Kisspeptin Influence on Glucose Homeostasis

NCT04958109

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Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2018

Protocol Title: Kisspeptin Influence on Glucose Homeostasis

Principal Investigator: Margaret Lippincott, MD

Site Principal Investigator:

Description of Subject Population: healthy men and women

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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.

Why is this research study being done?

We are doing this research to study how kisspeptin changes insulin levels and whether kisspeptin may be helpful for people with metabolic problems, like diabetes.

Kisspeptin is a chemical that is naturally made in the body. It is involved in reproduction and metabolism, and is made in very high levels in women during pregnancy.

Recently studies have suggested that kisspeptin causes the body to change insulin levels. Some studies in humans have shown that taking kisspeptin causes the body to produce hormones called gonadotropins (pronounced "go-nad-oh-trope-ins"). Gonadotropins travel through the body in the bloodstream. In men, they cause the testes to produce the male hormone testosterone and to make sperm. In women, they stimulate the ovaries to release an egg every month.

Kisspeptin is not approved by the U.S. Food and Drug Administration (FDA). This means that kisspeptin can only be used in research studies.

Over 300 volunteers taking part in research studies have received kisspeptin so far and no adverse effects related to kisspeptin have been observed.

This research study will compare kisspeptin to placebo. The placebo looks exactly like kisspeptin, but contains no kisspeptin. During this study, you may get a placebo instead of kisspeptin. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons. At some time during the study, we will give you kisspeptin. At another time, we will give you placebo.

We are asking you to take part in this study because you are either a healthy adult female or a healthy adult male. About 360 subjects will be enrolled in the study at the Massachusetts General Hospital (MGH).

Harvard Catalyst - The Harvard Clinical and Translational Science, National Institutes of Health, and Massachusetts General Hospital are paying for this research study to be done

How long will I take part in this research study?

It will take you about up to 1 year of participation, depending on scheduling, to complete this research study. We anticipate that that participation will typically take 3-4 months.
During this time, we will ask you to make **3-4** study visits to MGH. You will have **2** overnight visits in the Clinical Research Center. We will also call you 3-4 times during the study, after each overnight visit.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. Some study procedures may be done remotely over the phone or at a local facility. We will let you know how we plan to do study procedures.

Screening Visit – Visit 1: (about 30 minutes)
At this visit, we will do tests and procedures to see if you qualify to take part in this research study. The study doctor will review the results of these tests and procedures. You will be asked to fast for this study visit (for 10 hours prior to the visit, eat no food and drink only water). If you don't qualify, the study doctor will tell you why.

We will:

- Ask you about your medical history
- Do a physical exam, including height and weight
  - For women, this will include a breast exam
- Measure the circumference of your hip and waist.
- Draw a blood sample
- Test your blood for pregnancy, if you are a female able to become pregnant. Pregnant women cannot take part in this research study.

DEXA scan (15 minutes total, combined with any other visit)
During this study you will receive one DEXA scan. The DEXA scan is a noninvasive imaging technique used to assess total body fat. For this test you will be asked to lie down on a table for about 5 minutes. This quick test may be combined with one of your other visits to save you time.

CLINICAL RESEARCH CENTER ADMISSIONS – CRC Visits 2-3:
If your screening results tell us that you are healthy, you will return to the hospital to be admitted for **2** Clinical Research Center Visits. These visits will take place between 2 weeks and 10 months from the time of initial screening.

The CRC visits are 18 hour overnight visits. You'll be asked to arrive about 5 pm and will stay until 1pm the next day. Prior to these visits you will be asked to follow a balanced diet (instructions will be provided) for 3 days and avoid vigorous exercise for 2 days.

You will have **2** CRC visits. You will receive a placebo or kisspeptin at each visit. This will be administered as a continuous infusion. The continuous infusion will start shortly after dinner and last for 16 hours.

During the CRC visits we will:

- Test your urine for pregnancy, if you are a female able to become pregnant.
- Give you a standard dinner meal consisting of carbohydrates, protein, and vegetables, and will be asked to eat the entire meal. This meal helps prepare your body for the testing being done.
- After dinner, you will be asked to fast for 12 hours. You can drink water but cannot consume any other food or drink. You will then spend the night in the Clinical Research Center.
- Over the course of the visit, you will also be asked to fill out questionnaires about your appetite and hunger levels.

