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) / "A Phase 2 Randomized, Open-Label, Multisite Trial to Evaluate the Immunogenicity of Dose Reduction Strategies of the MVA-BN Vaccine"**

Protocol Number: **22-0020**

Principal Investigator: (Study Doctor) [redacted]

Telephone: [redacted]

Address: [redacted]

KEY INFORMATION

You are being asked to take part in this study because we would like to compare the safety and the immune response of different doses of the approved monkeypox vaccine (JYNNEOS) given by needle into the skin of the lower arm (injection by intradermal route) versus the standard dose of vaccine given by needle into the fat in the upper arm (injection by subcutaneous route) to healthy adult volunteers.

- Being in the study is voluntary – it is your choice.
- Your participation in this study will last for about 12 months.
- Procedures will include collection of health information, two injections given about 4 weeks apart, and blood draws.
- You may have phone call(s) with the study staff.
- There are risks from participating.
    - The most common risk is pain at the site of injection.
    - One of the most serious risks is anaphylaxis, or severe allergic reaction to the study vaccine. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study staff.
    - There is risk of loss of confidentiality of your health information.
- Two out of three participants in this study will get JYNNEOS in a dose and route that are currently recommended by the Centers for Disease Control and Prevention (CDC) and

approved or authorized by the Food and Drug Administration (FDA) for use during this monkeypox outbreak. However, you might not benefit from being in this research study. You may or may not get protection from the monkeypox virus. Society may benefit from the information gained from the study.

- As part of this study, we are obtaining extra blood samples from you. We will use your coded information, leftover samples, and extra samples for **secondary research** (that is, research that is not planned yet). When you give consent, you will take part in the vaccine study and allow for secondary research.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. They can explain words or information that you do not understand.

BACKGROUND

The purpose of this study is to provide additional data in support of the United Stated Food and Drug Administration's (FDA) approval of the monkeypox vaccine (JYNNEOS) and to study if giving it by a different route of administration and at different doses elicits an immune response comparable to the licensed route and dose.

Two (0.5 mL) doses of JYNNEOS given subcutaneously (SC) 4 weeks apart was approved for the prevention of monkeypox by the FDA in 2019. JYNNEOS is a Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN) vaccine with a well-known safety profile.

Vaccination is being given during the current monkeypox outbreak to people who have been exposed to monkeypox and people who may be more likely to get monkeypox. JYNNEOS (MVA-BN) is the only FDA approved vaccine for monkeypox and is the preferred vaccine. However, there are limited supplies of this vaccine and dose sparing strategies have been suggested.

The remaining sections describe more about the research study. Members of the study staff will talk with you about the information in this document. You are encouraged to ask questions and discuss this study with family, friends, and anyone you choose. If you decide to take part in this study, you will be asked to sign and date this consent form. A copy of this signed and dated consent will be given to you. Signing and dating this consent form indicates that you understand your involvement in the study, the risks of participating and that you agree to take part in the study.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this research is to test different doses and routes of the JYNNEOS (MVA-BN) vaccine. Vaccines tell your germ-fighting cells to make antibodies and other substances to fight infections (immune response). We want to study the effect giving the study vaccine in different doses and routes on the immune response.

SELECTION OF STUDY POPULATION

All arms of the study include adults aged 18-50 years who are in stable state of health. We will screen you for eligibility before performing any further study activities or giving you a study vaccination.

You are **not** eligible for this research study if you have/are:

- Ever received a licensed or investigational smallpox or monkeypox vaccine
- Any history of having monkeypox, cowpox, or vaccinia infection
- Close contact with anyone known to have monkeypox in the 3 weeks prior to signing this consent
- Immunocompromised
- Current or recent use of any immunosuppressing medications in the 4 weeks prior to signing this consent. *Note: topical (through the skin), ophthalmic (through the eye), inhaled (through breathing), intranasal (through the nose), and intraarticular (injection into joints) corticosteroids are acceptable, but systemic corticosteroids (taken by mouth or intravenously) are excluded.*
- Pregnant or breast feeding
- Received or plan to receive **a live vaccine** in the 4 weeks prior to signing this consent through Day 57 (4 weeks after the last study vaccination).
- Received or plan to receive **any other vaccine** in the 2 weeks prior to study vaccination and through Day 43 after first study vaccination (2 weeks after second study vaccine).
- Received experimental therapeutic agents or vaccine in the 3 months prior to signing this consent.
- Have a known allergy or history of anaphylaxis (severe allergic reaction) to a vaccine or vaccine products. *Note: this includes individuals with history of severe allergic reaction to gentamicin, ciprofloxacin, chicken or egg protein.*
- Tattoos, scars or other marks that would interfere with the assessment of the study vaccine sites on your arm.
- Female who could become pregnant and have not been using effective measures (chosen in consultation with your health care provider) to avoid becoming pregnant in the last month and are not willing to use effective measures through Day 57 of the study.
- Have any acute or chronic medical disease that the study doctor believes puts you at increased risk of injury or may interfere with study measurements.

