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

Sponsor / Study Title: **National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID) / "A Phase 1 Study to Evaluate the Safety and Immunogenicity of Two Doses of a Novel H5 Antigenically Central (AC)-Anhui mRNA-LNP Vaccine in Healthy Adults"**

Protocol Number: **24-0024**

Principal Investigator: (Study Doctor) [redacted]

Telephone: [redacted]

Address: [redacted]

Key Information

The purpose of this research is to test experimental flu vaccines. The goal is to test a study vaccine that is specific to one type of bird flu (called A/H5-Astrakhan) with a study vaccine that may cause a wider response to several strains of bird flu (called A/H5-AC-Anhui). During the study, these two messenger RNA (mRNA) study vaccines for avian influenza (bird flu) will be given to people for the first time.

- You will be in the study for approximately 7 months.
- There are two study vaccines being tested.
- There are two stages to the study. You may participate in one of the stages. If you are eligible and participate in the first stage, you could receive either 12.5 mcg, 25 mcg, or 50 mcg of the H5/AC-Anhui-mRNA vaccine. After enrolling stage 1, the study team will decide which dose is best to use in the second stage. If you are eligible and participate in this second stage, you could be assigned by chance, with equal odds, to receive either H5/AC-Anhui-mRNA vaccine or H5/Astrakhan-mRNA vaccine.
- You will have up to 8 study visits that could include a screening visit (if needed), 2 study vaccine visits, and 5 follow-up visits. You will receive 2 injections, approximately 1 month apart.

- You will have physical examinations, blood sampling, and laboratory testing for safety and immune responses.
- As instructed, you will complete a daily memory aid (like a diary) at home to record any side effects that you may experience for 7 days after each study vaccine.
- The possible risks of participating in this study include side effects of vaccine administration, in general, which include arm soreness, achiness, and other symptoms common after vaccines. There is a potential risk of rare side effects and there may be risks that we do not yet know about. These risks will be detailed below.

You may or may not benefit from being in this study. Since this is the first study in humans, we do not know yet if the study vaccine causes the type of immune response that is needed to protect against bird flu.

When you participate in this study, you are also asked to consent to secondary research (the research is not planned yet). We will use your coded information (not your name or any personally identifiable information), leftover samples, and extra samples for secondary research. The secondary research may include genetic testing, such as the genetic sequences of any antibodies that you make.

It is entirely your decision if you want to take part in this study; there are no changes to your healthcare if you decide not to take part.

Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

The remaining document will now describe more about the research study. Members of the study team will talk with you about the information in this document. You are encouraged to ask questions and discuss this study with site staff, family, friends, and personal health care providers to help you make your decision.

Purpose of This Research Study

Influenza (Flu) is a potentially severe disease caused by a virus that can spread from one person to another. In 2024, the United States experienced increased circulation of a strain of influenza called avian influenza (bird flu) among dairy cattle. In addition, there have been sporadic cases of bird flu among individuals with exposure to dairy cows and poultry. Researchers are looking for new ways to prevent or minimize bird flu through the use of a vaccine.

The purpose of this research study is to test experimental mRNA-based bird flu vaccines called mRNA-H5-AC-Anhui and mRNA-H5-Astrakhan and to measure the safety and immune system responses. Vaccines tell your germ-fighting cells to make antibodies. Your body uses antibodies to fight infections.

"Experimental" means this vaccine is not approved for use by the United States Food and Drug Administration (FDA), however, the FDA is allowing this vaccine to be used in this study. The vaccine tested in this study cannot cause influenza infection.

There will not be a placebo used in this study; everyone will receive one of the two study vaccines.

In Stage 1 of the study, all participants will receive the mRNA-H5-AC-Anhui vaccine. We will vaccinate with the lowest dose of 12.5 mcg first, then a higher dose of 25 mcg, and then the highest dose of 50 mcg to see if it is safe and how your body responds to the study vaccine.

In Stage 2 of the study, participants will be randomly assigned (like the flip of a coin) by a computer program to receive one of the two study vaccines. Participants and the research staff will not know which study vaccine that they receive.

The study vaccine is given as two doses, about 4 weeks apart.

We will take blood from you to see how your body responds to the study vaccine. This will help us to understand how the study vaccine works.

