INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)/ "Phase 1 Dose Ranging Study to Assess the Safety, Reactogenicity, and Immunogenicity of PepGNP-COVID-19, a synthetic nanoparticle-based, T-Cell Priming Peptide Vaccine against SARS-CoV-2 as a Booster Dose"**
Protocol Number:	**25-1105**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	[redacted]

KEY INFORMATION

You are being asked to participate in this research study because we want to test the safety and immune response to an experimental COVID-19 vaccine given as a booster dose. This page will give you key information to help you decide whether you want to participate in the study. More detailed information can be found on the following pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

What is the purpose of this research study?

The purpose of this research study is to test a next generation, experimental COVID-19 vaccine for safety and to measure your immune (infection fighting) response to the vaccine.

How long will I be in this research and what will I have to do?

Your participation in this study will last for about 6 months, consisting of up to nine planned study visits. This includes a screening visit, one study product administration visit (where you will receive the study product), six follow-up visits, and one study contact (conducted by phone call, text message, or email) to check on you. During the study, you will have physical exams, blood draws, and nose swabs. If you can become pregnant, you will also give urine samples for pregnancy testing. You will receive one dose of the study product given just under the skin by injection in your upper arm and will complete a daily memory aid (like a diary log) at home to

record any side effects that you may experience for one week after the study product administration.

What are the reasons I might choose to volunteer for this study?

There is no direct benefit to you for participating in this study. If you participate, your body may develop an immune response against SARS-CoV-2 (the virus that causes COVID-19) which may protect you from infection and/or serious illness. Also, the information we collect from this study may help others in the future.

What are the reasons I might not choose to volunteer for this study?

There are potential risks associated with this study. The most common side effect of injected vaccines is pain at the injection site. One of the most serious risks is anaphylaxis, or a severe allergic reaction to the study product. There is also a risk of loss of confidentiality of your health information, including genetic test results. See the "Risks of Participation" section for more information. You should discuss these risks in detail with the study team.

Do I have to take part in this study?

Taking part in this research is voluntary. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Does this study include genetic testing?

This study will include genetic testing to see how well the study product works in people with different genetic backgrounds. We are not looking for inherited diseases. We explain this later in this form.

What happens to my research samples?

If you participate in this study, you will be asked to consent to **secondary research** (research that is not planned yet). We will use your coded information, leftover samples, and extra samples for secondary research. This may include **genetic** research to study immune responses. You should not enroll in this study if you do not want your samples and data used for secondary research.

Please read this form carefully. Take your time to ask the study team your questions. The study doctor or staff will explain words or information you do not understand. If you decide to participate in this study, you must sign and date your name at the end of this form.

DETAILED CONSENT FORM

Background

COVID-19 is a disease caused by infection with the SARS-CoV-2 virus. COVID-19 can cause symptoms including fever, cough, shortness of breath, tiredness, sore throat, body aches, nasal congestion, and/or loss of taste or smell. Researchers are looking for new vaccines to prevent or minimize COVID-19. Vaccines train germ-fighting cells to help fight infections.

Purpose of this Research Study

The purpose of this research study is to test an experimental COVID-19 vaccine called PepGNP-COVID19 to evaluate its safety and the immune system's response to it. The PepGNP-COVID19 study product is made of tiny particles of gold (microscopic, or too small to see with the naked eye) that carry small pieces of protein from the SARS-CoV-2 virus. The study product has been specially designed to stimulate special cells of the immune system that may prevent severe COVID-19 or cause your body to develop immune responses that will stop COVID-19 infection and block it from being passed between people. We will take samples of blood and swabs of your nose to see how your body responds to the study product. This will help us to understand how the study product works.

