COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: Pathophysiologic mechanisms leading to intrahepatic fat accumulation in obese youth

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Phone Number: 203-7376356

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to understand what causes fatty liver disease. Fatty liver is a disease that is present prevalently among obese individuals and can be associated with high lipids, high blood sugar and insulin resistance. Therefore, it could lead in the long term to develop cardiovascular diseases.
- Study procedures will include a cross sectional part composed by three studies and a longitudinal part for which you will be asked to come back about every six months for two years. The cross sectional part will include: 1) an oral glucose tolerance test (OGTT) and a belly scan; 2) a study to assess how the liver metabolize the carbohydrates (DNL and TCA assessment) and; a study the measure how your insulin works (euglycemic hyperinsulinemic clamp). We will ask you if we can follow you up for about two years. During this time we will ask you to undergo an OGTT every year and an MRI every 6 months. Moreover we will ask you to wear for 10 days every six months a device called continuous glucose monitoring (CGM) to measure your blood glucose.
- About 3 visits are required for the first part of the study, and 5 visits over the course of 2 years for the longitudinal part of the study.
- These visits will take 39 hours total (over the two years).
- There are some risks from participating in this study. The risk of the procedures are the bruise of the skin that the catheters that we use to draw blood may cause. The use of the CGM may cause bruise or local infections. These events are very rare.
- The study may have no benefits to you. We will learn more about your lipids and glucose metabolism. The studies that we perform will inform us about whether you have fatty liver, dyslipidemia or prediabetes and diabetes**.** We will also instruct you on a healthy diet and on how to eat. The results from this study will be of benefit for other people as they will allow to learn more about the disease and how it starts and progresses.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

You are invited to take part in a research study that will look at fatty liver disease. Fatty liver is a

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disease that affects mostly children with obesity and is characterized by an accumulation of fat into the liver that usually should not contain a lot of fat. We are inviting you to be in the study because you might have fatty liver disease or are at risk of developing fatty liver.
In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This assent form gives you detailed information about the study, which a member of the research team will discuss with you and your parents. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures and possible benefits. Once you understand the study, you will be asked if you wish to be in the study; if you do, you will be asked to sign this form. We are looking for about 250 participants to be part of this research study.

Who is paying for the study?
NIH

Who is providing other support for the study?
Yale University

What is the study about?
The purpose of this study is to determine what causes fatty liver in youth.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will ask you to come back for several visits.

Visit 1.
Food record: we will ask you to list the foods and beverages consumed during two week days and one week-end day. This will give us the opportunity to learn about your usual diet. This can be done at any time at home.

Anthropometric assessments: When you come in for your study visit, we will ask you to step onto a Tanita scale, which is a special scale that delivers a very mild electrical current, which you won't be able to feel, throughout your body. It's a scale that will allow us to measure the amount of fat and muscle in your body. You have probably been on one before when you go to your doctor's appointments.

Assessment of glucose tolerance. You will complete an oral glucose tolerance test (OGTT) that will last for three hours, but will give us the opportunity to learn if you have diabetes during this study we will take no more than 6 tablespoon of blood (about 86 ml). A thin plastic tube (I.V.) will be placed in a vein in your arm. You will then be asked to drink about 8 ounces (one cup) of a high-sugar cola- or orange-flavored drink. The I.V., which will remain in place for the duration of the test, will allow a member of the research team to take out small amounts of blood for measuring the concentration of glucose and other substances that circulate in the blood. A television and VCR are available to watch. Lunch or snacks will be provided at the end of the test.

Belly scan. You will complete an MRI scan so that we can take some pictures of your belly and liver. This will allow us to look at fat in your belly and liver. The MRI scan is approximately 15 minutes. A member from the study staff with be with you for the entire duration of the MRI scan. This scan is painless and is thought to be very safe. You will be asked to remove any loose metallic items, such as watches, jewelry and hairclips. We ask you to lie down on a movable