If you agree to take part in secondary research, an investigator may use blood from you to do genetic testing, which could identify your DNA. DNA is inherited material in your cells that tells us how your body works. One of the ways that we can measure how your immune cells respond to a vaccine is by studying the antibodies that your body makes.

Approximately 80 people will participate in this study at 3 sites over 15 months.

Selection of Study Population

Only healthy adults, age 18-49 years old may enroll in this vaccine study. We will screen you for eligibility prior to performing any further study activities or giving you the study vaccine.

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

- You have received a vaccine or investigational drug recently or plan to receive an investigational drug during your study participation
- You have any serious chronic medical or psychiatric condition
- You are on certain medications
- You are pregnant or breastfeeding
- You have a history of myocarditis or pericarditis
- You have any medical condition the study doctor thinks would make your participation unsafe

Procedures

If you agree to take part in this study, your involvement is expected to last for approximately 7 months.

Screening (Pre-Vaccination)

You may have a Screening Visit to check if you are eligible to enroll in this study. This visit can also happen at the same time as your Enrollment Visit. The Screening Visit includes:

- Reviewing and signing the informed consent form
- Medical and mental health history, medication and birth control, vaccinations, and any drug or alcohol use
- Physical examination including height and weight
- Vital signs (heart rate, blood pressure, temperature)
- Urine or blood pregnancy testing for those of childbearing potential

If you are excluded because your screening results require medical attention, the study doctor will refer you to a health care provider.

All participants of childbearing potential must use an effective method of birth control at least 30 days prior to first study vaccination and for at least 60 days following the last study vaccination. Effective birth control methods may include, but are not limited to:

- Abstinence
- Monogamous relationship with a vasectomized partner
- Intrauterine devices
- Birth control pills
- Hormone birth control products that are injectable, implantable, insertable, or placed on the skin.

General Study Visit Procedures

Study visits will generally last from 30 minutes to 1-2 hours and may include:

- Questions or updates about your recent medical history, illness or symptoms
- Review of your memory aid and any side effects/reaction
- Review of your medications
- Review your test results
- Vital signs
- Recheck birth control methods and/or pregnancy status

- Physical examination, as needed
- Collection of blood samples
- Vaccination administration or assessment of the injection site
- Receiving further instructions for participation

Sampling for Research Purposes
Blood samples: Blood will be taken through a needle in your arm. We will draw approximately 4-5 tablespoons of blood at each visit.

Collection of urine: We may ask you to provide a sample of urine in a collection container for urine pregnancy testing.

Study Vaccination Visits
During these visits, we will review your history to confirm that you are eligible for study vaccination.

Study Vaccination Visits may take up to 1-2 hours. These occur on Day 1 and Day 29. If you are one of the first 10 participants in the study, you will receive 12.5 mcg of H5/AC-Anhui mRNA vaccine. If you are one of the next 10 participants, you will receive 25 mcg of H5/AC-Anhui-mRNA vaccine. If you are one of the next 10 participants, you will receive 50 mcg of H5/AC-Anhui-mRNA vaccine. Then, the study team will decide which study vaccine dose is best. In Stage 2, a computer program will randomly assign you to one of two study groups before your first dose. Neither you or the staff giving you the study vaccine will know what study vaccine you will be given or if you receive the Anhui vaccine or the Astrakhan vaccine.

You will receive 2 doses of study vaccine approximately 1 month apart. There is no placebo group; everyone will receive a type of bird flu study vaccine. After you receive the shot in your arm, we will watch for any immediate side effects for about 30 minutes. At the end of your visit, we will provide a thermometer and memory aid (diary) with instructions to measure your temperature and write down any side effects. At home, you will complete the memory aid daily for one week after each vaccine dose and return the form with you at your next visit. The memory aid will also include study team contact information.

Follow Up Visits (Post-Vaccination)
You will come to the clinic for follow up after each study vaccine. After your enrollment visit (Day 1), you will return to the clinic one week later (Day 8). You'll return on Day 29 for your second study vaccination and again return one week after that (Day 36). We will then see you at approximately 1 month later (Day 57), two months later (Day 119), and 6 months later (Day 209). Follow-up Visits may take up to 30-45 minutes and may include activities performed in the general study visits.