"Experimental" means the United States Food and Drug Administration (FDA) has not approved this study product for routine use but allows it to be studied in this research study. The PepGNP-COVID19 vaccine has already been tested in 20 healthy adults in Switzerland: volunteers were given two injections of either the middle or highest dose of study vaccine that will be tested in the study described in this consent form. In that study, the study vaccine was safe and well tolerated. The most common reactions were mild discoloration (bluish-brown color) at the injection site that lasted a few days before completely going away. Pain, redness and swelling at the injection site have generally been mild. In the Swiss study, mild redness and swelling at the injection site sometimes appeared late, even more than 7 days after getting the study vaccine, and could last for months.

Selection of Study Participants

Approximately 60 people will participate in this study at three study sites. Adults aged 18 through 64 years who are in a good state of health may enroll. We will screen you for eligibility before conducting further study activities or administering the study product. If more than 28 days pass after your screening visit and you haven't received the study product, we will repeat the procedures listed below, if you agree to continue participating in the study.

You are **not** eligible for this research study if:

- You have not received a complete COVID-19 primary vaccine series and at least one subsequent COVID-19 vaccine booster
- You received a COVID-19 vaccine or have had a SARS-CoV-2 infection in the 16 weeks before the study product administration

- You are positive for SARS-CoV-2 infection at screening
- You received an investigational drug in the past 60 days OR plan to receive one during your participation in this study
- You received or plan to receive a non-live vaccine within 14 days or a live vaccine within 28 days of getting the study product
- You have certain chronic medical or psychiatric conditions
- You are on certain medications
- You are pregnant, plan to become pregnant during the study, or could become pregnant but have not been using effective contraception
- You are breastfeeding

There are other reasons why you may not be able to participate in this study, which we will discuss with you.

Lifestyle Considerations

During the study, you will be asked to:

- Not receive an investigational study product or drug outside of the study until after your 6-month visit.
- Attend all scheduled study visits.
- Refrain from receiving a live vaccine from the day you get the study product through Day 29. Refrain from receiving any other vaccine through Day 15. If you receive a licensed vaccine outside of these windows, you should inform the study team.
- Refrain from receiving a COVID-19 vaccine/booster vaccine through Day 181 (the final study visit).
- Avoid the use of nasal irrigation or sinus rinsing treatments (e.g., neti pots, saline washes) for 28 days after getting the study product and for 7 days before study visits for the remainder of the study.
- Follow public health guidance on preventing SARS-CoV-2 infection.
- Contact the clinical site immediately if you develop signs and symptoms consistent with COVID-19 to schedule an illness visit at the study site.

What Will Happen During the Study?

This study will enroll participants into one of 3 study groups: participants within each group will get a different dose of study product, either a low dose, a medium dose, or a higher dose. The group that you are assigned to will be chosen randomly as you enter the study, like flipping a

coin. We will not tell you which dose of study product you got until your final study visit. You will only receive a dose of the study product once.

Group	Number of Participants	Study Product Dose
1	20	0.83 nmol PepGNP-COVID19 injected just under the skin in a volume of 0.05mL
2	20	2.5 nmol PepGNP-COVID19 injected just under the skin in a volume of 0.05 mL
3	20	7.5 nmol PepGNP-COVID19 injected just under the skin in a volume of 0.05 mL

Your participation in this study will last approximately 6 months with 9 planned study visits: this includes this screening visit, one visit where you will receive the study product, six clinic visits to check on your reaction to the study product, and one study contact (phone call, text, or email).

Screening

You will have a Screening Visit to check if you are eligible to enroll in this study, which will take about an hour and will include:

- Learning about the study and asking questions
- Reviewing and signing this consent form
- Collecting information about your health, medications, vaccination history, and any drug and alcohol use
- A physical exam
- Checking your vital signs (temperature, blood pressure, and heart rate)
- Measuring your height and weight
- A nasal swab to test for SARS-CoV-2 infection
- For people of childbearing potential, we will ask about your use of birth control and a urine sample will be obtained for a pregnancy test
- A sample of your blood will be drawn to check your kidney and liver function, blood cell counts, and for testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the results of these tests to the local health authority

If you are excluded because your screening results require medical attention, the study doctor

will ask you to follow up with your doctor.

