HIC#: 2000023149

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Effect of Adiposity on Hepatic and Peripheral Insulin Resistance in Pediatric Diabetes
Principal Investigator: Michelle Van Name, MD
Funding Source: NIH, Yale Diabetes Research Center

If you are enrolling your child, the term "you" or "your" listed in the document below is referring to your child. If you are the person enrolling in the study, the term "you" or "your" is referring to you.

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to look at the impact of puberty and obesity on the action of insulin in the body. The study will look at insulin's effect on glucose in the liver and in the periphery (such as muscle). It will also see how the distribution of fat in the body is related to insulin action. You have been asked to participate because you have type 1 diabetes. The study will enroll 72 adolescents and 36 young adults with type 1 diabetes. The study will also enroll 8 children/adolescents with type 2 diabetes who are interested in starting treatment with liraglutide, to understand how metabolism changes with this medication.

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 consent form gives you detailed information about the study, which a member of the research team will discuss with you. 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 participate; if so, you will be asked to sign this form.

Description of Procedures

The study consists of the following tests:

- Glucose, insulin, and glycerol infusion study
- DEXA scan
- Belly scan (Abdominal MRI)
- Participants with type 2 diabetes will also have an oral glucose tolerance test and fasting blood draws as well as repeat the above testing after treatment with liraglutide.

These tests are described in more detail below.

If you agree to participate in this study, those with type 1 diabetes will be asked to participate in 2-3 study visits. Those with type 2 diabetes will be asked to participate in up to 10 study visits.

Visit 1:

APPROVED BY THE YALE UNIVERSITY IRB 6/28/2022

We ask that you follow your normal diet the three days prior to the infusion study, and should refrain from strenuous exercise the three days before these tests. This will help us to obtain more reliable information from the tests.

Participants with type 1 diabetes: The evening prior to the Infusion Study, you will be asked to come to the Hospital Research Unit (an area of the hospital where research studies are conducted) in the Yale Center for Clinical Investigation of Yale-New Haven Hospital. The study nurse will do a nursing assessment, including measuring your height, weight, temperature, blood pressure, and pulse. The nurse may also obtain a family and medical history. If you are female, a urine pregnancy test may be performed. For adolescents, the study doctor may also look for changes that take place at puberty if this information is not available from the medical chart. A television and movies will be available for you to watch during these studies.

Participants with type 1 diabetes: Prior to going to bed in the hospital, your insulin regimen will be stopped and you will be transitioned to an insulin infusion to keep your blood sugar stable overnight. To give this insulin and to prepare for the study in the morning, two small I.V.s (small plastic tubes) will be put into a vein in each arm. If you prefer, a numbing cream (Emla) can be used prior to the IV insertion. One I.V. will be used to take out small amounts of blood for measuring glucose and other substances that circulate in the blood. The other I.V. will be used to inject insulin, glucose, and glycerol solutions. The I.V will be used to obtain blood samples to make sure you are not anemic before proceeding with the study, and may also include testing of liver function, kidney function, cholesterol levels, levels of puberty hormones, and other metabolic testing. You will not eat overnight and will not eat in the morning. Once the 6-hour infusion study is completed you will be served lunch.

Participants with type 1 diabetes not staying overnight in the hospital: If not staying overnight in the hospital, these a blood test and the nursing assessments will instead be completed the day before the clamp study. You will be asked to fast for at least 10 hours overnight prior to arriving the next day for the fasting study. We will plan to be in contact with you as needed to help with diabetes management overnight. The next day you will come to our Church Street Research Unit early, and at that time the I.V.s will be placed and IV insulin and 6-hour infusion study will be started.

Participants with type 2 diabetes: The day prior to the Infusion Study, you will be asked to come for a study visit that should last no more than 20 minutes. The study nurse will do a nursing assessment, including measuring your height, weight. The nurse may also obtain a family and medical history. If you are female, a urine pregnancy test may be performed. For adolescents, the study doctor may also look for changes that take place at puberty if this information is not available from the medical chart.

