COMPOUND AUTHORIZATION AND CONSENT AND PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: Very Low Carbohydrate Diets in Youth with Type 1 Diabetes
Principal Investigator (the person who is responsible for this research): *Laura Nally, MD*
24-Hour Phone Number: 203-785-5831

In the following document, "you" can also refers to "your child".

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to see how very low carbohydrate diet can help you manage your blood sugars and see how hormone levels and metabolism changes as a result of the diet.
- Currently, the American Diabetes Association does not recommend any specific diet for individuals with type 1 diabetes.
- Study procedures will include: wearing a continuous glucose monitor (CGM), following a very low carbohydrate diet, measuring daily blood ketone levels, keeping a food journal, talking to research staff 2-3 times per week, sharing your CGM data and insulin pump data or written records of insulin dosing.
- Three visits are required. The first visit is an enrollment visit where we gather information about you and teach you about the study. During the second and third visits, we will perform an infusion study, calorimetry, and an arginine stimulation test.
- These visits will take 1 to 5 hours total.
- There are some risks from participating in this study. Risks of the diet include developing low to moderate levels of ketones. Any study involving changing insulin doses has the risk of developing high and low blood sugar levels, however these will be monitored closely with CGM. The study requires than at I.V. catheter is placed, which may cause pain and bruising. An infusion study will be performed in the hospital that uses stable isotopes. There is a very low, theoretical risk of infection with stable isotope infusions. Calorimetry will be performed which involves wearing a plastic hood that can sometimes make people feel claustrophobic or nauseas. An arginine stimulation test will be performed which rarely can cause some pain at the I.V. site. Any time you participate in a research study, there is a risk of loss of privacy.
- You may benefit from the study, and develop more stable and predictable blood sugar control with fewer high blood sugars and fewer low blood sugars. If you do not already use a CGM, you may benefit from wearing a CGM during this study.
- 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?

We are asking you to take part in a research study because **you have type 1 diabetes**. We are looking for **10** participants to be part of this research study.

Who is paying for the study?
This study is funded by a National Institutes of Health – National Institutes for Diabetes and Digestive and Kidney Diseases (NIH/NIDDK) Grant.

Who is providing other support for the study?
Continuous glucose monitors may be supplied by Dexcom, Inc.

What is the study about?
The purpose of this study is to evaluate how blood sugar levels, hormone levels, and metabolism changes for youth with type 1 diabetes who undergo a very low carbohydrate diet.

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 happen: If you decide to participate in the study, we will review this consent document with you and you will be asked to sign the document.

Visit 1 (Enrollment Visit)	We will ask you about your medical history and perform a physical exam. We will do a blood test to measure your Hemoglobin A1c level. We will provide instructions on the diet that you will follow and ask about your usual diet. We will give you a blood ketone meter and CGM (if you do not already have one) and show you how to use it.
Visits 2 & 3 (Hospital Visits)	You will be admitted to the hospital and 2 IV's will remain in place for the study. Blood tests will be done and you will receive a medication (arginine, an amino acid). We will monitor your blood sugars closely during the study. The study will last about 5 hours and you will have lunch after 12:30pm and be sent home.

Visit 1: Enrollment

- We will ask you questions about your diabetes management, past medical history, social history, and gather demographic information about you. If you have an insulin pump or CGM, we will collect information as well.
- We measure your height, weight, waist circumference, and will perform a physical exam. 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.
- We will measure a Hemoglobin A1c level if one has not been checked in the past 1 month.
- We will give you instructions on eating a standard carbohydrate diet of at least 130 grams of carbohydrates per day (or at least 26% of your total daily caloric intake). We will also explain the dietary requirements of the very low carbohydrate diet portion of the study.
- The very low carbohydrate diet portion of the study will require that your diet should not exceed ~50 grams of carbohydrates per day. However, the dietary requirements may change to some degree based on your blood sugar and ketone levels.
- We will provide you with a blood ketone meter and show you how to use it.
- If you do not already have a CGM, we will provide you with one and show you how to use it.