You will undergo one of the following tests to evaluate your metabolism, which will include:

Mixed Meal Tolerance Test/Oral Glucose Tolerance Test

- Place two thin, plastic tubes called intravenous lines (IVs) in your arms. The IVs allows us to take many blood samples and deliver study drugs without having to use a needle each time.
- Early the morning after admission, be given a standard breakfast, such as an egg sandwich or meal replacement drink (e.g. boost, ensure) or a sugary drink containing glucose to consume. You will be asked to consume this food/drink within a specific period of time (5-15 min depending upon the food/drink).
- Through the IV, we will draw a small amount of blood up to every 5 minutes for 4 hours to measure your response to the food/drink that you have consumed.

Hyperglycemic Clamp

- Place two thin, plastic tubes called intravenous lines (IVs): one IV will be placed in the hand or forearm, the other IV will be placed in your arm. The IVs allows us to take many blood samples and deliver study drugs without having to use a needle each time.
- The hand/forearm with the IV will be placed in a warming box for the duration of the clamp procedure, although it may be withdrawn if the you find the warmth uncomfortable.
- Through the IV, we will draw a small amount of blood up to every 2 minutes for 3 hours to measure your response to the food/drink that you have consumed.
- In addition to kisspeptin or placebo infusion, you will also receive an infusion of sugar in the form of a dextrose solution.
- After the infusion of sugar is stopped, your blood sugars will be monitored.

Hyperinsulinemic-Euglycemic Clamp

- Place two thin, plastic tubes called intravenous lines (IVs): one IV will be placed in the hand or forearm, the other IV will be placed in your arm. The IVs allows us to take many blood samples and deliver study drugs without having to use a needle each time.
- The hand/forearm with the IV will be placed in a warming box for the duration of the clamp procedure, although it may be withdrawn if the you find the warmth uncomfortable.
- Through the IV, we will draw a small amount of blood up to every 2 minutes for 3 hours to measure your response to the food/drink that you have consumed.
- In addition to kisspeptin or placebo infusion, you will also receive an infusion of sugar in the form of a dextrose solution and insulin.
- After the infusions stop, your blood sugars will be monitored.

Each clinical research center visit may be separated by up to 4 months depending upon your schedule and the schedule of the Clinical Research Center.

FOLLOW-UP PHONE CALLS or EMAILS – (about 10 minutes per contact, 3 total)
You will receive a phone call within 72 hours of your visit to the CRC to check if there are any problems, and to see if you have any questions or concerns. If you are having any problems, we may ask you to come for a follow-up visit.

FOLLOW-UP VISIT – Visit 4: (about ½ hr) If on your follow-up phone call you are experiencing any symptoms that could be related to the study, we may ask that you return for a follow up visit. We will:

- Do a short physical exam
- Draw a blood sample to check your blood count. If your blood count is low, we will ask you to take iron tablets and to return for repeat checks until your blood count is back to your screening level.

Stopping the Study Early
If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 30 minutes. We will:

- Do a physical exam
- Ask you about any side effects or health problems since your last visit
- Draw a blood sample, based on your physical exam and history

Also, the study doctor may take you out of the study without your permission. This may happen because:
The study doctor thinks it is best for you to stop taking the study drug

- You can't make the required study visits

- The Sponsor decides to stop the study
- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study. We will ask you to come in for a final study visit as described above.

Storing Samples and Health Information at MGH for Future Use
We would like to store some of your samples and health information for future research related to kisspeptin, metabolism and/or reproduction. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password protected computer/locked file.

Do you agree to let us store your samples and health information for future research related to kisspeptin, metabolism, or reproduction?

☐ Yes ☐ No Initials_____

If later you change your mind and want your samples destroyed, you may contact the study doctor.

Study Information Included in Your Electronic Medical Record
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs).

Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

What are the risks and possible discomforts from being in this research study?

Risk of Allergic Reaction:
With any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, tell the study staff immediately. If you are not in the Clinical Research Center and are having trouble breathing, call 911 immediately.

Risks of Kisspeptin:
Kisspeptin is naturally made in the human body. This drug has been given to healthy men and women, patients attempting fertility and patients with reproductive disorders. We have studied the effects of high doses of kisspeptin on rats and dogs and no side effects were seen. There have been no serious side effects seen in either animal or human studies. However, there may be risks of kisspeptin that are currently unknown, including side effects that may happen when taking kisspeptin with other drugs.