platform, and a belt will be placed around your belly. This belt allows the scanner to know when you are breathing in and out, which helps reduce blurring of the pictures caused by breathing. We will also place a thin rectangular-shaped coil across your belly in order to get better pictures of the liver. You may head loud buzzing noise when scanner is taking picture. We will provide protective headphones or earplugs to wear so the noise will not be too loud. The scanner will take several pictures of your belly. The MRI operator will tell you when each scan will be performed. It is important to lie still at this time. If any of the pictures do not develop correctly, we may need to repeat them. Towards the end of belly scan, you will be asked to hold your breath for about 15 to 30 seconds each time. The MRI operator will go through some breathing exercises with you and will tell you exactly when to hold your breath. You can catch your breath between pictures. If any of the pictures are blurred, you may be asked to repeat this picture by holding your breath once more. You will be able to head by the MRI operator during the scan, and the operator will be able to talk to you through a microphone when necessary. The entire belly scan should take no more than 30 minutes. If you want to get out of the magnet at any time, for any reason, we will take you out immediately.

The procedure for the MRE is similar to an MRI. The difference is that in an MRE a small piece of equipment called a driver will be placed on the right side of your lower rib cage. The driver will vibrate while the scan is conducted and this is how we detect if your liver has any scarring. The scanning table, where you are lying on, will slide your body into the MRI machine. Earplugs will be provided to mask the noise, and the technologist will be communicating with you during the study. A research staff will accompany you before, during and after the exam.

Visit 2 .Measurement of liver metabolism (lipogenesis and TCA cycle). To understand how much fat produces your liver from the carbohydrates and how the carbohydrates are metabolized we will need to measure two important pathways 1) de novo lipogenesis, which is the conversion of carbohydrates into fat and 2) TCA cycle that will tell us about the ability of the liver to metabolize carbohydrates through alternative routes without converting them into lipids. To participate in this portion of the study, you will have the option to check in at the Hospital Research Unit (HRU) at Yale New Haven Hospital the night before the study and stay overnight, or check-in at the Hospital Research Unit or at Church Street Research Unit (CSRU) at 7:00AM the morning of the study and complete the water and meal component at home the night before. If you choose to stay overnight with us, you will check in at 4:30 PM on Day 1 and stay overnight. A dinner will be given to you and we will also have you drink the special water (deuterated water), a naturally occurring compound. The next morning we will ask you to drink a substance called propionate (400 mg) in three doses. Propionate, a natural substance abundantly present in our body tastes like water and then you will have you drink a sugar beverage (75g fructose) and a thin plastic tube (IV) will be placed in a vein in order to draw blood throughout the study. Another small tube will be placed in a vein in the other arm to infuse some glucose (initial dose of 2.25 mg/kg for five minutes and a continuous dose of 0.0225 mg/Kg/min). Taking these blood draws will allow us to see how your body is metabolizing carbohydrates. If you choose to stay at home the night before, we will give you a specially prepared dinner and the deuterated water beforehand to consume that night. Then you will check in at the HRU or CSRU at 7:00AM the next morning. The study will last about six hours. Blood draws will be taken 15 minutes before ingestion of the sugar beverage, then for every half hour for 6 hours. We will take up to 9 tablespoons of blood (about 136 ml). During the visit you will also undergo an indirect calorimetry. This is a very simple study, in fact, we will ask you to wear a hood for about 30 minutes. We will ask you to do that before the ingestion of the sugary drink and one hour after.

Visit 3. Euglycemic clamp. During a third visit we will ask you to come in the morning to perform a study (euglycemic clamp) to measure how your insulin works. You will arrive at HRU at 7.00 AM and to catheters will be placed in both arms. In one arm we will infuse glucose and glycerol while from the second catheter we will draw blood. At the start, a primed infusion (0.4 g/m2) of 6,6D2-glucose and (0.6 µmol/m2) of D5-glycerol will be given. Thereafter, 6,6D2- glucose and D5-glycerol (4 µ mol/m2·min) will be infused continuously throughout the studies. After an initial 2.30 hours infusion, we will give you a low dose (4U/m2/min) of insulin for two hours and a second higher dose (80U/m2/min) for other two hours The study will last about 7 hours. The total blood drawn during the study will be about 10 tablespoon (140 ml). This will take place about 3-4 weeks apart from the other visits. Also during this study you will be asked to do an indirect calorimetry. You will be asked to wear a hood for about 30 minutes three times about every two hours.

