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

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health / "A Phase 1, Open-Label, Safety and Immunogenicity Trial of Boost-2867, an IgG-Fc-RBD Fusion Protein Next Generation SARS-CoV-2 Booster Vaccine, Via Intranasal and Intramuscular Routes in Previously Vaccinated Adults"**
Protocol Number:	**DMID 25-1106**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	[redacted]

KEY INFORMATION

You are being asked to participate in this study because we want to test the safety and immune response to an experimental COVID-19 vaccine given as a single booster dose.

- This study includes seven study groups. Participants in four of the groups will receive vaccine by injection in the upper arm; participants in the other three groups will receive vaccine given as a nasal spray.
- **You will receive the nasal spray COVID-19 vaccine.**
- Each of the three groups that will receive the nasal spray vaccine will receive a different dose.
- Being in the study is voluntary – it is your choice.
- Your participation in this study will last up to 7 months.
- You will have up to nine planned study visits, including a screening visit, one vaccine visit, six follow-up visits, and one phone call to check on you.
- During the study, you will have physical exams, blood draws, saliva collection, and nose swabs.

- Additionally, as instructed, you 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.
- You will also be asked to adjust some of your daily routines for varying periods of time. This information is described under the "Lifestyle Considerations" section below.
- You will be asked not to receive another COVID-19 vaccine for six months after you receive the study product.
- There are risks to participating.

Side effects of nasal spray vaccines include cold or flu-like symptoms such as a runny nose, nasal congestion, sneezing, sore throat, tiredness, and body aches. One of the most serious risks is anaphylaxis — a severe allergic reaction to the study product. See the "Risks of Participation" section for more information. You should discuss these risks in detail with the study team.

There is also a risk of loss of confidentiality of your health information.

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

You will not benefit from being in this study.

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.

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 your germ-fighting cells to help fight infections.

Approximately 140 people will participate in this study.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this first-in-human research study is to test an experimental COVID-19 vaccine called Boost-2867 to evaluate its safety, its reactogenicity, and the immune system's response to it. Reactogenicity refers to reactions that occur soon after study product administration, such as irritation of the nose or fever. Boost-2867 is a protein vaccine that targets the SARS-CoV-2 KP.2 strain. The vaccine will cause your body to develop immune responses to the vaccine protein but the study vaccine cannot cause a COVID-19 infection. We will take blood and saliva samples 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 clinical study.

SELECTION OF STUDY POPULATION

Adults aged 18 through 64 years who are in a stable state of health may enroll. We will screen you for eligibility before conducting further study activities or administering a study product. 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 COVID-19 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 vaccine. (Please contact the study team if you plan to receive any vaccine in the 28 days after getting the study vaccine.)
- You have certain chronic medical or psychiatric conditions.
- You are on certain medications.
- You are pregnant, or you could become pregnant, and you have not been using effective contraception, or you are breastfeeding.
- You have a history of hypersensitivity or a severe allergic reaction to a vaccine.
- You are a current smoker (including cigarettes, marijuana, or vaping) or have smoked within the last three months.
- There are other reasons why you may not be able to participate in this study, which we will discuss with you.

LIFESTYLE CONSIDERATIONS

<u>During the study, you will be asked to:</u>

- Not receive a COVID-19 vaccine outside of the study until after your final 6-month visit.
- Avoid the use of nasal irrigation or sinus rinsing treatments (e.g., neti pots, saline washes) for 28 days post-study product administration and for 7 days before study visits for the remainder of the study.
- Not donate blood or plasma outside the study until after your final 6-month visit (platelet donation is okay).

WHAT WILL HAPPEN DURING THE STUDY?

You will be assigned to be in one of the three study groups below. Each group will include 20 people. You cannot select which group you are assigned to. For each group, we will first give the nasal spray study product to 3 people. One week later, we will review the safety data for those 3 people before administering study product to the remaining 17 people in the group.

Vaccine Groups

Cohort	Number of participants		Study Product Dose
5	3	17	20 mcg Boost-2867
6	3	17	50 mcg Boost-2867
7	3	17	125 mcg Boost-2867

Your participation in this study will last up to 7 months, with approximately 9 study visits, including one phone call.

Screening

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

- Learning about the study and asking questions
- Reviewing, signing, and dating the consent form
- Collecting information about your health, medications, vaccination history, and any illicit drug use
- A physical exam
- Checking vital signs (temperature, blood pressure, heart rate)
- Measuring height and weight
- A nasal swab to test for SARS-CoV-2 infection
- For people of childbearing potential, a urine pregnancy test will be obtained
- Blood sampling will be performed 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 result of some 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 regular doctor.

Study Visits

The study product administration visit will generally last about 2-3 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, and temperature before the study product administration, at three of the six later in-person visits, and at other visits if needed)
- Having a physical exam if needed
- Collection of blood, nasal, and saliva samples (this may include testing for other respiratory viruses)
- For people who can become pregnant, a urine pregnancy test before the study product administration

At the study product administration visit, we will review your medical history to confirm your eligibility for study product administration. You will get the nasal spray study product, at that visit. 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 the study product administration and continuing for the next seven days. Study staff will call you the day after the study product administration visit to ask about any side effects. 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) you develop after receiving study product. You will also visit the clinic (or speak with us by phone) 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. This may be for your safety or for research purposes.