LIFESTYLE CONSIDERATIONS

You will be asked to:

- Follow CDC guidance on preventing monkeypox infection and notify the study staff if you are exposed to an individual with monkeypox or if you become sick with monkeypox-like signs and symptoms.
- Refrain from receiving any other vaccine through Day 43. Refrain from receiving a live vaccine from enrollment through Day 57.
- Decline participation in another study evaluating investigational vaccines until Day 181.

- Decline participation in another investigational smallpox, monkeypox or MVA-based vaccine study through the end of the trial.

WHAT IF YOU ARE EXPOSED TO MONKEYPOX DURING THE STUDY?

During the study, if you are exposed to someone who has monkeypox (but you are not yet sick), please seek care with your health care provider as soon as possible and contact the study clinic. CDC guidance states that people can be vaccinated after exposure to monkeypox virus to help prevent monkeypox disease; this is known as post-exposure prophylaxis or PEP. CDC recommends initiating PEP vaccination within 4 days following the date of exposure for the best chance to prevent onset of the disease. If PEP vaccination is given between 4 and 14 days following the date of exposure, vaccination might be less effective. Vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit.

WHAT WILL HAPPEN DURING THE STUDY?

You will be asked to attend 8 in-person study visits, including an initial screening visit (that may be combined with the first study vaccination visit), two study vaccination visits, and 6 in-person follow-up visits. You will be asked to come in person if you get infected with monkeypox virus and get sick during the study. You will be in the study for approximately 12 months. Study visits may include a physical exam, and all will include a blood draw.

This study will have three arms (groups) and participants in each group will receive different doses of the study vaccine given in one of two ways:

- Intradermal (ID): an injection just under the surface of the skin of the lower arm (inner side).
- Subcutaneous (SC): an injection just under the skin into a fatty area on the upper arm.

You will not be able to choose which group you are in. This will be randomly assigned (like flipping a coin).

Study Treatment Arms

Arm	Number of participants	First Study Vaccination (Day 1)	Second Study Vaccination (Day 29)
1	70	MVA-BN 2 x 10^7 Intradermal (ID) (one fifth the approved dose)	MVA-BN 2 x 10^7 ID (one fifth the approved dose and Authorized for Emergency Use by the FDA)
2	70	MVA-BN 1 x 10^7 Intradermally (ID) (one tenth the approved dose)	MVA-BN 1 x 10^7 ID (one tenth the approved dose)
3	70	MVA-BN 1 x 10^8 Subcutaneous (SC) (approved dose)	MVA-BN 1 x 10^8 SC (approved dose)

Screening Procedures
You will have a Screening Visit to check if you are eligible to enroll in this study. The Screening Visit may be combined with the first study vaccination visit (Day 1). If it is a separate visit, it will take about 60 minutes and will include:

- Reviewing, signing and dating the consent form
- Collecting information about your medical history, medications, and smallpox vaccination history
- A targeted (symptom-driven) physical exam
- Checking vital signs (temperature, blood pressure, heart rate, breathing rate)
- For females of childbearing potential, a urine or serum pregnancy test

General Study Visit Procedures
Study visits may include the following:

- Being asked question about your recent medical history and medications, illnesses or symptoms, and side effects or reactions in visits after study vaccination given
- Doing vital signs
- Having a targeted (symptom driven) physical exam
- Having blood samples drawn at all study clinic visits (and if you can become pregnant, urine or serum for pregnancy testing at each of the study vaccination visits)
- Getting a study vaccination or an assessment of the site of a previous study vaccination

Study Vaccine Visit Procedures (Day 1 and Day 29)
In addition, to general study visit procedures, study visits Day 1 and 29 include receiving a study vaccination and will generally last about 2-3 hours. The Day 1 study vaccination visit may be combined with the screening visit and will include the screening visit procedures (see Screening above). On Day 1 and Day 29, you will receive an injection of the study vaccine either:

- **ID Study Arms**: the study vaccine will be injected just under the skin on your lower arm.

