# Informed Consent Form

Use of Oral Antidiabetic Agents in Hospitalized Patients with Diabetes

IRB Approval Date: August 20, 2025

NCT04416269

# You Are Being Asked to Be in a Research Study

**Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of up to 286 people who are being studied, at Emory University Hospital, Emory Hospital Midtown and Grady Memorial Hospital

**Why is this study being done?**
This study is being done to answer the question: Can patients taking oral antidiabetic agents at home with mild to moderately elevated blood sugars be continued on their home regimen during hospitalization? You are being asked to be in this research study because you have a history of type 2 diabetes and were on a diabetic medication before being admitted to the hospital.

**Do you have to be in the study?**
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

**What do I have to do if I choose to participate in this study?**
If you are eligible and want to be part of the study, you will participate during this hospital stay for up to 10 days. The researchers will ask you to do the following: Either to take insulin injections with up to 4 injections per day or continue on your home diabetic medication. All medications will be given to you by your treating nurse. Since treatment of diabetes is standard hospital practice, none of these medications will be paid for by the study.

**How is this study going to help you?**
If you are in the study, you will be helping the researchers answer the study question.

**What are the risks or discomforts I should know about before making a decision?**
The study will take time. The drug that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include side effects related to taking either your regular diabetic medication or using insulin. The medications may lead to low blood sugars or may not work well enough to prevent high blood sugars. Additional risks include, loss of privacy, and breach of confidentiality. A full list of

expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

**Alternatives to Joining This Study**
If you decide to not participate in the study, you will receive insulin treatment for management of high blood sugars while you are in the hospital. You may discuss your treatment regimen further with your hospital treating physicians.

**Costs**
You WILL have to pay for some of the study procedures, in particular those that are not covered by your medical insurance. All of the medications included in this study have been used in the hospital and are covered by most insurance companies. If you are selected to receive a glucose monitoring device, you will not have to pay for any costs related to use of the device.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

**What Should I Do Next?**
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

**Emory University and Grady Health System**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Use of Oral Antidiabetic Agents in Hospitalized Patients with Diabetes

**Principal Investigator:** Maya Fayfman, MD

**Sponsor:** National Institute of Health, National Institute of Diabetes, Digestive and Kidney Diseases

**Introduction**
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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.

**What is the purpose of this study?**
The purpose of this study is to compare the effects of continuing home diabetic medications to use of standard of care insulin regimens in hospital patients with mild to moderately elevated blood sugars. The study will evaluate the effectiveness (controlling blood sugars) and safety of oral diabetic medications as compared to insulin which is used most often to control blood sugars in the hospital.

**What will I be asked to do?** Depending on the treatment group you are assigned to, you will be asked to either continue your home diabetic medication or receive insulin. All treatments will be provided to you by your hospital nurse. These medications will be continued for up to ten days of your hospital stay. The treatment you will receive will be decided randomly (by chance or like flipping a coin). You will be continued on your other diabetes medications during the study period. At the end of the study, you will be asked to fill out a short (5 minute) survey about your experience with the treatment you received.
If you are assigned to receive insulin (standard of care), you will receive one injection under the skin of long acting insulin (Levemir or Lantus) daily and 3 injections of short acting insulin (Humalog or Novolog) before each meal. You may also receive a dose of short acting insulin at bedtime if your blood sugar level is high. If you are not eating, you may receive short acting insulin every 6 hours if your blood sugar is high.

If you are assigned to continue your home diabetes medication, you will continue to take the same category of medication that you were taking at home for your diabetes. If the exact medication you take at home is not available, you will receive a similar medication based on the hospital's formulary. The dose of the medication may be adjusted if your kidney function changes during your hospitalization. The medication may be stopped if there is a change in your medical condition making it unsafe to continue the medication. If your blood sugar is elevated, you may receive an injection of short acting insulin (Humalog or Novolog) to bring the sugar down.