Study Visits

The study product administration visit will generally last about 2 hours. Other visits will generally last about 30 minutes. Visits may include the following procedures:

- Questions about your recent medical history and medications, illnesses or symptoms, and side effects or reactions
- Measuring vital signs (heart rate, blood pressure, temperature) before the study product administration and at other visits if needed
- Having a physical exam if needed
- Collection of blood and nasal samples (this may include testing for other respiratory viruses)
- For people who can become pregnant, urine for pregnancy testing before study product administration

At the study product administration visit, we will review your medical history to confirm if you are still eligible, and then administer the study product to you. The study product is given by injection just under the skin of the upper arm. This injection will be given to you using an FDA-cleared device called a "NanoPass MicronJet" that has three very small needles at the end of a syringe that inject the study product just under the skin.

You will stay in the clinic for at least 30 minutes after the study product administration so that study staff can check for any immediate reactions.

We will give you a thermometer and a memory aid with instructions to record your temperature, medications, and any side effects. You will complete the daily memory aid at home, beginning on the evening of the day of study product administration and continuing for the next seven days. Study staff will contact you the day after the study product administration visit to ask about any side effects and to remind you to complete the memory aid. The memory aid will include the study team's contact information. You will be asked to bring the memory aid to your next clinic visit.

We will ask you to keep track of any symptoms (expected or not) that you develop after receiving study product. You will also visit the clinic (or communicate with us by phone, text, or email) for follow-up visits.

We may ask you to visit the clinic for an extra study visit. The staff will perform visit procedures and may collect additional samples if needed, based on the reason for the visit. This may be for your safety or for research purposes.

The study staff will contact you after your study product administration to check on your health status, to remind you of an upcoming visit, or for other reasons. We may also contact you by email or text message when appropriate.

Unscheduled Visits

You should immediately contact the study staff using the contact information found on the first page of this form if you become sick or have any significant or concerning reactions after the study product administration. You may be asked to return to the study clinic or have a remote visit if needed. For example, if you have a reaction or illness that should be evaluated before the next scheduled visit, the study doctor will determine what activities will be needed after reviewing any symptoms that you are having.

Collection of Samples for Research Purposes

Blood: We will collect blood samples at all scheduled in-person research clinic visits.

Nasal: We will use a swab (like a "Q-tip") and nasal strip (a short, narrow strip of thin paper) to collect mucus from inside your nose at all scheduled in-person research clinic visits.

Lab Testing of Specimens

The blood and nasal specimens collected from you will be used for research tests of the immune response to the study product. We will also look at how different cells of your immune system help to fight the virus. Nasal specimens will also be tested for SARS-CoV-2 and other respiratory viruses if needed.

Giving blood and nasal samples for the research tests will not benefit you. It may help others in the future by leading to new vaccines or treatments for COVID-19. The results of these tests are useful only for research purposes.

Your research test results will not be available to you or your regular doctor and will not be included in your medical record.

Genetic Testing

For this study, we will perform genetic testing on your biological samples. This genetic testing will focus on COVID-19 and provide information about how your body responds to the study product and/or disease. We will not do genetic tests that check for disorders or biomarkers for other diseases. You will not receive the results of the genetic testing. A summary of the genetic results from all participants in this study, without personal identifiers, may be placed in a public, open-access database that anyone can freely use. No individual genetic testing information or results will be placed in an open-access database, so the risk of anyone identifying you with this information is very unlikely. We will share your genetic information (data) through a "closed" database, also called a restricted data repository. NIH may allow qualified researchers to access and use your genetic information for other research. Types of research using your data may be related to COVID-19, infectious diseases, or other types of research. Your data will not contain information that can easily identify you. It may be possible to identify you with your DNA; however, the researchers must follow rules specifically not to identify you. If you change your mind and want to remove your data from the database, you should contact the research site that collected your information and specimens. If possible, your information can be removed for secondary research. Your data cannot be removed if it has already been used.

