Kisspeptin Physiology in the Human

NCT04648969

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Protocol Title: Kisspeptin Physiology in the Human

Principal Investigator: Stephanie B. Seminara, M.D.

Site Principal Investigator:

Description of Subject Population: Adults with hypogonadotropic hypogonadism, polycystic ovarian syndrome, or hyperprolactinemia

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 study to learn how a chemical called kisspeptin (pronounced "kiss-pep-tin") affects human reproduction. We also want to know how it controls the reproductive system in men and women, and what effect kisspeptin has on reproductive hormone levels. Reproductive hormones are chemicals the body makes naturally. A person needs a certain amount of reproductive hormones to be able to father a child or become pregnant.

Kisspeptin is an investigational drug, which means that it is not approved by the U.S. Food and Drug Administration (FDA). At this time, kisspeptin can only be used in research studies.

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

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.

We are asking you to take part in this study because you have been diagnosed with hypogonadotropic hypogonadism, polycystic ovarian syndrome, or hyperprolactinemia. We're interested in understanding how the administration of repetitive boluses of Kisspeptin over a period of time will affect your reproductive system.

About 156 people with reproductive disorders will take part in this study at Massachussets General Hospital (MGH).

As part of the study, you will also receive a hormone called GnRH (short for "gonadotropin-releasing hormone"). GnRH stimulates the pituitary gland to produce gonadotropins and will be given to you to make sure your body is able to respond fully to kisspeptin.

Over 100 healthy volunteers taking part in research studies have received kisspeptin so far. No adverse effects related to kisspeptin have been observed. GnRH has been given to thousands of subjects and patients, and only one adverse effect has been reported. This was an allergic reaction, and it was not clear whether this reaction was related to GnRH.

The National Institute of Child Health and Human Development (part of the National Institutes of Health) and the Massachusetts General Hospital Executive Committee on Research are paying for this research to be done.

How long will I take part in this research study?

You will be in this research study for 1-3 months. During this time, we will ask you to make up to 5 study visits to MGH.

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.

You will come for as many as 5 study visits:

1) a screening visit to see if you are eligible (about 1 hour)
2) a visit where you will be admitted to the Clinical Research Center (CRC) at the hospital for blood tests and will receive the kisspeptin and GnRH (3-53 hours)
3) if applicable, a second admission to the Clinical Research Center for blood tests and administration of kisspeptin and GnRH (3-15 hours)
4) if applicable, a brief follow-up visit within a month of your last research center stay (about 30 minutes)
5) an optional brief visit during which a GnRH pump will be placed

We may modify or skip some of these visits, depending on your specific situation. You will be paid only for the visits you come for.

WASHOUT PERIOD

If you qualify for the study, we may ask you to stop taking any hormone medications you are on. We will go over which hormones you can't take, and for how long. Washout takes from 2 to 8 weeks, depending on your medication. This "washout period' allows your regular medications to leave your body before you begin taking the study drug. Without your regular medications, you may have symptoms of low sex hormone levels. These symptoms included decreased energy level, decreased libido (sex drive) and occasionally hot flashes. If this happens, please call the study doctor at the number provided in this consent form.

If you are currently taking the dopamine agonist bromocriptine, we will ask you to stop taking it for at least 2 weeks before any visit where we will give you kisspeptin or GnRH.

SEX STEROID REPLACEMENT

If you are a woman who qualifies for the study, we may ask you to start taking one or more hormone medications (estradiol and/or medroxyprogesterone) for up to two weeks. This may cause one to two days of light menstrual bleeding.

SCREENING VISIT – Visit 1: (about 1 hr)

For the screening visit you will come to the outpatient clinic of the MGH Reproductive Endocrine Unit for your initial evaluation. At this visit, we will:

- ask you about your health history,
- give you a physical exam, including an exam of your testicles (men)

- draw blood to measure your blood count, hormones, and to make sure you are generally healthy (may be conducted at the MGH Clinical Research Center).

Women who can become pregnant will also have a pregnancy test at this visit.

If you have hypogonadotropic hypogonadism, you may need a Magnetic Resonance Imaging (MRI) scan of the brain to confirm your diagnosis. We may ask for a record of an MRI done by your clinical provider or we may ask, if you are eligible, for you to undergo an MRI scan of the brain at MGH. An MRI scan uses a magnetic field to produce pictures of your brain. We will ask you to lie still on a table that slides into a tunnel that is slightly wider than your body. The top and sides of the tunnel will be very close to your face and body. The MRI makes loud banging noises, as if it were being pounded on the outside. We will give you earplugs to help reduce the noise. You will be able to talk to the MRI technologist and the technologist will be able to talk to you during the procedure. If you want to stop the procedure at any time, just tell the technologist, and the test will be stopped. Total time for MRI is approximately 1 hour.