Optional Study: If you decide to participate in the main study, you may be randomly selected (flip of a coin) to take part in the optional study. For this study, you will be asked to wear a Dexcom G6 Pro continuous glucose monitor during the study period. This is a commercially available device that has cleared by the U.S. Food and Drug Administration (FDA) for diabetes management. It is placed under the skin and measures your blood sugar every 15 minutes. If you need any imaging such as MRI or CT scan, the study team will remove the device and reapply it after the study. You will not be able to see the readings yourself. At the end of the study, the device will be removed and kept by the study team to review your blood sugar recordings during your hospital stay.

We will call you approximately 4 weeks after your discharge to find out about any complications after your discharge from the hospital.

**Who owns my study information and samples?**
If you join this study, you will be donating your study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

**What are the possible risks and discomforts?**
There may be side effects from the study drug or procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

**1. Risks from Blood Draw**
The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of dizziness and fainting.

**2. Risk of insulin glargine, levemir, aspart, lispro and risk of glipizide**
The less common risks and discomforts expected in this study are:

**Low blood sugar (hypoglycemia)**
Low blood sugar (less than 70 mg/dl) can occur in about 20% (20 patients out of one hundred) of insulin treated patients in the hospital. Low blood sugars may also occur with use of glipizide. The rates of low blood sugars in the hospital are not well known but appear to be like insulin. Symptoms of low blood glucose include sweating, nervousness, confusion, agitation, sleepiness and even coma (loss of awareness). If it occurs, low sugar will be managed by a standard protocol, including decreasing the amount of insulin and by using dextrose (sugar) solution.

Low blood sugar can be treated by taking some form of sugar, such as juice, honey, or hard candies/jellybeans. If hypoglycemia (low blood sugar) becomes severe, accidents, injuries, coma, or death may occur. To raise blood glucose (sugar) levels in persons having a severe hypoglycemic episode, glucose (sugar) may need to be given IV. In rare cases, glucagon (a protein that stimulates the liver to increase blood glucose [sugar] levels) may be given.

To know if you have low blood sugar, the site staff will check your blood sugar frequently during the time you are staying at the study site. At home, you will check your own blood sugar. We will review your blood sugar levels at each clinic

visit. We will also ask you to write down any blood sugar that is less than 70 mg/dL, any symptoms you had and what did you do to treat the low blood sugar.

**Shot (Injection) Site and Allergic Reactions:** Shot site reactions with insulin includes redness, pain, itching, hives and swelling, skin thickening or pits at the injection site (regularly changing of the place where insulin is given may help to reduce or prevent these reactions), swelling of your hands and feet, and weight gain. Most minor reactions resolve in a few days to a few weeks. Generalized allergy is rare and may cause skin rash, shortness of breath, fast heartbeat, sweating and a drop in blood pressure.

Rare but possible risks include (1% or less):

**Heart Failure:** Taking certain diabetes pills called thiazolidinediones or "TZDs" may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure, it may get worse while you take TZDs. Tell your healthcare provider if you have any new or worse symptoms of heart failure including shortness of breath, tiredness, swelling of your ankles or feet and sudden weight gain. Treatment with TZDs may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

**Lactic Acidosis:** Lactic acidosis is dangerously high levels of lactic acid in the blood that can occur from build-up of metformin in the body. This is most common in people with liver and kidney problems. During your hospital stay, your treating provider will be monitoring for both of these. The dose of metformin may need to be adjusted or stopped if you develop worsening liver or kidney problems. Because certain dyes given before CT scans can cause worsening of kidney function, if you already have lower than normal function, the medication will be held for up to 24 hrs after CT scan to ensure that your kidney function is not affected by the dye.

**Pancreatitis:** Pancreatitis or inflammation (irritation) of the pancreas is a rare complication of Sitagliptin. Symptoms of pancreatitis include vomiting and persistent, bad abdominal pain. If you experience any of these symptoms, please notify your treating doctors immediately.

**Risks of continuous glucose monitoring:** When the sensor is inserted you should expect to feel a feeling like a needle-stick. After insertion, you may feel some tenderness, but you should not feel any large amount pain. Pain, redness, swelling, minor infection, and minor bleeding at the sensor insertion site are possible risks with use of the device. In very rare cases an infection might spread to other parts of the body. Significant or serious health risks with the study device are not expected.