We will remove the codes from your information or samples so that we cannot identify you and may then use these samples in other research.

Use of Samples or Data in Other Research Studies

Biological Samples

Some of the biological samples (blood and nasal) collected for measuring immune responses to the study product may not be needed for the research tests. We will store and use these leftover samples and your information for secondary research. Secondary research is not part of this study but will be performed in the future. You will not be told about the future research.

We will also collect extra biological samples at each visit to store and use for secondary research. Secondary research may help us understand how the study product works, develop tests, study other infections or diseases, or develop treatments. **You cannot enroll in this study if you do not want to give your leftover and extra samples for secondary research.**

Your biological samples will be stored indefinitely at a site determined by the NIH. Leftover and extra samples will be labeled only with a barcode and an ID code (not your name, initials, or any other information that could readily identify you). These leftover and extra samples will be stored using the same confidentiality measures as the main specimens.

Leftover and extra biological samples may be used in the future for research about this study product and your body's response to this study product. This may include genetic testing. Genetic testing looks at the material in your cells that tells each cell in your body how to work. Future genetic testing may include whole genome sequencing (DNA testing) or other types of genetic testing (including tests that have yet to be developed) to inform the development of new vaccines or for the studies of coronaviruses or other infections. The genetic testing is for research purposes only, and it cannot tell you about relatives, paternity, or country of origin. The genetic research testing done in this study will not tell you about diseases that you may get in the future. We will not give you the results of the genetic research testing.

At any time during or after this study is over, biological samples may be shared with other study doctors/institutions and used for secondary research, including genetic testing. Also, after future genetic testing, the resulting data may be shared with other researchers. We will share your future genetic information through a "closed" database called a restricted data repository. NIH may allow qualified researchers to access and use your genetic information for other research. A summary of participant data may be shared in an "open-access" database, but this will not contain your data. The risk of anyone identifying you with this information is very unlikely. However, there is still a risk of loss of confidentiality.

Your data will not contain information that can easily identify you. Although it may be possible to identify you with your DNA, the researchers must follow rules specifically not to identify you. If, after you have provided consent, you change your mind and want to remove your data from the database, you should contact the research site that collected it. If possible, your data can be removed for further research. However, your data cannot be removed if it is already used.

Leftover and extra biological samples will be used only for research purposes. This may include

reproducing or growing your cells. These blood samples will not be sold or used directly to make commercial products. However, the research studies in this study or in the future may lead to identifying antibodies or other treatments that could indirectly lead to a commercial product that protects against viral infection or disease.

Although the results of any future research may be patentable or commercially profitable, you will not receive payment if this happens. You will have no legal or financial interest in any commercial development resulting from any future research.

If these biological samples are tested in the future, the results may be published. You will not be identified in such a publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

There are no benefits to you in the collection, storage, and future research use of your biological samples. Future research tests may benefit others by leading to new approaches in developing vaccines or treatments for coronavirus infections. The results of any future research testing will be kept confidential, just as the results of other testing done for this study. The results of any future research will not be available to you or your regular doctor and will not be placed in your medical record.

You may change your mind about secondary research and withdraw consent to store and use your coded samples or information at any time. To do so, you must contact the study doctor using the contact information on page 1 of this form. If you have visits after this, we will stop collecting extra biological samples. When the study is completed, your samples will be removed from future use. Only stored samples with an ID code not used in this research can be removed or destroyed. Research that has already begun using your specimens cannot be withdrawn. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, if the specimens and data have been shared already with other researchers, withdrawing the specimens and data might not be possible.

Ask us if you have questions about how your biological samples may be used.

Potential Risks and Discomforts

There may be some risks to participating in this study. You may experience one or more risks or side effects explained below. You should discuss these with the study doctor or study staff. Many side effects go away shortly if treated, but in some cases, they can be serious, long-lasting, or permanent.

