

Informed Consent Form

A Phase I Study of Subcutaneously Administered Natural Progesterone for the
Treatment of Recurrent GBM

NCT05091866

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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. For this study, glioblastoma patients at 1st-3rd recurrence will be treated with daily natural progesterone given by subcutaneous injection (just under the skin) to assess for the achievable blood levels of drug, safety/tolerability and efficacy of this treatment. If you agree to be in the study, you will be one of up to 32 people who are being studied at Emory.

Why is this study being done?

This study is being done to understand the safety, tolerability and actions of subcutaneous progesterone for patients with recurrent glioblastoma. You are being asked to be in this research study because you have recurrent glioblastoma and are failing your current glioblastoma therapy.

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 for up to 7 months (up to 6 months of drug therapy and 1 month follow-up after completion of drug therapy) including up to 10 study visits and 4 MRI scans. The researchers will ask you to do the following: Administer study drug subcutaneously daily for up to 24 weeks. Complete adverse event assessment, study drug diary, and medication list every week for 4 weeks, then every 4 weeks. Undergo a visit during which a doctor would complete a history and physical every 2 weeks for the 1st 4 weeks, then every 4 weeks thereafter. Undergo blood draws every 4 weeks. There may be an increased number of blood draws and assessments if you are one of the first 3 patients enrolled on a dose level in the study. You will complete an MRI study at 4, 8, 16 and 24 weeks after starting therapy. Quality-of-life assessment will also be done every 8 weeks. Some of these procedures and study drug supplies 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. You may or may not benefit directly from use of subcutaneous natural progesterone for the treatment of your recurrent glioblastoma.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The use of the drug being tested (subcutaneously administered natural progesterone) may not work any better than regular care. It 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 the risks associated with subcutaneously administered natural progesterone, loss of privacy, and breach of confidentiality. Some of the risks of subcutaneously administered natural progesterone are developing an injection site reaction, breast pain or tenderness, vaginal discharge or discomfort, gastrointestinal upset, headache, and mood. 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 are eligible but choose not to enroll on this study, you may be eligible for another clinical trial exploring different potential therapies. If you choose not to pursue treatment on a clinical trial, you may be offered the option of other salvage therapies including systemic therapies (eg. chemotherapies, targeted therapies, immunotherapies, etc.), radiation therapy, surgery and/or other therapies that are not otherwise classifiable in one of the previously named categories depending on your current clinical situation.

Costs

You WILL NOT have to pay for some of the study procedures that are specific to the study and not part of standard-of-care. However, you WILL be responsible for paying for other study procedures that are considered as standard-of-care. These items may or may not be covered by your medical insurance.

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 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 Consent to be a Research Subject / HIPAA Authorization

Title: Pilot study of subcutaneously administered natural progesterone for the treatment of recurrent glioblastoma

Principal Investigator: Hui-Kuo Shu, MD, PhD

Sponsor-Investigator: Hui-Kuo Shu, MD, PhD

Study-Supporter: IBSA Institut Biochimique SA, Lugano, Switzerland

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 on 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?

Glioblastoma Multiforme is a very aggressive primary brain tumor (cancer that started in the brain) that is almost never cured by standard treatment consisting of surgery, radiation therapy (RT) and chemotherapy. The purpose of this study is to determine whether natural progesterone given by daily subcutaneous injection is safe, tolerable and effective for the treatment of patients with glioblastoma that has come back or is progressing after initial or subsequent treatment. This formulation has not been approved by the FDA for use in the US and its use in this study is experimental.

Natural progesterone is known to have many different effects on both cancerous and normal cells. Interestingly, this drug was found to protect brain cells following traumatic brain injury and other brain disorders in animal models. It was also found that progesterone stopped growth of glioblastoma cells in both cell cultures and animal models. Because of this, there is a possibility that it may help in treatment of glioblastoma multiforme in patients. Due to the limited effective treatment options

available for glioblastoma patients, identifying new drugs that can stop growth of glioblastoma would have a significant impact.

What will I be asked to do?

If you agree to be in this study, we will ask you to do the following things:

Before the research starts (screening):

After signing this consent form, you will be asked to have some screening tests or procedures to find out if you can be in the research study. These tests and procedures are part of regular cancer care and are routinely done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may not have to be repeated.