Risks and Discomforts

There may be some risks to participation in this study. You may experience one or more of the risks or side effects explained below. You should discuss these with the study team and/or your health care provider.

Risks and side effects that you may experience with this study vaccine

After this bird flu study vaccination, a person might experience:

- **Minor to moderate events:**
    - Sore arm from the injection (shot)
    - Redness, swelling, hardness or itching at injection site
    - Rash (hives)
    - Fever, chills, or fatigue (tiredness)
    - Flu-like symptoms, such as runny nose or cough (although again, the study vaccine cannot cause the flu)
    - Headache, muscle aches, pain and stiffness in the joints
    - Nausea, or vomiting
    - Swelling of the lymph nodes under the arm
    - Temporary abnormal laboratory tests
    - People sometimes faint after vaccination
- **Severe events could occur very rarely:**
    - Any reaction above could be severe
- **Severe allergic reactions are rare (i.e., approximately 1 in a million).** The symptoms would start a few minutes to a few hours after the study vaccination. An allergic reaction can include:
    - Difficulty breathing
    - Swelling of the face and throat
    - A fast heartbeat, dizziness, and weakness
    - Anaphylaxis (also known as allergic shock)
- Guillain-Barré Syndrome (GBS): an illness of muscle weakness, numbness and tingling in the extremities, and can progress to temporary paralysis. GBS after influenza vaccine is exceedingly rare, occurring at approximately 1-2 per million doses of vaccine.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received authorized and FDA-approved mRNA-COVID vaccines, most commonly in males 12-29 years of age. Cases have also been seen in other age groups (including older and younger males) and in females. In most of these people, symptoms began within a week following receipt of

vaccine and have been described most commonly after the second dose of COVID-19 mRNA vaccines. While some cases required intensive care support, data from short-term follow-up suggest that symptoms resolve in most individuals with supportive care and standard treatment. Information is not yet available about potential long-term consequences of myocarditis. The chance of having this occur is very low.

During the study, we want you to be mindful of any symptoms that may be related to myocarditis or pericarditis. These symptoms include chest pain, shortness of breath, or feelings of a fast beating, pounding, or fluttering heart. You should seek medical attention right away and notify the study team if you have any of these symptoms after receiving the study vaccine.

- As with any medicine, there is a very rare chance of the study vaccine causing a serious injury or death.
- If you have any of the above reactions after leaving, you should immediately seek medical attention and contact your study team.

You will be closely monitored for 30 minutes after study vaccination.

It is important that you tell the study team about any side effects. We may ask you to come to the clinic for a visit to check you. The study team may perform additional research or safety procedures, if needed. Emergency treatment will be available to you if you experience illness or reactions while participating in this study. You will be closely monitored until the side effect resolves.

Risks Related to Pregnancy

If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the vaccine being studied that could increase the risk of harm to a fetus. You need to wait at least two months after the last study vaccination before you become pregnant.

If you can become pregnant, you will have a pregnancy test before receiving each dose of the vaccine. You must use effective birth control methods and agree not to become pregnant **until at least 60 days (approximately 2 months) after receiving the second dose of vaccine.**

If you think that you have become pregnant while participating in this research study, please contact the study team as soon as possible. The study team will ask your permission to follow-up with you about your health and the health of your baby until the end of your pregnancy.

Risks of Blood Sampling

Having your blood taken from a vein in your arm can cause temporary pain, fainting, bruising, and rarely infection. These risks/discomforts will be minimized by the study team's use of proper blood sampling techniques. Rarely, anemia (low blood counts) can occur with blood sampling, though the amount we are collecting is not expected to do this.

Risks of Storage and Sharing of Samples and Data

When we store your information and blood samples, we take precautions to protect your information from others that should not have access to it. When we share your information or 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.

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 protections against genetic discrimination. If you have any questions, please ask your study doctor. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your information as described below. Risks may also result if you disclose information yourself or give separate consent to have your research records released. New methods may be created in the future that could make it possible to identify you by your data or samples.

GENETIC INFORMATION NONDISCRIMINATION ACT

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 deciding 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.

Unknown Risks

You may experience unknown side effects that are harmful and/or long-lasting. You may experience unknown side effects or discomforts that are not listed in this form. Tell the study team right away if you have any problems.