The possible risks of participating in this study include those associated with having blood drawn, reactions to the injected study product, adverse effects (side effects) of the study product(s), having nasal swabs/strips collected, and the possibility of a breach of confidentiality.

Having your blood taken can cause pain and may also cause lightheadedness or fainting. Although it is unlikely due to the small amounts of blood that will be collected during the study, having your blood taken may cause you to have low red blood cell counts (anemia). The needle stick can cause bruising, which can be prevented or reduced by putting pressure on the site for a

few minutes after removing the needle. It is possible to get an infection at the site of the needle stick. To reduce the risk of infection after the blood draws or study product injection, the study staff will wipe the area, clean the area with alcohol, and use sterile equipment.

The risks associated with having nasal swabs/strips collected may include discomfort, eyes watering, nose bleeding, coughing, and sneezing.

Risks and Possible Side Effects that you may Experience with the Study Product

After a study product administration, a person might experience fever, chills, fatigue, body aches, nausea, diarrhea, headache, dizziness, swollen lymph nodes, or discoloration, redness, swelling, or pain at the injection site.

There is a small risk of a serious allergic reaction. These reactions can start with your tongue swelling, feeling lightheaded or dizzy, rash, a fast pulse, sweating, wheezing or having difficulty breathing. If this happens, study staff can give you emergency medications that can usually stop the reaction. Most people who experience these reactions recover completely although in very rare cases death can result if the reactions are not treated.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COVID-19 mRNA vaccines. However, the study product being tested in this study does not contain mRNA and we anticipate the chance of myocarditis or pericarditis caused by the study product is very low. In any case, we will monitor your safety closely throughout your participation in the study.

The study product tested in this study cannot cause SARS-CoV-2 infection.

This study product has been tested in animals and in one study of 20 adults in Switzerland, and no concerning side effects were identified.

In addition to these risks, there may be risks of the study product that are not yet known. If new information about risks becomes known during the study, we will share this with you. Your safety and the safety of all study participants will be monitored throughout the study by a group of independent experts who can recommend that study product administrations are stopped if there are any safety concerns.

Please tell the study staff immediately if you have any side effects. Please tell them if you have any other health problems, how you feel during the study, and whether you think these problems are related to the study product.

For Participants of Childbearing Potential, Risks Related to Pregnancy

You cannot be enrolled in this study if you are:

- Pregnant
- Planning to become pregnant within 60 days after study product administration
- Breastfeeding

There may be unknown risks to the embryo, fetus, or breastfed child. If you can become pregnant, you must have a negative urine pregnancy test at screening and before study product administration. You must also use an effective method of contraception from 30 days before study product administration until 60 days after study product administration.

If you become pregnant while in this study, you should report this immediately to the study staff. With your permission, the study staff will ask about your health, collect information from you through the outcome of your pregnancy, and collect scheduled biological samples. The study staff may share this information with the study sponsor and with the Advarra Institutional Review Board (IRB), a group of people who review research studies to protect the rights and welfare of research participants.

Risks of Storage and Sharing of Samples and Data

When we store your data and samples, we take precautions to protect your information from others who should not have access to it. When we share your data and samples, we will do everything we can to protect your identity by removing information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known, or someone may gain unauthorized access to your information.

Data placed in the NIH-designated database will have identifiers removed, such as name, address, and identification numbers. Because it may be possible to re-identify genetic data, even if access to data is controlled, confidentiality cannot be guaranteed.

Risks of Genetic Testing

Since your genetic data and health information may be stored and shared with other researchers, there may be a risk that information resulting from research genetic testing could be misused for discriminatory purposes. However, state and federal laws provide some protection against genetic discrimination. If you have any questions, please ask the study doctor. Researchers who have access to your genetic information will take measures to maintain the confidentiality of your information, as described below. Risks may also result if you disclose the information yourself. New methods may be created in the future that could make it possible to identify you by your data or samples.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Benefits

You may not benefit from being in this study. However, the results of this research might help others by contributing knowledge that could lead to the development of next generation COVID-19 vaccines and/or findings that could be helpful for the development of future vaccines.