Unknown Risks
There may be other risks of kisspeptin that are currently unknown.
For your safety during this study, call your study doctor BEFORE you take any:

- new medications prescribed by your own doctor
- other medications sold over-the-counter without a prescription
- dietary or herbal supplements

Risks to an Embryo or Fetus, or to a Breastfeeding Infant
We do not believe that kisspeptin has any risk to an embryo or fetus (unborn baby in the womb). This is largely based on studies showing very high levels during pregnancy. There may be harmful risks that are unknown. Therefore, women cannot take part in the study if they are:

- pregnant
- trying to become pregnant
- breastfeeding

For women, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), and transvaginal occlusion (plugging the opening of the tubes with a coil). All other female subjects must have a negative pregnancy test before starting the study drug. If you are a menopausal woman and have not had a period for the past 12 months or more, you will not need to have a pregnancy test.

If you are sexually active and able to become pregnant, you must agree to use two of the birth control methods listed below until after you complete your last CRC Visit.
Acceptable birth control methods for use in this study are:

- birth control pills, patches, injections, vaginal rings, or implants
- barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- intrauterine device (IUD)

- abstinence (no sex)

Hormone medications that suppress ovulation are allowed. This includes hormonal methods of birth control such as birth control pills, patches, injections, vaginal rings, or implants. Hormonal medications that do not suppress ovulation, such as intrauterine devices (IUDs) with levonorgestrel, are only allowed if you continue to have a regular menstrual cycle. The study investigator will discuss your choices for birth control during the study.

If you think you might be pregnant during the study, you must tell the study doctor. If you become pregnant, you must stop taking part in the study. The study doctor may ask for your permission to collect information about the outcome of your pregnancy and the condition of your newborn.

For men, if you are sexually active and able to father a child, you and your partner must agree to use two of the birth control methods listed below until after you complete your Clinical Research Center visit.
Acceptable birth control methods that you can use in this study are:

- condoms with spermicide (a foam, cream, or gel that kills sperm)
- abstinence (no sex)

Acceptable birth control methods that your partner(s) should use are:

- hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- intrauterine device (IUD)

If your female partner becomes pregnant, a study doctor may ask to follow the outcome of the pregnancy. You should notify us if your partner becomes pregnant. She may be asked to sign a release of medical information form that gives her doctors permission to provide information to a study doctor.

Risks of Blood Draws and IV Lines:
The total amount of blood drawn in this study is less than 550 mL (about 2 cups plus 3 tablespoons). By comparison, the Red Cross allows a healthy adult to donate 1 unit (about 2 cups) of blood every 8 weeks. A healthy person will normally replace this amount of blood in that time period.

You should not donate blood or have large amounts of blood drawn for 8 weeks after the study.

You may have a bruise (a black and blue mark) or pain where we take the blood samples and/or put in an IV line. There is also a small risk of infection, lightheadedness, and/or fainting, as well as a slight chance that an IV line may stop working. If an IV line stops working, we will put in a new one. You may feel fatigued after blood-drawing.

Also, it is possible that you could develop anemia, low red blood cell counts, from blood-drawing, should you develop symptoms of anemia, such as fatigue, you will be tested. If you develop anemia, you will be asked to take iron supplements until the anemia resolves.

Risks of Iron Supplements
Iron supplements may occasionally cause mild gastrointestinal (stomach and digestion) problems, including constipation and darkening of the stool.

Risks of Mixed Meal Tolerance Test: Approximately 85 participants will be asked to undergo mixed meal tolerance test, in which they will be asked to drink a nutritional drink (for example, Boost®). Subjects may feel sick after drinking the liquid meal and may vomit.

Risks of Oral Glucose Tolerance Test: Approximately 50 participants will be asked to undergo an oral glucose tolerance test - the drink may taste very sweet making it hard to drink. Subjects may feel sick after drinking the glucose liquid and may vomit. There is a risk of low blood sugar or symptoms of low blood sugar without low blood sugar levels. These symptoms include weakness, hunger, sweating, and feeling nervous or restless. If you develop these symptoms during the test, your blood glucose level will be checked by glucometer. If you have a low blood sugar level and are experiencing symptoms, you will be provided with glucose tabs and the study will be stopped.