- A medical history (questions about your health, current medications, and any allergies) will be taken.
- A physical examination including height and weight will be performed.
- Your performance status or how your disease affects your daily activities will be assessed.
- Your life expectancy will be assessed.
- An assessment of your tumor will be made by MRI (magnetic resonance imaging) obtained within 14 days of initiating therapy.
- Labs will be drawn within 14 days prior to registration.
- A pregnancy test for women of childbearing potential will be obtained.
- You must be off all other anti-tumor therapy (except Avastin) for at least 4 weeks before starting progesterone therapy. Patients on Avastin can be maintained on the same dose of that drug with progesterone.

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study you will have the following tests and procedures:

Administration of natural progesterone (research activity):

Natural progesterone will be self-administered subcutaneously daily. A dose level from 25 mg to 100 mg of this drug will be used depending on where we are in the study and the overall tolerance of the drug in previous study patients. The first 3-6 patients enrolled in the trial at each dose level will be used to help identify the best tolerated dose. The drug will be administered subcutaneously daily for 24 weeks or until either glioblastoma is found to have progressed (worsened) on MRI or patient is unable to tolerate the drug. If a patient is still potentially benefitting from this drug treatment after 24 weeks, continuation on therapy (compassionate use) can be considered on a case-by-case basis.

Pharmacokinetic assessments (research activity):

The first three patients enrolled in the study at each dose level will undergo pharmacokinetic testing to identify levels of progesterone in the body. These samples will be obtained prior to administration of drug, 30 minutes after administration, 1 hour, 2 hours, 4 hours, 6 hours and 8 hours after drug injection. Additional sample will be obtained on day 8 prior to drug injections on those days. Samples will be sent to an internal Emory lab for testing of progesterone levels in the body.



MRI Scans (standard):

A diagnostic MRI scan with and without intravenous contrast will be done ≤ 14 days before starting natural progesterone and after 4 and 8 weeks of progesterone therapy, and then every 8 weeks until study end.

These MRI scans will allow us to look at the status of your tumor. Any additional follow-up diagnostic MRI scans will be ordered by your doctor according to the standard care schedule of your tumor.

Blood work (standard):

Standard blood work will be obtained ≤ 14 days before starting natural progesterone and then every 4 week interval until study end.

History and Physical Exam (standard):

Standard history and physical exam, including KPS and neurologic assessment, will occur ≤ 14 days before starting natural progesterone, day 15, day 29, and beginning of every subsequent 4 week interval until study end.

Adverse Event Assessment (standard):

Assessment of side effects/toxicities you may be experiencing with progesterone will be assessed on or around day 1, day 8, day 15, day 22, day 29, and the beginning of every subsequent 4 week interval until study end.

Quality of life assessment, drug diary documentation, current medication documentation (research activity):

We want to know how your life has been affected by your brain tumor and its treatment. Your documentation regarding medication use and side effects (drug diary), list of other medications being used (steroid/anti-seizure medication documentation), and general sense of well-being (quality-of-life) will be evaluated by a tests and questionnaires. These will be done in your doctor's office. It takes about 40 minutes to complete these tests and questionnaires.

The timing of these tests is as follows:

1. Quality-of-life assessments - Initial evaluations will be performed ≤ 14 days before starting natural progesterone. Subsequent evaluations will be at approximately 4 weeks, 8 weeks, and 24 weeks, with a possible off-study evaluation.
2. Steroid/anti-seizure medication documentation – Initial evaluation will be performed ≤ 14 days before starting natural progesterone. Subsequent evaluations will occur day 1, day 8, day 15, day 22, day 29, and beginning of every subsequent 4 week interval until study end.
3. Drug diary documentation – Drug diary form will be given each time a supply of drug (1-2 week supply) is given to the patient and the previous drug diary will be collected at that time.

How will my medicine be provided?

The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you at predetermined intervals (1-2 weeks). If you have questions about the medicine, you should ask the study doctor or study nurse. You may also call the pharmacy at [REDACTED] if you have questions about the medicine.

Who owns my study information and samples?

If you join this study, you will be donating your samples and 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 unless you specifically request that data and samples not be used for our study.

What are the possible risks and discomforts?