OR

- **SC Study Arm**: the study vaccine will be injected into a fatty area on the upper arm (deltoid).

You will stay in the study clinic for at least 30 minutes after the study vaccination for study staff to check for any immediate reactions.

We will give you a memory aid (like a diary card), thermometer, and ruler (to measure the size of any redness or swelling at the study vaccination site) with instructions to record your temperature and any side effects with specific questions about pain and itching. At home, you will complete the daily memory aid, beginning on the evening of the day of each study vaccination and continuing daily for at least 14 days. The memory aid will include contact information should you need to contact the study staff. Bring the memory aid with you to your scheduled study clinic visits on Day 15 (after first study vaccination) and Day 43 (after second study vaccination).

If you become sick or have any reactions after a study vaccination, you should immediately contact the study staff. We may ask you to come to the study clinic for an extra study visit. The study staff may perform additional research or safety procedures, if needed.

You will not receive the second dose of study vaccine if you:

- Become pregnant
- Develop monkeypox
- Have any of the conditions listed above that disqualify you for the study
- Refuse the second study vaccination

Follow Up Visit Procedures (Day 15, 43, 57, 90, 181 and 365)

In addition to the study vaccination visits, you will also come to the study clinic for follow up visits on Day 15, 43, 57, 90, 181 and 365. Follow-up visits will take about 30 minutes and involve general study visit procedures described above.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or wish to obtain more detail, you should discuss this with the study staff.

Unscheduled Visit Procedures

You may be asked to come back to the study clinic at other times if needed, for example, if you have a serious reaction to the study vaccine or if you become sick with monkeypox. During unscheduled visits, a review of your current medical history, medications taken since your last visit, a symptom-targeted physical exam (if sick or you have a change in medical status) and blood collection will be done.

Laboratory Testing of Specimens

The blood specimens collected from you will be used for research tests of the immune response to the smallpox and monkeypox viruses. We will look at your antibodies, which are proteins that your body uses to fight off the virus.

Giving blood samples for the research tests will not benefit you. It may benefit others by leading to new approaches in vaccine development or treatments for monkeypox infection. The results of these tests are useful only for research purposes. **Your individual research results will not be available to you or your regular doctor and will not be placed in your medical record.**

Blood samples for these research tests may be sent to a central storage facility or sent directly to the research testing laboratories. These samples will not be labeled with your name or initials, or any other information that could readily identify you. These samples will be labeled only with a barcode and a unique tracking number (Identification Code) to help protect your confidentiality. Staff at the central storage facility and research testing laboratories will not know your identity, or even the study identifier you were assigned. However, the study staff who enrolled you will keep a list in a secure area with your name, contact information and the

Identification Code (called a code key) that can link the samples to you, if needed. Access to the code key is limited to study staff working at the study clinic where your samples were collected.

We may remove the codes from your information or samples so that we cannot identify you and use these in other research. These de-identified samples may be shared with other researchers without your additional consent.

Leftover and Extra Blood Samples
Some of the blood collected for measuring immune responses to the study vaccines may not be needed to do the research tests. **We plan to store and use these leftover samples and your information (identified only by Identification Code) for secondary research.** Secondary research is research that is not part of this study but will be performed in the future. You will not be told about the future research.

Blood samples will be stored indefinitely at a site determined by the National Institutes of Health (NIH) and will be labeled only with a barcode and an Identification Code (not with your name, initials, or any other information that could readily identify you). These leftover and extra blood samples will be stored with the same confidentiality measures used for the main specimens.

Leftover and extra blood samples may be used in the future for research about this study vaccine and your body's response to this study vaccine. You will not be contacted about the types of future research. At any time during this study or after this study is over, extra blood samples may be shared with other study doctors/institutions and used for secondary research

Leftover and extra blood samples will be used only for research purposes. These blood samples will not be sold or used directly for production of any commercial product. However, the research studies in this study or in the future may lead to identification of 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 have commercial profit, 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 blood samples are tested in the future, the results may be published. You will not be identified in such publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

By signing and dating this consent form, you are agreeing to the collection, storage and future research use of your blood samples and information collected for this study. There are no benefits to you in the collection, storage and future research use of your blood samples. Future research tests may benefit others by leading to new approaches in the development of vaccines or treatments for monkeypox infections. The results of any future research testing will be kept

confidential in the same way 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 for the storage and use of your coded samples or information at any time. You will need to contact the study doctor using the contact information listed on page 1 of this form. If you have visits after this, we will stop collecting extra blood.