Alternatives to Participation

The only alternative is to not participate in this study. You can receive vaccinations as recommended by the FDA or choose to receive none.

New Findings

We will contact you about any new information and explain how this may affect your health or willingness to stay in this study. You may be asked to sign and date a revised consent form if this occurs.

Source of Funding for the Study

The study site is receiving payment from the NIH, National Institute of Allergy and Infectious Diseases, the study's sponsor.

Compensation for Participation

You will be paid for your time and expenses related to participation in the study, such as transportation. You will receive [redacted] for the vaccination visit, [redacted] for each non-vaccination study visit where you must come to the clinic and [redacted] for a safety contact (telephone call, text, or email). Therefore, you will receive [redacted] in total if you complete all scheduled study visits. When you are asked to come into the clinic for an unscheduled visit, you will be compensated [redacted] for each visit.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid following each visit; however, you will not be compensated for any missed visits.

[redacted]. Information about this system is provided in a separate document you will be asked to sign if you wish to receive payments.

Payments may be considered taxable income. Your name and social security number will be reported to the University for the purposes of making and recording payments. If you get [redacted] or more, from this or other studies at [redacted], in taxable payments within a calendar year, the University is required to report the amount you received to the Internal Revenue Service (IRS) on a Form 1099-MISC. This form tells the IRS that payment was made to you but does not say you were paid for taking part in a research study. You are responsible for paying income taxes on any payments provided by the study and should consult your tax advisor regarding the proper use of this Form 1099-MISC.

If you have any questions regarding your compensation for participation, please contact the study staff.

Cost of Participation

You will not have to pay to receive the study product. There are no costs for the study visits, tests, or procedures performed as part of this study.

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that is not a part of this study.

To find out more about costs, ask the study staff.

Compensation for Injury

You may have medical problems or side effects from taking part in this research study. If you are injured because of being in this study, you should notify the study doctor as soon as possible. If there is an emergency, call 911 immediately or go to the emergency room and contact your study doctor as soon as possible.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- [redacted]
- Your physician; or
- Treatment center of your choice.

If you are directly injured by the study product being studied or by medical procedures needed because of this study and receive medical care for the injury, you or your insurance will be responsible for payments to cover the cost of medical care and treatment needed for your research injury. You might not be reimbursed for all of the costs for care and treatment covered and paid for by a third party like your health insurance provider or costs such as required co-payments or deductibles related to that coverage. No long-term medical care or financial compensation for research-related injury will be provided by the NIH or the Federal Government. There are no plans for the [redacted] to pay you for any injuries or illnesses.

You do not give up any of your legal rights by signing and dating this form.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a participant in clinical studies utilizing COVID-19 countermeasures, such as the study vaccines, PepGNP-COVID19. Because this study is covered by the PREP Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers, and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program (CICP). This is a program set up by the Health Resources and Services Administration (HRSA) of the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. **If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.**

Confidentiality

Paper documents containing personal information about you will be kept in locked file cabinets, and computerized information will be kept in password-restricted files. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access to personal information with your identifiers, all of which will be kept only at the study site.

By signing and dating this consent form, you are giving permission for representatives of the NIH, the Office for Human Research Protections (OHRP), the FDA, and the Advarra IRB (a group of people who review research studies to protect the rights and welfare of research participants), as well as the study doctor and other employees of the study site involved with this research study, to inspect sections of your medical and research records related to this study.

The FDA may choose to inspect your records since you are a participant in this research study. When a study is submitted to the FDA, the study doctor agrees to allow the FDA access to the study records. The FDA will treat the information as confidential, but on rare occasions, disclosure to third parties may be required by law. Therefore, absolute protection of confidentiality cannot be promised.