Benefits of Being in The Study

You might not benefit from being in this study.

However, the potential benefit to you might be personal protection against bird flu if the vaccine is effective.

Even if you receive no benefit, the results of this research might benefit others by leading to new or novel approaches in vaccine development for influenza.

Alternatives to Participating in This Study

You can choose to not participate in this study.

Early Withdrawal from the Study and Follow-Up

You can stop being in the study at any time. There is no penalty or loss of any benefits to which you are otherwise entitled if you choose not to enroll, stop or change your mind. Always tell the study team if you wish to stop. They will discuss any concerns about your safety and whether you need any follow up or medical care.

Also, the study doctor may take you out of the study if this research is not in your best interest or for the following reason(s):

- You are unable to comply with study procedures or instructions (including use of effective birth control)
- If you withhold information about your health history or medication taken
- You have a severe or unexpected reaction

If you decide to stop or the study doctor withdraws you, we will 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/samples for research when you withdraw your consent for the research or are withdrawn by the study doctor. However, any information and specimens collected prior to any withdrawal may continue to be used for this study.

The Institutional Review Board (IRB), the Food and Drug Administration (FDA), other regulatory agencies, or the sponsor (NIH/NIAID) who oversee the conduct of this study can stop the study at any time for safety concerns or other issues.

New Findings

We will contact you about any new information about risks, and explain how this may affect your health, well-being, or willingness to stay in this study.

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.

Return of Results

You will not receive individual results from the research tests during your participation. If you have any abnormal clinical test results that may require medical care, we will share these results with you.

We are doing genetic testing (sequencing) for research purposes and not to look for inherited disease or defects, therefore, we will not return results from any antibody sequencing that is performed.

Confidentiality and Privacy

We will make every effort to protect the privacy of your information.

Your information will be stored on secure, password-protected computers or servers. Research samples and data will be linked to you using an assigned study code. The code does not include your name or other information that could be used to easily identify you. A code key, kept only at your study site, links the samples and information with your name and contact information. Access to the data and samples is limited to people working on this study and to those who provide oversight.

Your data may be shared with people who oversee the conduct of this study. Monitors, sponsor, auditors, the Institutional Review Board (IRB), and regulatory authorities such as the FDA will be allowed to look at your medical and research records. They check that the procedures are being done correctly. They will protect your confidentiality to the fullest extent possible.

If the study results are published in a scientific paper, no information will be included that can identify you.

Any identifiable, sensitive information about you used in this study is protected by a NIH Certificate of Confidentiality, which prohibits researchers from disclosing that information to persons not connected to the research under certain circumstances.

Certificate of Confidentiality

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

Use of Samples or Data in Other Research Studies

CONSENT FOR SECONDARY RESEARCH WITH CODED INFORMATION OR SAMPLES

Secondary research means other research using data and/or samples collected during this study, for purposes that are not planned in this study. Data and samples may be coded or may be completely "de-identified" when used for secondary research. "Coded" is explained below. By "de-identified" we mean that the samples and data are not linked to the person. De-identified data may be entered into a public database after the study has ended.

As part of the study at some of the study visits, we will be saving blood samples that will be stored for secondary research. Any samples of blood that remain after we do the testing for this study will be stored for secondary research. You will not be contacted about the secondary research.

Secondary research may help us understand how the study vaccine works, develop tests, study other infections or diseases, or develop treatments. Your samples may be used for secondary research to learn more about the immune response to influenza vaccine. Your samples may also be studied, tested, and used for research related to infectious diseases. This may include genetic research to study immune responses.

STORAGE OF DATA AND SAMPLES FOR SECONDARY RESEARCH

Your data and extra/leftover samples will be stored indefinitely (time does not expire) once this study is completed.

Samples will be stored in a Biospecimen Repository that is approved by NIH/NIAID. Stored samples and your information may be shared with other investigators, institutions, or drug companies. The samples will not be sold or used directly for production of any commercial product. You will not receive compensation for this research. You will not share in the commercial profit if your specimens provided for this study lead to a licensed product.