There may be side effects from subcutaneously administered natural progesterone at the doses used that are not known at this time. The below risks and discomforts are based on daily administration of natural progesterone at a dose of 25 mg.

The most common risks and discomforts expected from subcutaneously administered natural progesterone (occur in 10% of patients or greater):

- Uterine spasm (tightening of the muscles of the uterus)
- Vaginal hemorrhage
- Administration site reactions such as irritation, pain, itching, swelling

The less common risks and discomforts expected from subcutaneously administered natural progesterone (occur in 1% to 10% of patients):

- Headache
- Abdominal distention (bloating, or increased pressure and size of the belly)
- Abdominal pain
- Nausea, vomiting
- Constipation
- Breast tenderness or pain
- Vaginal discharge
- Vulvo-vaginal itchiness, discomfort or inflammation
- Ovarian hyperstimulation syndrome

Rare but possible risks expected from subcutaneously administered natural progesterone (occur in <1% of patients):

- Feeling hot, pain or malaise
- Itching or rash
- Breast disorders
- Gastrointestinal disturbances
- Dizziness
- Somnolence (feeling sleepy)
- Altered mood

Risks related to progesterone potentially promoting tumor growth:

While this trial is studying whether high dose progesterone is safe and have anti-tumor activity against recurrent glioblastomas, research studies in animals suggest that low dose progesterone may promote tumor growth which gives the theoretical risk that this treatment could make your tumor grow faster.

Risks and side effects related to MRI (research activity):

Less Likely:

- Some people who are claustrophobic (have a fear of enclosed places) might feel anxiety or nervousness during MR scan.
- Increased discomfort from the noise that the MRI instrument makes

Risks and side effects related to blood draws (research activity):

Less Likely:

- Injury to surrounding structures with needle when drawing blood.
- Pain or discomfort at site of blood draw.

Risks and side effects of study questionnaires (research activity):

Less Likely:

- You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

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 4-6 weeks after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

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 recurrent glioblastoma brain tumor 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 the safety and actions of progesterone in patients with your disease. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You may receive any one or combination of the following treatment approaches for recurrent glioblastoma:

- Chemotherapeutic drugs (such as temozolomide, lomustine, irinotecan, etc.).
- Biologic or targeted therapies (such as bevacizumab, epidermal growth factor receptor inhibitors, etc.).
- NovoTTF device (applies alternating low electrical fields, called tumor treating fields).
- Surgery alone or with implantation of Gliadel wafers (local delivery of carmustine chemotherapy) or GammaTiles (embedded Cesium-131 seeds for focal radiation delivery).
- Radiation therapy with either external beam modalities (photons or protons) or brachytherapy (radioactive implant, see GammaTiles above).
- Experimental therapies on another clinical trial.
- Supportive care.

The study doctor will discuss these with you. You do not have to be in this study to be treated for your recurrent glioblastoma brain tumor.

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.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

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 and specimens 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 and/or specimens 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.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An

Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: research blood collection.

Tests and procedures done at non-Emory places may not become part of your Emory 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

If you believe you have become ill or injured from this research, you should contact Dr. Hui-Kuo Shu at [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 will help you to get medical treatment. Emory will not 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 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, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory 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 study supporter will pay for certain items and services that you may receive if you take part in this study.

These study-related costs provided by the study supporter will include but are not limited to the following:

- 1) subcutaneously administered natural progesterone,
- 2) administration of quality-of-life tests and assessments.

You will have to pay for the items or services for which the study supporter does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory 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 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 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. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

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.

The study doctor also has the right to stop your participation in this study without your consent if:

- He believes it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

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 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.

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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

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 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.
- Dr. Hui-Kuo Shu 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 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 Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
 - Government agencies that regulate the research including: Food and Drug Administration.
 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
 - Study-Supporter: IBSA Institut Biochimique SA
- 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.

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:

Hui-Kuo Shu, MD
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

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 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 Dr. Hui-Kuo Shu 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 Institutional Review Board at [REDACTED] 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>.

Consent and Authorization

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

____:____ am / pm
Time (please circle)

Signature of Legally Authorized Representative

Date

____:____ am / pm
Time (please circle)

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

**Signature of Person Conducting Informed
Consent Discussion**

Date

____:____ am / pm
Time (please circle)