Your samples will be removed from future use when the vaccine study is completed. Only stored samples with an Identification Code and 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, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw the specimens and data.

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

POTENTIAL 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 doctor or study staff. The possible risks of participating in this study include those associated with having blood drawn, reactions to the injection, adverse effects (side effects) of the study vaccine, and the possibility of a breach of confidentiality.

Having your blood taken can cause pain and may also cause lightheadedness or fainting. The needle stick can cause bruising, which can be prevented or reduced by putting pressure on the site for a few minutes after the needle is removed. It is possible to get an infection at the site of the needle stick. To reduce the risk of infection after the blood draw or study vaccine injection, the study staff will wipe the area clean with alcohol and use sterile equipment. Throughout this year-long study, we will collect about 14 tablespoons (204 mL) of blood. The amount of blood collected in any 8-week period during the study will not exceed the amount of blood allowed to be drawn under the American Association of Blood Banks standards.

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. There may be other risks that are unknown.

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

After a study vaccination, a person might experience:

- **Mild to moderate reactions**
  - Pain at injection site
  - Itching at the injection site
  - Redness, swelling or hardness at injection site
  - Muscle aches
  - Headache
  - Fatigue (tiredness)
  - Nausea
  - Chills
  - Elevated heart rate (tachycardia)
  - Changes in electrocardiogram (ECG, traces the electrical activity of the heart)
  - Hyperpigmentation (patch of skin that is darker than the surrounding skin)
  - Nodule (rounded swelling or lump)

- **Non-fatal serious events**

  Prior to FDA approval of JYNNEOS, more than 22 research studies with about 7,000 participants studied the vaccine and found 1.5% of participants had a serious adverse event and four non-fatal serious events were related to study vaccination, including:
  - Crohn's disease (a type of inflammatory bowel disease)
  - Sarcoidosis (the growth of tiny collections of inflammatory cells [granulomas] in any part of your body, most commonly the lungs and lymph nodes)
  - Eye muscle weakness
  - Throat tightening (an allergic reaction)

- **Severe allergic reactions**

  Severe allergic reactions are uncommon but may occur and present as:
  - Skin rash (hives)
  - Sweating
  - A feeling of dread
  - Swelling around the mouth, throat and eyes
  - Wheezing
  - Difficulty breathing
  - Increased pulse
  - Fainting or feeling dizzy due to low blood pressure
  - Inability to breathe without assistance

If an allergic reaction occurs, emergency medications administered by study personnel can usually stop them. Most people who experience anaphylaxis recover completely. Rarely, people can die. If you had an allergic reaction after being vaccinated in the past, or if you are allergic to any product, including gentamicin, ciprofloxacin, chicken or egg protein you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If

you have an allergy to some products, you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

Per CDC guidance, health departments may consider administering JYNNEOS SC instead of ID for people who have a history of developing keloid scars. A previous NIH study that evaluated ID dosing of JYNNEOS found no keloid scarring after study vaccination among the 192 study participants who were in the ID dosing arm. Since you cannot choose which group you will be assigned to and the location you will receive your study vaccine, you may not want to participate in this study if you have a history of keloid scar formation.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Risks Related to Pregnancy
You cannot be enrolled in this study if you are:

- Pregnant
- Nursing a child

If you become pregnant while you are in this study (through 2 months after your first dose), you should report this immediately to the study staff. With your permission, the study doctor or study staff will ask about your health, collect information from you through the outcome of your pregnancy, and collect scheduled blood samples. The study doctor 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.

BENEFITS
Two out of three participants in this study will get JYNNEOS in a dose and route that are currently recommended by the CDC and approved by the FDA for use during this monkeypox outbreak. However, you may or may not get protection from the monkeypox virus. The results of this research might benefit others by contributing knowledge that may lead to dose sparing of the currently approved vaccine.

ALTERNATIVES TO PARTICIPATION
The only alternative is to not participate in this study. You also may be able to receive a monkeypox vaccine outside of the study.