CLINICAL RESEARCH CENTER ADMISSIONS – Visits 2 and 3: (about 3-53 hrs)

If your screening results tell us that you are healthy, you will return to the hospital to be admited for Visits 2 and/or 3. These visits will take place between 2 weeks and 3 months from the time of screening. Either at screening or during a follow-up phone call after Visit 2, you will be informed as to whether there will be a Visit 3. Below is a description of what will occur during both Visit 2 and Visit 3.

If you are a woman who can become pregnant, we will first have a urine pregnancy test at the beginning of the admission to make sure you are not pregnant.

If you are not pregnant, we will place a thin, plastic tube called an intravenous line (IV) in your arm. The IV allows us to take many blood samples without having to use a needle each time.

Through the IV, we will frequently draw a small amount of blood for 2-52 hours, where the shortest time frame for a blood draw is 10 minutes, to measure your hormones, including the gonadotropins (luteinizing hormone [LH] and follicle stimulating hormone [FSH]), testosterone, and others. The IV will stay in your vein for the whole study visit.

During Visits 2 and 3, we may administer kisspeptin and GnRH boluses through the IV line or subcutaneously (SC, an injection method under the skin). Injections are most likely to occur in the abdomen but may also occur in the leg or arm. If we administer through IV, after the last blood draw we will remove the IV line, and you can go home.

We will call you within 48 hours and again 5-7 days after you leave the Clinical Research Center 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.

GnRH PUMP

If you have hypogonadotropic hypogonadism, including hypothalamic amenorrhea, you may be asked to wear a GnRH pump. You will be informed either at screening or during a follow-up phone call after Visit 2 if you will wear a GnRH pump. You may be asked to wear the GnRH pump twice, once before each Visit to the CRC.

At Visit 2 and/or at an optional separate visit before or after Visit 2 (Visit 5), we may place a pump device that will administer GnRH subcutaneously. You may also be instructed in how and when to place the pump yourself at home. The pump is the size of a pager, and it can be carried in your pocket or clipped to your belt. A tube (catheter) will carry GnRH from the pump to your skin. The pump should not interfere with your daily activities. It is possible to disconnect the pump for periods of time in between doses. You will be asked to wear this device for at least 4 days and up to 14 days. After you have worn the pump for the allotted time period, it can be removed by you at home or by study staff at the beginning of a visit to the CRC (this may be Visit 2 and/or Visit 3).

FOLLOW-UP VISIT – Visit 4: (about ½ hr) (some subjects only)

Within a month after the hospital admission visit, you may return for a short physical exam and blood tests 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.

You need to tell us if you have taken part in, or plan to take part in, any other research study while you are in this study. Also, please let us know about any medical, diagnostic, or treatment activites, such as a new medicine or a trip to the doctor, during this study. This is for your safety.

Stopping the Study Early

You may decide to stop taking part in the study for any reason. 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
- The study doctor thinks it is best for you to stop participating in the study
- You can't make the required study visits
- 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.

Review of Medical Records from Hospital Admissions or Emergency Department Visits

Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

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 physiology or reproductive disorders. 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.

Do you agree to let us store your samples and health information for future research related to kisspeptin physiology or reproductive disorders?

☐ Yes ☐ No Initials_____

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

Use of your Information from this Research Study

In the past you may have participated in a study in the Reproductive Endocrine Unit including providing a blood sample, spending a night in the hospital, or receiving medication/treatment. All study information, past and future including genetic studies will be used collectively for ongoing research and to improve our understanding of reproductive disorders. This includes information from other Reproductive Endocrine Unit studies you have completed or will take part in.

As we learn more about your condition, we may want to contact you about additional studies.

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?

The risks involved with this study include:

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, call the study doctor right away. If you 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 also 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.

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. A group in the UK is using kisspeptin to induce ovulation in women undergoing in vitro fertilization treatment. All women who have given birth have been reported to have live, healthy babies. There may be harmful risks that are unknown. Therefore, women cannot take part in the study if they are:

- pregnant
- breastfeeding

All female subjects must have a negative pregnancy test before starting the study drug.

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 Clinical Research Center visit.

Acceptable birth control methods for use in this study are:

- 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)

In many but not all protocols hormonal medications are not allowed. This includes hormonal methods of birth control such as birth control pills, patches, injections, vaginal rings, or implants. 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 will not be able to participate in any study visit in which you would get study drug and you will be withdrawn from the study.