- We will schedule telephone follow up calls. After you go home, our research staff will call you 2-3 times per week to review your diet, your blood sugars, insulin doses, and blood ketone levels.
- A handout with 2 examples of the type of diet required will be provided to you prior to consent.

Visits 2 & 3: Infusion Study & Arginine Stimulation Test

- Prior to the infusion, we recommend that you avoid strenuous exercise 3 days before these tests. This will help us collect more reliable information from the tests. The night before the test you should not eat any food or drink liquids other than water after 10pm. You will not eat breakfast the morning of the Infusion Study.
- The morning of 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 at 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 at visit 2. A television and VCR will be available for you to watch during these studies.
- We will have you complete 3 questionnaires at this visit. These questionnaires will ask questions about how diabetes makes you feel, what causes you stress about your diabetes, and your satisfaction with your diabetes management. One of the questionnaires will ask questions about nutrition.
- You may be transitioned to an insulin infusion to keep your blood sugar stable during the study. To give this insulin and to prepare for the study, 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 measure electrolytes, liver function, kidney function, hormones and other metabolic testing (glucagon, c-peptide, fatty acids, ketone levels.
- 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 sugar levels in a harmful way. It will allow us to measure 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 sugars stable.
- During the infusion study, measures of glucose and glycerol, will be collected through the I.V line every 15 – 30 minutes.
- After ~2 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 if needed. 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, so that if your glucose level drops, it can be treated right away.
- About 30 minutes after, we will give you a small dose of I.V. arginine (an amino acid found in foods like nuts, seeds, and meat) for the arginine stimulation test. Arginine directly stimulates beta cells in the pancreas. During this time, blood samples will continue to be collected every 5-30 minutes to measure hormones (glucose, glucagon, ketone levels, c-peptide) released from the pancreas for ~60 minutes.
- Up to 3 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.
- If you need to urinate during the infusion study, you will be allowed to use a bedpan if necessary.
- The nurse will make sure your blood glucose is at the proper level before removing the I.V.s. Once the infusion study is completed you will be served lunch. The duration of this test is about 5 hours, and should finish at approximately 12:30 pm.

What are the risks and discomforts of participating?

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 you by study identifiers only.

Risks of Very Low Carbohydrate Diet:
- A low carbohydrate diet can cause symptoms, including headaches, nausea, vomiting, abdominal pain, constipation, fatigue, and lightheadedness. You will be asked about these symptoms at follow up. It is important to stay well-hydrated and transition to the very low carbohydrate slowly to avoid these symptoms.

Risks of 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 placed. 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 the I.V. 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 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.
- 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 total amount of blood that will be collected at each study visit is ~14 tablespoons (~120 mL or ~1/2 cup). The total amount of blood that will be drawn at both study visits over the course of 1 month is ~28 tablespoons (240 mL or 1 cup). For those who weigh at least 100

pounds (48 kg) or more, this is within the accepted guidelines (5 mL blood/kg body weight) and should not present any significant problem. If you weigh less than 100 lbs, we will adjust the infusion study to limit the amount of blood drawn to no more than 5 mL of blood per kilogram 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.

- Blood samples collected as part of this research will be stored by the YCCI core lab services. Samples sent to the laboratory will be given a unique code number. The number is used in place of your name and other personal information to safeguard your confidentiality.
- 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.

Risks of Arginine Stimulation Test

- For the arginine stimulation test, you may notice a metallic taste in your mouth about 10-15 seconds after the Arginine is given. If this occurs, this metallic taste will last for less than 5 minutes. You may also feel burning and/or redness at the I.V. site where the Arginine is given. Rarely, an infection or swelling may occur. As with any mediation, there may be unexpected side effects. Arginine, however, is an amino acid, which is a substance found naturally in the body. Therefore, it is very unlikely that you would have an allergic reaction. If your blood glucose is high at the end of the test, we will help you with your insulin dosing to get it back to a desirable level.

Risks of study questionnaires

- You may experience some distress when discussing factors important to diabetes, diabetes management, and psychosocial stressors (food insecurity, housing insecurity, need for social support).