All participants: Overnight we will also have your child drink a special type of water (deuterated water), a naturally occurring compound. This will allow us to track the origin of sugar made by the liver. The amount of deuterated water given depends on body weight and body water. For participants weighing <154lbs, the volume of deuterated water will be less than ½ cup, divided up into 3 doses. For participants weighing 154 lbs or more, the volume of deuterated water will be slightly more. For participants with type 1 diabetes this will be given in the hospital. For participants with type 2 diabetes, it will be given at the visit the day prior to the infusion study with instructions on when to drink it.

At approximately 7:30am in the morning, we will start the infusion of glucose and glycerol solutions labeled with a stable isotope (a nonradioactive, naturally occurring atom). This will not be enough glucose to affect your blood glucose in a harmful manner. It will allow us to follow the release of glucose from the liver and glycerol from fat tissue. The insulin infusion will continue and will be adjusted to keep your blood glucose stable.

After two hours, the dose of insulin will be kept stable, while the glucose will be adjusted to maintain a stable blood sugar at a level appropriate for you. Your blood glucose will be monitored closely during the study by taking blood samples from the second I.V. Readings of the blood glucose on each sample will be made at the bedside, and thus a fall in blood glucose can be fixed right away. After another 2 hours, the insulin infusion will be increased, and the glucose infusion will be adjusted to continue maintaining a stable blood sugar.

If you need to urinate during the infusion study, you will be allowed to use a bedpan if necessary. During the infusion study, measures of glucose and glycerol, as well as other samples, will be collected through the I.V line. The nurse will make sure your blood glucose is at the proper level before removing the I.V.s. The duration of this test is about 6 hours and should finish at approximately 1:30pm.

At three other times during the infusion study, we will ask you to wear a plastic hood (like an astronaut space helmet) for about 30 minutes, this is called Indirect Calorimetry. These measurements will allow us to calculate how much glucose and fat your body is burning when we give insulin.

We will use a DEXA scan to measure how much muscle and fat is in your body and how dense your bones are. The DEXA is an x-ray that is done while you lie still on a moving table and a scanning bar moves above. You will feel no sensations. We may ask you to step onto a Tanita scale, which is a special scale that delivers a very mild electrical current that you won't be able to feel. This will allow us to measure the amount of fat and muscle in your body.

Visit 2:

Visit 2 will be scheduled within 1 month of the first visit. At this visit, a *Belly Scan* will be used to take pictures of your belly. We will measure how much fat tissue is in your belly with a technique called magnetic resonance imaging (MRI). The is painless and are thought to be very safe. You will be asked to complete a safety questionnaire prior to the scan, and we will ask you to remove any loose metallic items, such as watches, jewelry and hairclips, insulin pumps, or continuous glucose monitors (CGM). No person should have an MRI test for any reason while either using a CGM device normally or if there is possibly a broken sensor under the skin.

These pictures will allow us to calculate how much fat tissue you have just below the skin and how much fat is deeper inside the belly. We will also be able to estimate the percentage of fat and iron are in the liver. This impacts how well insulin works.

Your will be asked to lie down on a movable platform that slides into a hollow cylinder-shaped scanner. A belt will be placed around your belly, near the bottom of the ribcage. 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. This will allow us to get better images of your liver. Other than slight vibrations, you will feel no unusual sensations. However, the magnet will make a loud buzzing noise when it is taking pictures. You will be given protective headphones or earplugs to wear so the noise won't 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 that you lie still at this time. If any of the pictures do not develop correctly, we may need to repeat them. For most of the scans, you will just need to lie still. However, toward the end, there will be a few pictures where you will be asked to hold your breath for about 15 to 30 seconds each time. You will be told exactly when to hold your breath and will be allowed to catch your breath between pictures. If any of the pictures are blurred or do not develop correctly, you may be asked to repeat this picture by holding your

breath once more. You will be able to be heard by the MRI operator during the scan, and the operator will be able to talk to you through a microphone when necessary. The entire scan should take no more than 45 minutes. If you want to get out of the magnet at any time, for any reason, you should tell us and we will take you out right away.

