and discomfort associated with the study. Potential risks, inconveniences, and discomforts are listed below:

1. **Physical examination.** A doctor or nurse practitioner will examine your child with your child's clothes off. Although measures will be taken to protect your child's privacy, some children may find this embarrassing.
2. **The body composition** measurements used in this study have no known risk. Measurement of body circumference takes only a few minutes, and is not associated with any significant discomfort, other than the inconvenience of standing in underwear while measurements are taken.
3. **Fasting blood testing and frequent blood draws.** We will be drawing no more than 3 tablespoons of blood during the first, screening visit and no more than 4 tablespoons of blood during final visit on Day 6. This is well below the NIH guideline for a safe amount of blood withdrawal. For the blood draw on the final visit, Day 6, we will put a heparin lock (intravenous catheter or "IV") in your child's arm vein to draw blood. Putting this plastic catheter in can be painful and cause some anxiety for your child. Rarely, someone faints when a heparin lock is placed or blood is drawn. To decrease the pain, we will use ELA MAX cream to help "numb" the skin. An area of white or red rash that usually goes away within a few hours may be seen on the skin after the use of ELA MAX cream. Once the plastic catheter is in the vein, we can draw blood samples from it without any pain. There is a small risk of infection with these plastic catheters, but the skin will be cleaned with antibiotic soap before insertion.
4. **Continuous Glucose Monitor (CGM).** Your child will wear a CGM for days 1-6 and will have the CGM removed on their final visit. It may be slightly inconvenient for your child to wear a CGM but the device is very small. There are few risks from wearing a CGM. The CGM works by placing a very small ("micro") plastic tube through a person's skin. Most people do not feel pain when it is inserted, but it is a minimally invasive needle stick so pain is possible. Additionally, there is a very small chance of irritation or infection in the site of placement. The research team will monitor the device and replace it if necessary.

5. **DXA X-ray.** These tests are not painful, but may be inconvenient for your child because your child will need to lie still for 20-30 minutes.
6. **Radiation Safety**: This research study involves exposure to **radiation** from a DXA X-ray scan to determine body composition. Please note that this radiation exposure is not required for your child's medical care and is for research purposes only. The amount of radiation your child will receive in this study is 0.003 mrem, which is well below the guideline of 500 mrem per year allowed for child research subjects by the NIH Radiation Safety Committee.

   The average person in the United States receives a radiation exposure of 300 mrem per year (0.82 mrem per day) from natural sources, such as the sun, outer space, and the earth's air and soil. The dose that your child will receive from participation in this research study is much less than the amount he/she would normally receive in one day from these natural sources. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, *An Introduction to Radiation for NIH Research Subjects*.

   Please tell your doctor if your child has had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that your child will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into the body.
7. **Exercise.** Risks of exercise include the possibility of slipping and falling while exercising and muscle soreness and fatigue caused by exercising that could last several days. In adults, abnormal blood pressure, heart rate (too rapid or too slow), or, in rare cases, heart attacks, can occur during exercise. Statistical surveys show that in over 600,000 adult exercise tests, the fatality rate was between 0 and 3 deaths/100,000 exercise tests. This rate should be even lower for exercise tests in children who do not have known heart disease. During the more than 15 years in which exercise testing has been conducted by our research group, there have been no fatalities or major medical complications. If your child's cardiac evaluation suggests your child is at increased risk from exercise, this study will not be performed and your child will not be able to take part in other study visits.
8. **Time required.** The actual time required for participation in this study is: One 5-hour outpatient screening visit and five 3-hour afterschool outpatient visits, and one 4-5 hour final outpatient visit.
9. **False positives.** Abnormal test results may cause anxiety and could lead to additional medical evaluations.

USE OF STORED SAMPLES AND DATA

Our specific research plans have been summarized in this consent form. In the course of the research, we will obtain blood samples. While we can do some of our tests immediately, we may want to store your child's blood samples in the freezer for future studies. In addition, certain information will be stored in your medical record. In the future, it is possible that your child's blood samples or your child's medical records will be used for other research purposes that are not specifically outlined in this consent form. If this is done, samples will be coded, and your child will not be identified by name. These samples may be stored at a separate site (called a repository) that specializes in storing clinical samples.

You have the option, in the future, of requesting that these samples not be used for any additional testing. In addition, it is possible that some information obtained from these studies will be published in the medical literature. However, your child's identity will not be included in any publications.

Please put your initials next to one of the following:

_____I understand that samples collected during these NIH visits will be saved and used for future experimental testing related to body weight and metabolism. This testing may be done by research laboratories that are not at the NIH. I authorize use of these samples for other purposes without my additional consent. I understand I will not be contacted if these samples are used in the future.

_____I understand that samples collected during these NIH visits will be saved and used for future experimental testing related to body weight and metabolism. This testing may be done by research laboratories that are not at the NIH. I do NOT authorize use of these samples for other purposes without my additional consent. I must be contacted and give consent if these samples are to be used in the future.