Redness may occur where the adhesive pads are placed. This will occur in most research participants and will clear up no more than a week after removal. You may develop an allergic reaction to one or more parts of the sensor and transmitter. This is like allergies that occur due to hospital tape or jewelry. Allergic reactions will usually be mild and require only a skin cream to make them better. Major allergic reactions are rare. If you have an allergic reaction you should notify the study researcher or study staff. On rare occasion, the sensor may cause skin to blister or peel. If this happens you should notify the study staff as soon as possible.

There is a chance that the sensor or needle may break. This is not expected to occur; but, if it does, you should talk with your Study Clinician about what to do. Usually, if there is no sign of infection or irritation and you cannot see the sensor above the skin, it is not recommended to remove it.

**If you are a woman**: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

**If you are a man:** the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for one week after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

**What if researchers learn something new during the study period?**

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Will I benefit directly from the study?**

This study is not designed to benefit you directly. Your diabetes may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about whether oral diabetic medications may be as safe and effective in controlling blood sugar in the hospital as insulin treatment. The study results may be used to help others in the future.

**Will I be compensated for my time and effort?**

You will get $_50 at the end of your hospital stay or after 10 days of participation in the study, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the time you have completed. You will get $_10___ for each day of participation in the study (up to $50 maximum), if you do not complete all study days. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

**What are my other options?**

If you decide not to enter this study, there is care available to you outside of this research study. The standard of care for treatment of diabetes is insulin treatment. If you decide not to participate in the study, your treating doctor will order insulin treatment as per the standard hospital protocol during your stay in the hospital. The study doctor will discuss these with you. You do not have to be in this study to be treated for diabetes.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

**How will you protect my private information that you collect in this study?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

**Certificate of Confidentiality**

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in

this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**Medical Record**

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be placed in a locked filing cabinet in a secure office in the Grady Campus. They will not be added directly to your Emory and Grady Health System medical record

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

**In Case of Injury**

The sponsor may choose not to pay for injury costs for any subject, no matter if the subject is insured, or uninsured.

If you believe you have become ill or injured from this research, you should contact Dr. Maya Fayfman at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Neither Emory, Grady Health System nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, Grady Health System and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Grady Health System, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Grady Health System employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

**Costs**

*The sponsor will pay for certain items or services associated with the study.*
The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Grady Health System will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Grady Health System will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Grady Health System and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Grady Health System will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

**Withdrawal from the Study**
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- You have very high blood sugar that does not get better with your study medication
- You have a side effect or reaction that is believed to be from your diabetes medication
- You are transferred to the intensive care unit

# Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

## Main Study

**PHI that Will be Used/Disclosed:**
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results
- Hospital records of emergency room visits and readmissions for 30 days after your hospital discharge
- Hospital Billing Records

**Purposes for Which Your PHI Will be Used/Disclosed:**
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

**Use and Disclosure of Your Information That is Required by Law**:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

**Authorization to Use PHI is Required to Participate**:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

**People Who will Use/Disclose Your PHI:**
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

**Optional Study: <u>Continuous Glucose Monitoring</u>**

If you participate in the main study, you may be selected for this optional study. You will have placement of a continuous glucose monitor (CGM) on your arm for the duration of the study. The data from this study will be stored in the same way as for the main study.

> **Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study**:
> You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

**Expiration of Your Authorization**

Your PHI will be used until this research study ends.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Maya Fayfman, MD

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

**Other Items You Should Know about Your Privacy**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to

follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

**Contact Information**

Contact Maya Fayfman at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory University Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

**Consent and Authorization**

**Consent and HIPAA Authorization for Optional Study/Studies:**
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

**Continuous Glucose Monitoring Optional Study _____Initials**

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***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

**Name of Subject**

_____ _____

**Signature of Subject (18 or older and able to consent)** **Date** **Time**

_____ _____

**Signature of Legally Authorized Representative** **Date** **Time**

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**Authority of Legally Authorized Representative or Relationship to Subject**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

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**Name of Person Conducting Informed Consent Discussion**

_____ _____

**Signature of Person Conducting Informed Consent Discussion** **Date** **Time**