Pregnancy testing:

- Female subjects of childbearing potential will require urine pregnancy testing prior to proceeding with the protocol. An additional urine pregnancy test will be performed prior to starting the VLCD (visit 2). If she is 13 or older, only your daughter will be told the results. We will, of course, counsel your daughter to seek appropriate healthcare and the support of an adult if she were found to be pregnant. 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.
- Methods of contraception (birth control pills, condoms, etc.) must be used for the entire duration of the study.

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. You will be aware of your blood glucose levels throughout the study. We can provide information on your individual results of calorimetry and arginine stimulation testing. You will not receive information about the infusion study.

How can the study possibly benefit me?

You may not experience any direct benefit from this study. However, you may experience improved glycemic control by participating in the study. We can provide you with information

about your lab results (electrolytes, kidney function, liver function). You may benefit from wearing a CGM if you are not wearing one currently. You may also learn more about nutrition by participating in this study.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of how a very low carbohydrate diet affects metabolism and glucose levels in youth with T1D, which will help to inform future treatment strategies.

Are there any costs to participation?

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

Will I be paid for participation?

You will be paid for taking part in this study. To help offset the cost of your participation in the study, you will receive $50 for each of the HRU/CSRU visits. For each day that you take photos of your food and speak with study staff regarding dietary recall, you will receive $5. The maximum total compensation you could potentially earn is $160. This will be sent to you in the mail in the form of a Bank of America card. You will only receive compensation for parts of the study that you complete. 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.

What are my choices if I decide not to take part in this study?

The alternative to participation in the proposed studies is not participating.

Instead of participating in this study, you have some other choices. You could:

- Get treatment without being in a study. You can follow a very low carbohydrate diet without participating in the study, however we do not know the long-term risks and benefits of following this diet.
- Take part in another study.

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. Information about you will be kept in a locked research office, and any electronic forms will be maintained on a computer that requires a password for authorized users. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific permission for this activity is obtained.

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, 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 him or her. 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 anonymous. The data will be kept in this anonymous form indefinitely.

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.

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.

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.
- The entire research record and any medical records held by Yale University and Yale New Haven Hospital. The medical records will be used to collect past medical history, social history, medications, laboratory testing, and othe information that relates to your health and the research.
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Physical exams
    - Records about phone calls made as a part of this study
    - Records about your study visits
    - Laboratory, x-ray, and other test results
    - Infusion studies, arginine stimulation testing, indirect calorimetry
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Records about any study medications you received
- We will not collect information about whole genome sequencing (e.g., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
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.
- 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, Laura Nally, MD.
- Study sponsor or those providing devices for the study.
- 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
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the use of Arginine, H2 glucose and H5 glycerol involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.

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.

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

Laura Nally
Pediatric Diabetes Research Center
One Long Wharf Drive, Suite 503
New Haven, CT 06510

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. You will not have the option to destroy samples or data that has already been collected if you withdraw your participation from the study. This is because the samples and data will be anonymized and that sample destruction is not possible.

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. 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.

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. The researchers may withdraw you from participating in the research if necessary. This may occur if you are not following study procedures or if you develop side effects from participating in the study. 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. If you choose not to participate or you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

What will happen with my data if I stop participating?

When you withdraw from the study, 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.

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 Laura Nally, MD, 203-785-5831.

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.

Optional Specimens for Future Storage

- You are invited to allow some of your blood samples (called specimens) and related information collected in this study to be stored (banked) for future research. About 25 mL (less than 2 tablespoons) of blood from each study visit will be kept for storage in case we need to perform additional testing. At this time, it is not known which tests might be done in the future but they will be related to diabetes and metabolism. Your blood will never be tested for drugs/alcohol, HIV or other sexually transmitted diseases, or for genetic information. The samples will be stored long-term in the facilities of the Core laboratories of the Yale Center for Clinical Investigation (YCCI).
- You can decide if you are willing to save part of the samples collected in this study for future banking by initialing below. If you choose to decline, you can still participate in the main study.

I agree to allow my samples and information to be stored and used for future research as described above: (initial your choice)

_____YES _____No

APPROVED BY THE YALE UNIVERSITY IRB 11/18/2021

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

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.