Visit 4. Sensor to measure the glucose. We will also ask you to wear a device to measure your blood sugar for 10 days every six months. The device is called a continuous glucose monitor (CGM) and it is made by a company called Dexcom. A CGM measures the glucose level in the fluid beneath the skin. It consists of a sensor which is inserted into the skin and a transmitter attached to the sensor. The sensor has a plastic body and contains a thin, small needle and sensor wire the size of a human hair. The sensor will be placed under the skin on your belly or arm. Once inserted, the needle is removed and the sensor wire remains. The transmitter snaps on top of the sensor and tape can be used to keep the sensor in place. The sensor wire measures the sugar level in the fluid beneath the skin every 5 minutes. You will not be able to see the measurements. Before you agree to be in the study, we will show what the CGM looks like. While you are wearing the CGM, you will need to write down on a log any exercise you do (duration and intensity), the start time of all meals and snacks you eat and drink, and what time you go to bed and wake up each day. After you have worn the CGM for approximately 10 days, you will be asked to mail it back to us. This device will allow us to learn if changes in glucose metabolism may be associated with the development of fatty liver disease. Note that CGM will never be worn during the MRI.

The order of the visits might be different and you may be asked to do first Visit 2 and then Visit1 for example.

Longitudinal Studies

Another part of study is designed to understand how fatty liver develops and progresses in kids. To learn more about the disease we ask to follow you up for about two years.

In particular, we would ask you to repeat the OGTT every year and the belly scan every six months for two years.

Sensor to measure the glucose. We will also ask you to wear a device to measure your blood sugar for 10 days every six months. The device is called a continuous glucose monitor (CGM) and it is made by a company called Dexcom. A CGM measures the glucose level in the fluid beneath the skin. It consists of a sensor which is inserted into the skin and a transmitter attached to the sensor. The sensor has a plastic body and contains a thin, small needle and sensor wire the size of a human hair. The sensor will be placed under the skin on your belly or arm. Once inserted, the needle is removed and the sensor wire remains. The transmitter snaps on top of the sensor and tape can be used to keep the sensor in place. The sensor wire measures the sugar level in the fluid beneath the skin every 5 minutes. You will not be able to see the measurements. Before you agree to be in the study, we will show what the CGM looks like. While you are wearing the CGM, you will need to write down on a log any exercise you do (duration and intensity), the start time of all meals and snacks you eat and drink, and what timeyou go to bed and wake up each day. After you have worn the CGM for approximately 10 days,

you will be asked to mail it back to us. This device will allow us to learn if changes in glucose

metabolism may be associated with the development of fatty liver disease. Note that CGM will never be worn during the MRI

Pregnancy test
We will ask you to have a pregnancy test before you start this study. Only you will be told the results. If you are pregnant, we will also advise you to get care for your. You will be asked not to be in the study or you will be removed from the study if your pregnancy test is positive.

You need to know that your parents may ask you why you cannot be in the study or why you were asked to leave the study. So if there is any chance that you are pregnant or you might become pregnant during the time of this study, we would recommend that you think really carefully about whether you should be in the study. It is okay if you decide that you do not want to be in the study or to stay in this study. You do not need to give a reason for not being in the study.

What are the risks and discomforts of participating?

The study involves the placement of an I.V. catheter in a vein in your hand or arm, which can cause a bruise or discomfort. Rarely, infection, a blood clot, inflammation, or bleeding can occur at the site. If pain is a concern, we can use a special numbing medicine that will minimize the pain. If inflammation of the vein (also called phlebitis) does occur, application of a warm soak to the site and elevation of the arm will help. Very rarely, someone may faint, or more likely become lightheaded or nauseated, when the I.V. is put in. You may be given Tylenol if needed. All I.V.s will be placed and removed while you are sitting or lying in bed in case dizziness does occur. The Hospital Research Unit nurses who put in the I.V.s have special training and experience in drawing blood. This should help keep the risks at the very lowest level possible. Your blood pressure and heart rate will be checked at the beginning of the infusion studies to ensure that you are stable. The nurse will then assess you throughout the study. The risk of using deuterated water during the study appears to be negligible. In fact, this compound will be given orally, therefore there will not be any risk related to sterility and infections. This water that you drink has no known risks, and it has been given to younger children for clinical purposes with no negative effect.

Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines. You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them. There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet. We want you to read and answer very carefully the

questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you and your parents of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your parents and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be made available for health care purposes.

The CGM sensor may produce pain when it is inserted into the skin. Rarely, a skin infection can occur at the site of insertion of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may occur. The risk of skin problems could be greater if you use a sensor for longer than it should be used. Study staff will check your skin during the study visits, and will give information for skin treatments if needed.

The hyperinsulinemic-euglycemic clamp is used to assess insulin sensitivity. While high-dose insulin is infused into the body, normal blood sugar level is maintained endogenously as well as continuously by infusion through IV. We have extensive experience using this technique. Tough the chance of hypoglycemia occurrence is minimal, if hypoglycemia is observed, IV insulin infusion will be stopped, glucose infusion rates will be increased to achieve normal glucose level within few minutes.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

You will learn whether you have fatty liver, dyslipidemia, prediabetes or diabetes.
We will provide the results of the tests that we did to your doctor. These results may provide information to your doctor about your health and may be useful for your doctor in making decisions about follow-up, recommendations for prevention, and treatment options. You can discuss the results with your doctor.

How can the study possibly benefit other people?

We hope also that the study might gain our knowledge in the field of fatty liver and help developing new therapeutic and preventive strategies to cure fatty liver in youth.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?

You will receive a reimbursement of $150 for the Euglycemic clamp, $150 for the assessment of DNL and TCA, $60 for the MRI, $60 for the MRE, $50 for the glucose tolerance test, $20 for completion of a 3-day food log, $150 for completing the 10 days assessment with CGM. We will pay for parking for coming to the study visits.

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We will use a pre-paid debit card to provide payment for taking part in the study. We will have to share your name, address, and telephone number with the banking institution issuing the debit card for ePayments. You may receive a card in the mail with the first payment following completion of the first visit. You will need to activate the card over the phone. Payments for additional visits will be automatically added to your card after completion of each following visit. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments."

According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. You are responsible for paying state, federal, or other taxes for the payments you received from being in the study. Taxes are not withheld from your payments.

Should you withdraw from the study for any reason after it has begun, you will be paid for that portion of the study in which you have participated.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.
To safeguard confidentiality we will store the data in locked cabinets as well as in password protected and encrypted computers. The DNA will be stored deitentified and each individual will be coded with a number. Only the PI will have the link between the DNA number and the patient ID.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

Any identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility. We will not share biospecimens for commercial profit.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visit
- Information obtained during this research regarding dietary habits, medications, alcohol consumption and smoking.
- Physical exams
- Dairies and questionnaires

How will you use, store and share my information?
We will use your information to conduct the study described in this consent form.

Your information will be stored on password-protected computers, which are accessible only to members of our research team and those involved in managing our secure on-line database. In particular, the data will be stored in OnCore that is a Yale's Clinical Traisl Management System (CTMS). The data will be stored in encrypted computers according to Yale policy. Blood samples will be labeled with a code from your initials and medical records number and will be stored in laboratories that are locked when not in use. If research blood is sent to outside laboratories for analysis, we will de-identify with a unique code, and the code will be stored on password-protected computers accessible only to members of the research team.

In addition, if you have even been a patient at YNHH at any time, previous medical records of other visits or admission will become available to the researchers and to the staff of the HRU when information from these visits or admission is added into the medical records. If you do not have a medical records, we will create one for you.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Food and Drug Administration (FDA)
- The study sponsor or manufacturer of study drug/device
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information

in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information; agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Representatives from the Yale Human Investigation Committee and the National Institutes of Health (the study sponsor) may inspect study records during internal auditing procedures.
You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [The National Institute of Health] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.
The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research

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studies or distributed to another investigator for future research studies without additional informed consent.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Nicola Santoro at the Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and, Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. Your parents or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. For example if during the study you develop a condition that represents an exclusion criteria (such as taking medications that affect glucose metabolism) or if you develop serious side effects to the device used to monitor the glucose (CGM). This might also occur because of non-compliance with appointments.

What will happen with my data if I stop participating?

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you chooses not to participate or if you withdraws it will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **2037376356**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

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