Participants with type 1 diabetes can now skip to the section on Risks and Inconveniences. The remainder of study visits refer to participants with type 2 diabetes.

Oral Glucose Tolerance Test: The oral glucose tolerance test (OGTT) will be done within the Yale Center for Clinician Investigation of Yale-New Haven Hospital. The duration of the test is about four hours. We also ask that you refrain from strenuous exercise the day before the OGTT. This will help us to obtain more reliable information from the test. At the beginning of the test, we may obtain a family and medical history, and we will measure your height, weight, waist circumference, hip circumference, pulse, and blood pressure.

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 movies are available to watch. Lunch will be provided at the end of the test.

After baseline testing is complete, liraglutide will be prescribed by your clinician as planned prior to enrollment. As is clinically indicated with liraglutide, the dose will start at 0.6mg daily, increase after 1 week to 1.2mg daily and after another week to 1.8mg daily. Titration may be delayed while waiting for expected side effects of this medication to improve. You will continue to contact your clinician for any issues related to this medication, however the study team will also be checking in with you frequently to see how you are doing.

Blood Draws: One liraglutide is started, we will ask that you come in for a fasting blood draw weekly for the first 4 weeks to help us understand the shorter term changes on your glucose and fat metabolism. These visits can be done early in the morning and last no more than 20 minutes so that you can head to school right afterwards. If you cannot do all 4 of these visits that is OK.

Repeat Studies: After you have been on liraglutide for 14 weeks, we will ask you to return for follow up of the original testing, this includes with MRI, oral glucose tolerance test, and infusion study (visit day before and day of). The procedures for these days will be the same as the first time you complete these visits.

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.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences

Risk of loss of privacy: In order to protect your privacy, the HIPAA-trained personnel will assign you a study code. Identifiers will be protected—consent forms and study files will be kept in a locked file cabinet. Your name and date of birth will be kept in a password-protected computer database, located in a locked file on a

secure server with access restricted to study investigators. The Yale regulatory committee will be able to review study records but scientific publications will refer to the subjects by study identifiers only. See "Confidentiality" statement on page 6 for additional information.

Risks associated with the Infusion Study: This study involves the placement of an I.V. 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, a person may faint, or more likely become lightheaded or nauseated, when the I.V. is put in. Although also very rare, it is possible that you may feel nauseated, get a headache, or feel shaky or lightheaded during or after the studies involving I.V.s. 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. In addition, the nurse will make sure your blood glucose is at the proper level before removing the I.V.s. The YCCI nurses who put in the I.V.s have special training and experience in drawing blood and in working with adults, children, and adolescents. This should help keep the risks at the very lowest level possible. Your blood glucose will be watched very closely throughout the infusion studies to ensure that it does not fall too low or rise too high. Your blood pressure and heart rate will be checked at the beginning of the infusion studies to ensure you are stable. The nurse will then assess you throughout the study.

During the infusion study, no more than about 13 tablespoons (~200cc or 2/3 cups) of blood will be taken. For those who weigh 86 lbs (39 kg) or more, this is within the accepted guidelines (5cc blood/kg body weight) and should not present any significant problem. If you weigh less than 86 lbs, we will adjust the infusion study to limit the amount of blood drawn to no more than 5cc of blood per kg of body weight. You should not donate blood or have a large volume of blood taken for any purpose outside of this study for two months following each I.V. study. We will not study you if you are anemic. Your red blood cell count (hematocrit) level will be checked prior to the infusion studies; if it is less than 35%, we will not do the study. When you come to the YCCI the night before the infusion study, we will check to see whether you are anemic by doing a finger stick.