ANTICIPATED BENEFITS

Your child may not derive any health benefit from participating in this study. The information gained from review of your child's medical history and physical examination may be of use to you. Diagnostic tests (EKG, DXA, fasting blood tests, etc.) will be available to you or, with your permission, to your doctor.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You and your child may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you and your child from the study at any time if she or he believes that continuation is not in your child's best medical interest or if you are unable to comply with the requirements of the study.

RESULTS FROM THIS STUDY

Most of the information we obtain from this study will not provide information on your health. You will not receive any individual results. However, if the investigators learn of important new information that might affect you or your child's desire to remain in this study, you and your child will be told this information.

You WILL receive the following results about your child during the study:

- Abnormal fasting blood test results, such as high fasting blood sugar, from the outpatient screening visit.
- Abnormal findings from the physical exam or EKG at the outpatient screening visit.
- Questionnaire results from the outpatient screening visit if there is any evidence of significant emotional concerns on the anxiety or mood questionnaires.

You can get copies of the following tests by requesting your medical records from the NIH Medical Records Department:

- Results of blood tests run at the Clinical Center, the physical exam, and EKG

Once our study is complete, we will tell you what we have learned about how interrupting sedentary behavior changes metabolic and cognitive outcomes (the overall results of the study).

You WILL NOT receive results from your child's testing for the following tests:

- Results from the body composition, fitness, or activity tests.
- Results from the cognitive tests or the behavioral questionnaires, except as noted above.
- Results from the activity monitors.
- Results from the continuous glucose monitor.
- Results from the meal test.

STUDY TERMINATION

Your child's participation in this study may be stopped by the investigators at any time, without your or your child's consent.

ALTERNATIVES TO PARTICIPATION OR TREATMENT

The alternative to participating in this study is not to participate. This study does not provide treatment and does not replace any therapy that your own doctor is giving your child.

However, your child may be eligible for other pediatric studies that may be found at www.clinicaltrials.gov. This consent form specifically refers to your child's participation in the research protocol described above. In the future, it is possible that we may contact you to invite you to participate in other studies. Even if you sign this consent form, you are not obligated to participate in these other studies. If you are asked to participate in other research protocols, you will be provided with additional consent forms. As stated in the introduction to this protocol, you

are free to withdraw from any or all research studies at any time, without penalty or loss of any benefits to which you are otherwise entitled.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH. The study investigators and personnel do not have any conflicts of interest for this study.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

Children taking part in this study will be compensated for the time and inconvenience associated with participation according to NIH research volunteer guidelines. The details are listed below:

1. Complete screening visit: $100
2. Complete after-school visits: $100/visit (5 visits; $500 total)
3. Complete final visit: $150
4. Complete CGM wear: $20/wear (6 days; $120 total)
5. Complete wrist activity monitor wear: $10/wear (6 days; $60 total)

If your child completes all the things mentioned in the consent form, your child will receive $930 for the time and inconvenience of taking part in this study. Payments will be sent as checks through the mail or via direct deposit.

If you are unable to finish the study, you will receive full compensation for the parts you completed.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Review Service (IRS). A “Form 1099-Other Income” will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Information on your child's medical history and laboratory results will be kept in the electronic record system (CRIS) of the Clinical Center as well as in special research files in the Section on Growth and Obesity. Samples of your blood taken during this study will be kept stored in secure locked freezers. Before storing the samples, all identifying information, including your name, date of birth and the hospital medical record number, will be removed. The samples will be labeled with a code number but no other identifying information. The key to this code along with all other private information will be kept confidential and your privacy protected by keeping them in secure, locked places. Study documents and pertinent hospital or clinical records may be reviewed by qualified monitors within the NICHD quality assurance program.

.

You will be asked to supply your social security number in order to be compensated for your participation, but your social security number is not retained by the protocol study team after it is entered in the NIH payment system. You can participate in research but cannot be compensated without supplying your social security number.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- We will share some of your child's cognitive (brain) testing that is performed with the Cogstate LTD. software with Cogstate LTD. Our research team has signed an agreement with Cogstate LTD. that will provide de-identified data to Cogstate LTD when our study is complete. In exchange for these data, we are able to use Cogstate's software for our testing. "De-identified data" means that your child's information will be coded. It will not contain his/her name or date of birth. Cogstate LTD will receive the following de-identified information: Cognitive testing results, medical status (any neurologic or

psychiatric diagnoses), ethnicity, gender, year of birth, handedness, level of education, approximate yearly income and randomization assignment for this study.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Jack A. Yanovski, M.D., Ph.D.; Telephone 301-496-0858; email: jy15i@nih.gov. Other researchers you may call are: Sheila M. Brady, NP, Telephone 301-451-3783; email: Sheila.Brady@nih.gov. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.
Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated

the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.