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

STUDY INFORMATION

When the results of this study are available, which will likely be a year or more after your last visit, we will attempt to provide you with a summary of those results, and a summary will be posted on http://www.ClinicalTrials.gov. If you move after your last study visit, it is your responsibility to provide us with your new address if you want to receive this information.

SOURCE OF FUNDING FOR THE STUDY

The study clinic is receiving payment from the NIH, National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), the sponsor of the study.

The Strategic National Stockpile is providing the vaccine for this study to the NIH without charge.

COMPENSATION FOR PARTICIPATION

You will be paid for your time and expenses related to participation in the study. You will receive [redacted] for each vaccination visit and [redacted] for each scheduled or unscheduled visit for each study visit where you are required to come to the study clinic. You will receive up to approximately [redacted] for all completed study visits. For illness-related visits, you will be compensated [redacted] for each illness event where blood is collected.

You will be paid following each completed visit. You will not be compensated for any missed visits.

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

[redacted]

To receive payment for participation in this study, you will be asked to provide your home address and social security number. If you receive [redacted] for participation in this research study, or a combination of studies at [redacted] in one tax year, you will be sent an IRS Form 1099 for tax purposes. [redacted]

[redacted]

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

COST OF PARTICIPATION

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

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

COMPENSATION FOR INJURY

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment, which will be covered by the University. The University does not plan to pay for your injury if it is due to your own failure to follow the study doctor's instructions. There are no plans for [redacted] to pay for the costs of any additional care. You have not waived (given up) your legal rights by signing this form. If you have questions, please call the [redacted]
No long-term medical care or financial compensation for research related injury will be provided by the NIH or the 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 October 10, 2008 and amended on January 1, 2016. This Declaration limits the legal rights of a subject participating in clinical studies utilizing smallpox countermeasures against variola virus (smallpox) or other orthopoxvirus like monkeypox virus, such as the JYNNEOS (MVA-BN) 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). There are exceptions to this limitation, see https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3.

If you believe that you may have been harmed as a result of this research 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 United States Government. The monkeypox countermeasure will be covered by the CICP. Monkeypox is included under the smallpox declaration as an orthopoxvirus. Compensation is limited to the terms of the CICP and is not guaranteed.

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 date the study vaccine was administered that resulted in an injury.

CONFIDENTIALITY

Paper documents containing personal information about you will be maintained in locked in a secured area. Computerized information will be maintained in password-restricted files. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access.

The authority to collect this information is provided by Title 42, Section 285f, of the US Code of Laws, which specifies that the general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

Some information about your participation in this study will be kept in your [redacted] medical record. Authorized [redacted] staff have access to this information. Systems are in place to keep medical record information confidential. It is possible this information could be shared with insurance or healthcare providers who are authorized to have your medical records.

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 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 clinic 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 staff 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:

1. Is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH; or
2. 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;
3. Is necessary for your medical treatment and you have consented to this disclosure;
4. Is for other scientific research as allowed by applicable federal regulations;
5. 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

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include your name, address, phone number, date of birth, medical history and information about your study visits including all tests.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

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

- The Department of Health and Human Services
- The OHRP
- Additional governmental agencies in the United States
- Advarra IRB
- [redacted] IRB and IBC if they are involved
- Your regular doctor
- 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
- To study the results
- To see if the research was done correctly

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.

Permission to release your PHI expires when the research study is over and all required study monitoring has ended.

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. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, 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 keep from changing the study results. When the study is over, you can access your study health data.

The Notice of Privacy Practices can be reviewed electronically at [redacted] or if you prefer a paper copy, please request one at this time. By signing below, you are acknowledging receipt of the Notice of Privacy Practices either electronically or as a hard copy.

If you decide not to sign and date this form, you will not be able to take part in the study.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the [redacted]

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 and dating 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 clinic's decision to exclude 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: Pro00066029.

If you have questions about your rights as a research subject, you may also contact [redacted]

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 discontinue participation at any time without penalty if you agree to participate and then decide that 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 may change your mind at any time. Please contact the study staff if you decide to stop taking part 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 vaccine
- If 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 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 for the research or are withdrawn by the study doctor. However, any information and specimens collected prior to withdrawal may continue to be used for this study.

Advarra Institutional Review Board (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. I will receive a copy of this signed and dated consent document.

_____

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