The infusion study includes use of stable isotopes. Despite the theoretical risk of infection with infusion of stable isotopes, our team has been using isotopes during clamp studies for 15 years in children, adolescents, and adults and have not experienced any adverse events. Isotopes will be carefully monitored and administered and will be prepared in the investigational pharmacy to ensure proper technique.

The risk of using deuterated water during the diet 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 special water that your child will drink has no known risks, and it has been given to younger children for clinical purposes with no negative effect.

Although rare, during the Indirect Calorimetry portion of the study, you may feel nauseated and/or claustrophobic (anxious over being in an enclosed place) while wearing the plastic hood. In addition, the air under the hood may become warm and stuffy, which some people find uncomfortable. You can request to remove the hood if you are uncomfortable, and it will be removed.

Risk associated with the DEXA Scan: The DEXA scan (full-body x-ray) is a technique that is commonly used to check for osteoporosis. In this study, we will use it to measure the amount of fat and muscle you have in your body. This scan requires the use of x-rays, which means there is a small amount of radiation exposure, but the radiation is estimated to be less than 1/10 the radiation individuals receive during a chest X-ray. It is below the FDA limits for radiation exposure in research subjects. We have routinely used DEXA to monitor body composition in children and adults.

Risk associated with the MRI: 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 we require that all people involved with the study 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. Insulin pumps must be removed prior to going in the magnet room.

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 healthcare 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 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 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 healthcare MR exam and for that reason, they will not be made available for healthcare purposes.

Reproductive*:* You cannot participate in this study if you are currently pregnant or become pregnant at any time during the study.

The metabolic testing done in this research project may involve unexpected risks to your unborn child. If you are female, a pregnancy test will be performed before study procedures.

If you should become pregnant while participating in this study, or if you suspect that you have become pregnant, tell your study team.

For parents of minors - If your daughter is under the age of 13, your daughter will be told the results of the pregnancy test and a positive result will also be reported to the Department of Children and Families services (DCF). If your daughter is age 13 or older, only she will be told the results. A positive pregnancy test means that your daughter cannot participate in this study. Because she will be asked to leave the study, you may find

out that she is pregnant. If you or your daughter is uncomfortable with pregnancy testing, then we would recommend that you do not participate in the study.

Participants with Type 2 Diabetes: Risks Associated with Oral Glucose Tolerance Tests and Blood Draws: The blood draws and IV placement could result in discomfort or bruising, or rarely and infection or blood clot. There are potential complications associated with blood draws or indwelling IV catheters, such as are used during the Oral Glucose Tolerance Test. These include hematomas, discomfort, and rarely infection, blood. The risk of anemia exists in studies with frequent blood draws. The blood draws and IV placement will be performed by highly experienced nurses who will monitor the IV site for issues. For the Oral Glucose Tolerance Test a total of about 6 tablespoons of blood will be drawn. The 4 additional blood draws will take about a total of 26cc. To ensure these blood volumes drawn amongst the group of studies are safe, participants with T2D will need to be 56kg or more.

Participants with Type 2 Diabetes: Risks associated with use of liraglutide, which is FDA approved for treatment of diabetes in patients 10 years and older. In clinical practice liraglutide is standardly used either alone or in combination with metformin. It is contraindicated in patients with a personal or family history of medullary thyroid carcinoma on in patients with Multiple Endocrine Neoplasia Type 2. Patients taking liraglutide may be at increased risk of pancreatitis and gallstones. Since liraglutide helps to lower blood sugar, patients taking this, especially along with insulin or other diabetes medicines, are at more risk for low blood sugar. This risk may be greater when used in combination with metformin. Like any medication, liraglutide can cause an allergic reaction or a reaction at the injection site. The most common adverse reactions reported in ≥5% of patients treated with liraglutide are as follows: nausea, diarrhea, vomiting, decreased appetite, dyspepsia, constipation.