Risks of Hyperinsulinemic-Euglycemic Clamp/ Insulin: Approximately 45 participants will be asked to undergo an hyperinsulinemic-euglycemic clamp where the goal is to maintain a constant normal blood sugar using insulin and sugar (dextrose) infusions. There is a risk of low blood sugar or symptoms of low blood sugar without low blood sugar levels. These symptoms include nausea, vomiting, weakness, hunger, sweating, and feeling nervous or restless. If you develop these symptoms during the test, your blood glucose level will be checked by glucometer. A physician will be by your bedside monitoring your glucose levels and will adjust the sugar infusion as needed to maintain a normal blood sugar. If your blood sugar should be low and you have symptoms, medication will be available at the bedside to treat you.

Risks of Hyperglycemic Clamp: Approximately 36 participants will be asked to undergo a hyperglycemic clamp. This involves an infusion of sugar (dextrose) to examine your bodies insulin levels. During the study you may feel sick and may vomit. There is a risk of low blood sugar or symptoms of low blood sugar without low blood sugar levels. These symptoms include

weakness, hunger, sweating, and feeling nervous or restless. If you develop these symptoms during the test, your blood glucose level will be checked by glucometer. If you have a low blood sugar level and are experiencing symptoms, you will be treated.

Risks of Radiation Exposure

As a result of your participation in this study you will be exposed to radiation from the whole body DEXA scan. Please note that this radiation is not necessary for your medical care and is for research purposes only.

The total amount of radiation exposure you will receive from taking part in this study is equal to a whole body exposure of about 8.40 microSieverts (μSv). A μSv is a unit of radiation dose. This amount of radiation is about the same as you would normally get in 1 day from natural background sources from the earth and the sky. Scientists disagree on whether radiation doses at these low levels are harmful. A possible effect that could occur at doses used in this study is a slight increase in the risk of developing cancer later in life.

What are the possible benefits from being in this research study?

You will not benefit from taking part in this research study. This is not a treatment study. However, others with metabolic disorders, like diabetes, may benefit in the future from what we learn in this study.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

We will pay you:
If you participate in a mixed meal tolerance test or an oral glucose tolerance test (2 Clinical Research Center visits):

- $10 for the screening visit,
- $20 for the DEXA scan,
- $335 for each Clinical Research Center (CRC) Visit for a mixed meal or oral glucose tolerance test,
    - if CRC visit is terminated prior to mixed meal or oral glucose ingestion: $20
    - if CRC visit is terminated during mixed meal or oral glucose testing: $20 for visit, and an additional $20 for each hour of blood sampling
- $200 upon completion of Study Protocol
- This means that you will be paid up to $900 if you complete all parts of this study.

If you participate in clamp studies (2 Clinical Research Center visits):

- $10 for the screening visit,
- $20for the DEXA scan,
- $485 for each Clinical Research Center (CRC) Visit for a hyperinsulinemic-euglycemic clamp or hyperglycemic clamp,
    - if CRC visit is terminated prior to clamp: $20
    - if CRC visit is terminated during clamp: $20 for visit, and an additional $30 for each hour of blood sampling
- $200 upon completion of Study Protocol
- This means that you will be paid up to $1200 if you complete all parts of this study.

We will give you a parking coupon to pay for your parking in the hospital garage during study visits. We will also give you meals during visit(s) to the CRC.

If there is a follow-up visit because you have a problem during the study, we will not pay you for the follow-up visit.

Payment will be done in the form of a check mailed to your home address. You should receive the check within 4 weeks from the date of study completion. We will require your social security number (SSN) in order to process your payment.

What will I have to pay for if I take part in this research study?

Study funds will cover the costs of all the research procedures.

Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Margaret Lippincott, M.D. is the person in charge of this research study. You can call her at [redacted] (Monday-Friday 9-5) or page her ([redacted] pager # [redacted]) 24 hours a day, 7 days a week with questions about this research study. You can also call Stephanie Seminara, M.D. at [redacted] (Monday-Friday 9-5) or page her ([redacted]) 24 hours a day, 7 days a week with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Dr. Lippincott at [redacted].

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research

- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Permission for Future Contact

We may want to contact you about additional studies in the future. Do you give permission for us to contact you about future studies?

☐ **YES, I give permission to be contacted about future studies.**

☐ **NO, I do NOT wish to be contacted about future studies.**

Subject	Date

Consent Form Version: 5.0