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 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)

Risks of Gonadotropin-Releasing Hormone (GnRH)

GnRH has been given to patients for more than 30 years and it is approved by the FDA for ovulation induction in women. There have been no serious side effects that were felt to be related to GnRH in human studies aside from a single report of a possible allergic reaction.

Risks of Estradiol, an estrogen

Common undesirable effects of estradiol include tenderness or enlargement of the breasts, nausea, and headache.

Long term use of estrogens such as estradiol has been associated with rare but serious side effects that include abnormal vaginal bleeding, and increased risk of breast cancer, heart attack

and blood clots. Because of the short period of time that you will receive the estradiol, these side effects are extremely unlikely.

An earlier research study, called the Women's Health Initiative (WHI), showed that the benefits of oral (by mouth) estrogen alone, or estrogen and a progestin together, were not greater than the possible risks. There is no evidence for any increased risk associated with short periods of use as in this study.

Risks of Medroxyprogesterone acetate, a progestin
Common undesirable effects of medroxyprogesterone acetate include bloating, stomach discomfort, nausea, breast tenderness, headache, and dizziness or drowsiness.

Long term use of medroxyprogesterone acetate has been associated with rare side effects that include blood clots, changes in weight or mood, and discharge from the nipple.

If you take estradiol as a part of this study and have an intact uterus, you may be given 10 days of medroxyprogesterone acetate (5 -10 mg) around Visit 2. You may have one to two days of light menstrual bleeding after finishing this low dose progestin.

Risks of Blood Draws and IV and SC Administration:
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), irritation, 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. Also, it is possible that you could develop anemia from blood-drawing, should this happen we will provide iron supplements. You may feel fatigued after blood-drawing.

There is a possibility of a reaction at the site of SC administration including: pain, tenderness, warmth, itching, swelling, irritation, redness, or bruising.

Risks of Iron Supplements

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

Risks of Washout Period
If you take hormone medication and stop taking it, you may have symptoms of low sex hormone levels. These symptoms included decreased energy level, decreased libido (sex drive) and occasionally hot flashes.

Dopamine agonist treatment washout:
If you take the dopamine agonist bromocriptine and you stop taking it, you may notice that your original symptoms may come back. These symptoms may include a lack of menstrual period (women), sexual dysfunction (men and women), and/or a milky liquid coming out of your breast(s) (galactorrhea) (men and women). However, because our washout period is relatively short, we do not expect you to have these symptoms for very long and expect any short-term symptoms to quickly go away when you begin taking bromocriptine again.

Risks of MRI
MRIs use powerful magnets to make images. There is no radiation risks associated with MRI. Persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you have previously experienced claustrophobia, tell the study doctor or study staff before you start the study. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises.

The scan in this study is being done to confirm your diagnosis, and if you were not taking part in this study, the MRI would be done as a part of your medical care. The MRI will become a part of your medical record. This MRI scan will be read by a radiologist (a doctor who specializes in these scans). If the radiologist thinks there might be a problem, we will tell you and help you get follow-up care. If the radiologist thinks that you might have a medical problem, but it turns out that you don't, we may have caused you to worry needlessly about your health.

Unknown Risks
There may be other risks of kisspeptin and GnRH that are currently unknown.

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 reproductive disorders may benefit in the future from what we learn in this study.

What other treatments or procedures are available for my condition?

This is not a treatment study. You can choose not to take part and stay on any hormone medications you are currently taking.

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:

- Screening (visit 1): $40 for the screening visit,
- CRC admission (visit 2): amount will be variable depending on length of stay ($15-$25 per hour for a range of 3-53 hours)
- Wear GnRH pump: $140 for wearing the GnRH pump twice ($70 each time you wear the pump), if applicable
- CRC admission (visit 3): $25/hr up to a total of $300, if applicable

This means that you will be paid up to $890 if you complete all possible visits in this study.

We will give you meals during the Clinical Research Center admissions. We will give you a parking coupon to pay for your parking in the hospital garage during study visits. If you are traveling from a distance, we may also defray transportation and hotel costs.

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

We may use your samples and information to develop a new product or medical test to be sold. The hospital and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

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

You will not have to pay for any of the procedures and laboratory tests that are part of this research study. These will be paid by study funds.

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.

Stephanie Seminara, 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]) 24 hours a day, 7 days a week with questions about this research study. You can also call co-investigator Yee-Ming Chan, M.D., Ph.D. at [redacted] or page him ([redacted] pager #[redacted] 24 hours a day, 7 days a week with questions about this research study, or call co-investigator Margaret Lippincott, M.D. 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.

If you have questions about the scheduling of appointments or study visits, call [redacted] or email mghkisspeptinresearch@partners.org

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

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

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter | Date | Time

OR
Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name | Date | Time

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 Date: October 29, 2020