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.

Certificate of Confidentiality

To help us protect your privacy, we have a Certificate of Confidentiality from the NIH. Study staff cannot provide to any person not connected with the research your name or any materials that contain identifiable, sensitive information about you unless permitted by a legal exception, such as state laws that require reporting of some contagious diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of

your identifiable, sensitive information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission.

The study team will use the Certificate to resist any demands for information that would identify you.

Your information protected by the Certificate may still be disclosed or used when the information:

- is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH or;
- is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the FDA. This does not include disclosure for use during legal proceedings, as noted above;
- is necessary for your medical treatment, and you have consented to this disclosure;
- is for other scientific research as allowed by applicable federal regulations;
- is disclosed with your consent.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others, including, for example, child abuse and neglect, and by signing and dating below, you consent to those disclosures.

Authorization to Use and Disclose Protected Health Information

To be in this research study, you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short). Health information may include your name, address, phone number, date of birth, medical history information about your study visits, and information about your study visits, including all tests.

Health information (also called data) may come from your study records or from existing records kept by your doctor or other healthcare workers.

The types of information that will be used and shared include:

- Laboratory test results, EKG/ECG results, diagnosis, and medications
- Reports and notes from clinical and research records
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports

- If applicable, information concerning HIV testing or the treatment of AIDS, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes)

For this study, the study staff may share health data about you with authorized users, including:

- The Department of Health and Human Services (including the National Institutes of Health [NIH])
- The Office for Human Research Protections (OHRP)
- Additional governmental agencies in the United States
- Advarra (the Institutional Review Board for this study)
- Your physician
- The Food and Drug Administration (FDA) and other US federal and state agencies
- A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations, or interventions
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study
- Other research doctors and medical centers participating in this study

Your health data will be used to conduct and oversee the research, including, for instance:

- To do the research (including safety tracking)
- To study all the results
- To see if the research was done as planned

If the results of this study are made public, information that identifies you will not be used.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will last indefinitely.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. No new health data that identifies you will be gathered after your written request is received. However, your samples and health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to prevent changes to the study results. When the study is over, you can access your study health data. However, clinical health information or clinical laboratory results may be provided to you if you need medical care.

If you decide not to sign and date this form, you cannot participate in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

Whom to Contact About this Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant contact:

- By **mail**:

  Study Subject Adviser

  Advarra IRB

  6100 Merriweather Dr., Suite 600

  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00089846.

Voluntary Participation / Withdrawal

Your signature and date on this consent form means that you have received the information about this study and that you agree to be a part of the study. Your participation in this study is voluntary. You may decide not to participate, or you may stop your participation at any time without penalty if you no longer want to be in the study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You will be given a copy of this signed and dated consent form to keep. You are not giving up any of your rights by signing and dating this consent form. Even after you have signed and dated this consent form, you can ask questions at any point during the study, and you may change your mind about participating at any time. Please contact the study staff if you decide to stop participating in this study.

The study doctor or sponsor may decide to stop you from taking part in this study at any time without your consent. You could be removed from the study for any of the following reasons:

- You miss research visits
- You are unable to comply with study procedures or instructions
- You withhold information about your health history or medications
- Reasons related to your health
- If you have a serious reaction to the study product
- Because the entire study is stopped (the sponsor may stop the study at any time)
- If you do not later consent to any future changes that may be made to the study
- If you become pregnant
- Any other reason

If you decide to stop or the study doctor withdraws you, we may ask you to come for a final visit. This visit may include activities listed in the general study visits. We will stop collecting your information and specimens for research when you withdraw your consent or are withdrawn by the study doctor. However, any information and specimens collected before withdrawal may continue to be used for this study.

The Advarra IRB, the FDA, other regulatory agencies, or the sponsor (NIH) who oversee the conduct of this study can stop the study at any time for safety concerns or other issues.

Consent

I have read (or have had read to me) and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date