Samples will be coded so that your name cannot be readily identified. Each sample will be labeled with a unique tracking code. Personnel at the storage facility and testing lab will not know your identity. However, the researchers who enrolled you will keep in a secure area a list with your name and the tracking code that matches the samples to identify you, if needed. Often the secondary research is done with the codes, however, sometimes use of samples and data for secondary research may remove the codes.

The risks include a potential loss of confidentiality if someone can identify you, however, the risk is low because information is maintained with limited access by the study team. Researchers are asked to not re-identify the coded data or samples. There are no benefits to you for storing and using your samples or data in secondary research, however society may benefit from new knowledge.

Individual data without identifiers (de-identified data) may be placed in an NIH or public "data repository" for secondary research. The data in a repository may or may not have controlled access. The health data in the repository will not be associated with identifiers, so no one can identify you from the information. If you withdraw consent or Health Insurance Portability and Accountability Act (HIPAA) authorization, any data collected up to the date of withdrawal may be entered into the data repository.

Reports about research done with your samples or data will not be put in your health record. Results from secondary research using your samples and data may be presented in publications and meetings, but your name will not be identified. There are no plans to contact you if secondary research is performed on your samples or data.

GENETIC TESTING WITH EXTRA AND LEFTOVER SAMPLES

Leftover and extra samples for secondary research may include genetic testing. Genetic testing looks at the material in your cells that tells each cell in your body how to work. The genetic testing is for research purposes only and it will not be able to tell you about relatives, paternity, or country of origin, nor will it tell you about diseases that you may get in the future. We will not give you the results from the genetic research testing.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research might include this type of reading of your genetic code. A summary of the genetic results from all participants in this study can be placed in a public, unrestricted open access database that anyone can freely use. No individual genetic testing information or results will be placed in an open access database. The risk of anyone identifying you with this information is very unlikely.

We may share your genetic information (data) through a "closed" database, also called a restricted data repository. NIH gives permission to other researchers to use your genetic information for research. To qualify, researchers must receive approval from NIH to access and use the research information. Types of secondary research using your data may be related to the research in this study or other types of research. Your individual 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 to not 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.

If you enroll in this study, you are providing consent to store and use samples for secondary research which may include genetic research. You should not join the study if you do not want your data and samples stored and used for this purpose.

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

By signing and dating this consent form, you agree to the collection, storage, and future research use of your samples and information collected for this study.

WITHDRAWAL OF CONSENT FOR SECONDARY RESEARCH

You may change your mind and withdraw consent for the storage and use of your coded samples or information at any time. To do so, please contact the study doctor at the telephone number listed on the first page of this consent document and in writing. If you have study visits after this, we will stop collecting extra samples. We will destroy your samples that are in storage if you withdraw consent after the study tests have been completed. Secondary 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, it might not be possible to withdraw the specimens and data..

By signing this consent document, you are consenting to secondary research of leftover samples, as well as genetic testing for these secondary samples.

Compensation for Participation

You will receive compensation based on the number and type of study visits you complete and to which group you are assigned. You will receive:

- [redacted] for the screening/enrollment visit
- [redacted] for each of the 2 vaccination visits
- [redacted] for each remaining study visit (up to 4)

You will receive up to [redacted] if you complete all the study activities. You will not be compensated for any missed visits. If additional unscheduled study visits are needed, you will receive [redacted] per visit. You will be paid quarterly.

There may be situations where you are not allowed to accept money for taking part in the study, such as other government regulations. If this is the case, you can still be in the study, but please let the study team know that you will not be accepting compensation.

Cost to the Participant

There is no cost to you for taking part in this study.

Research-Related Injury

If it is determined by [redacted] the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at [redacted] to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for [redacted] to pay for the costs of any additional care. There are no plans for [redacted] to give you money for the injury.

No financial compensation or long-term medical care for research-related injuries will be provided by the NIH or the United States Federal Government.

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 December 11, 2024. This Declaration limits the legal rights of a participant in clinical studies utilizing influenza countermeasures, such as the study vaccine used in this study. 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.

If you sign this consent form, you do not give up any of the legal rights to which you are entitled by taking part in this research study.

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: Pro00086232.

Consent and Signature

If you are an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to voluntary participation in this study.

Signature of Research Participant	Print Name of Research Participant	Date
Signature of Study Team Member	Print Name of Study Team Member	Date