Prior to initiation of this medication, a clinical blood test will be performed to check your kidney function and a medical and family history will be obtained. Due to the way liraglutide works in the body, including slowing digestion, it is common to experience nausea, vomiting, indigestion, decreased appetite, constipation, and diarrhea. For this reason, the lowest dose is started, and once these side-effects resolve the dose can be increased. If you experience persistent abdominal pain, you should stop the medication and contact your diabetes provider or study team. The medication should also be stopped if you experience vomiting, diarrhea, or dehydration. Contact us if you experience side effects or reactions to the medicine. As this medicine should help lower blood sugar, your doses of other medicines may be reduced, if needed, as the dose of liraglutide is increased. These are the instructions we provide when starting this medicine in our regular clinic.

Benefits

Participants with Type 1 Diabetes: This study focuses on characterization of effects of obesity during puberty on metabolism in type 1 diabetes and is unlikely to have direct short-term benefits to you. We can provide you information regarding your cholesterol level and results of other testing, distribution of abdominal fat, and percent body fat. Long-term benefits of this research are a generalizable understanding of the changes of insulin resistance related to obesity and puberty in youth with T1D, which will help to inform future treatment strategies.

Participants with Type 2 Diabetes: This study focuses on characterization of effects of liraglutide on metabolism in youth with type 2 diabetes. In the short term we expect participants to attain benefit in diabetes management from taking the prescribed liraglutide. We can provide you information regarding your cholesterol level and results of other testing, such as percent body fat and how this changed with liraglutide. Long-term benefits of this research are a generalizable understanding of the changes in metabolism due to liraglutide treatment.

Economic Considerations

You will be compensated for time and effort participating in the study. There will be no compensation for travel. For your participation in this study you will receive payment(s) via a Bank of America pre-paid debit card. Please note that your name, address, and telephone number will be shared with Bank of America for ePayments. After the first payment milestone you will receive a card in the mail which will need to be activated over the phone, any subsequent milestones payments will automatically add additional funds to the card.

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.

Participants with **type 1 diabetes** will receive:

- $200 for an overnight hospital stay and an insulin clamp and DEXA scan
-If not doing the overnight hospital stay, $25 for the Pre-Clamp visit and $125 for the Clamp visit/DEXA scan
- $75 for MRI

Participants with **type 2 diabetes** will receive

-$25 for each Pre-Clamp visit (1a, 8a)
-$125 for each Clamp visit/DEXA scan (1b, 8b)
-$75 for each MRI
-$50 each OGTT
-$20 each blood draw visit

Treatment Alternatives/Alternatives

If you do not wish to participate in this study, you will continue to be treated by your clinician and your care will not be jeopardized in any way. The alternative to participation in the proposed studies is not participating. There are no risks of non-participation in this study.

Confidentiality and Privacy

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 National Institute of Diabetes and Digestive and Kidney Diseases, 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 of 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 consented to in this informed consent document, such as including research data in the medical record.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address, date of birth, and information from medical records. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 5 years, after which time the link will be destroyed and the data will become deidentified. The data will be kept in this deidentified form indefinitely. We may also share information about you with other researchers for future studies, but we will not use your name or any other identifiers.

The information about your health that will be collected in this study includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this study
- The entire research record and any medical records held by Yale University and Yale New Haven Hospital
- The following information:
  - Records about phone calls made as part of this research
  - Records about your study visits
  - Physical exams
  - Laboratory, DEXA, and MRI
  - The diagnosis and treatment of a mental health condition

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) The information may be used to meet the reporting requirements of drug regulatory agencies.
- Those providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator, Michelle Van Name
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study
- Co-Investigators and other investigators

- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

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.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

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 participation in this study, treatment will be provided. You 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.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. 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. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary. If this happens, you will be told and the study doctor will make arrangements for your care to continue.

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

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Michelle Van Name at the Yale Pediatric Diabetes. 1 Long Wharf Drive, Suite 503, New Haven, CT 06511.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject _____

Subject or Parent#1 (for subjects age <18) signature:_____

Date:_____

Parent#2 Signature (if minor):_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Michelle Van Name, 203-785-5831. *If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.*