The study staff will call you after study product administration to check on your health, 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 staff 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 evaluations will be needed after reviewing any symptoms that you are having.

Collection of Biological Samples for Research Purposes

Blood: We will collect blood samples at the study product administration visit and at five of the six later in-person visits.

Saliva: We will ask you to keep a small sponge inside your mouth for approximately two minutes at the study product administration visit and at five of the six later in-person visits.

Nasal mucus: We will use a swab and a nasal strip to collect mucus inside your nose at the study product administration visit and at all six of the later in-person visits.

Lab Testing of Specimens

The blood, saliva, and nasal specimens collected from you will be used for research tests of the immune response to the study product. We will look at your antibodies, which are proteins that your body uses to fight off the virus. 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, saliva, and nasal samples for the research tests will not benefit you. It may help others by leading to new vaccines or treatments for COVID-19. The results of these tests are helpful 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 that will focus on COVID-19 and provide information about how your body responds to the study product and/or disease. Genetic testing looks at the material in your cells that tells each cell in your body how to work. 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.

When you participate in this study, you are also asked to consent to **secondary research** (research that is not planned yet). We will use your coded information, leftover biological samples, and extra biological samples collected at each visit for secondary research. Secondary research may help us understand how the vaccine works, develop tests, study other infections or diseases, or develop treatments. This may include genetic research to study immune responses.

Secondary research is not part of this study but may be performed in the future. 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. We will share your future genetic information through a "closed" database called a restricted data repository. The National Institutes of Health (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.

You will not be told about the future research. **You cannot enroll in this study if you do not want to give your leftover and extra samples for secondary 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.

Future genetic testing may include whole genome sequencing (DNA testing), which determines someone's complete DNA make-up, or other types of genetic testing (including tests that have yet to be developed) to inform the development of new vaccines or for the study of coronaviruses or other infections. You will not be contacted about the types of future research. The results of any future research testing will be kept confidential, just as the results of other testing done for this study.

Your biological samples will be stored indefinitely at a site determined by the NIH. Leftover and extra future use 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). We may remove the codes from your information or samples so that we cannot identify you and may then use these samples in other research.

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.

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. 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.

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.

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 study product, adverse effects (side effects) of the study product, having nasal swabs and strips collected, having saliva collected using a small sponge, 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 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, the study staff will clean your skin with alcohol and use sterile equipment.

The risks associated with having nasal and saliva samples collected may include discomfort, a gag reflex, watery eyes, nosebleed, minor irritation, sneezing, coughing, and dry mouth.

Risks and Possible Side Effects That You May Experience With the Study Vaccine

After study product administration, a person might experience:

- fever,
- chills,
- fatigue,
- body aches,
- nausea,
- swollen lymph nodes, or
- headache.

Side effects of the nasal spray vaccine may also include:

- runny nose,
- irritation of the nose,
- stuffy nose,
- scratchy or sore throat,
- sneezing,
- cough, and
- teary or watery eyes.

There is a small risk of a serious, life threatening, allergic reaction, which can cause breathing difficulties, skin reactions, low blood pressure and other symptoms. If this occurs, emergency medications administered by study personnel can usually stop it. Most people who experience these reactions recover completely.

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, usually in the first 4 weeks after receiving the study product. Most of these people's symptoms began within a few days after study product administration. You should seek medical attention immediately if you have any of the following symptoms after receiving the study product: chest pain, shortness of breath, or feelings of a fast beating, pounding, or fluttering heart.

In this study, we will monitor for myocarditis and pericarditis because this is a COVID-19 vaccine, although we anticipate that the chance of this is very low. The study product tested in this study cannot cause COVID-19 infection.

This study product was tested in animals and no concerning side effects were identified.

Sometimes, vaccines are not protective. Rarely, they can cause more severe illness after virus exposure. We do not think this study product will increase your risk of severe illness, but we will continue to monitor you closely throughout the study.

In addition to these risks, there may be risks of the study product that are not yet known.

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 or 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 such as name, address, and identification numbers removed. Because it may be possible to re-identify genetic data, even if access to data is controlled, confidentiality cannot be guaranteed.

Risks of Genetic Discrimination

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 previously. 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

This research study is for research purposes only. The alternative is to not participate in this study.

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.

STUDY CENTER EMPLOYEES/FAMILY MEMBERS

Study center employees do not have to be in this study. No one should influence or pressure you to be in this study. Your decision to be in the study or to leave the study early will not affect your job or employment benefits.

Family members of study center employees do not have to be in this study. No one should influence or pressure you to be in this study. Your decision to be in the study or to leave the study early will not affect your family member's job or employment benefits

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] each for the screening and vaccination visits where you must come to the research clinic and [redacted] each for the other six research clinic visits. Therefore, if you complete all visits as scheduled, you will receive [redacted] in total. If you are asked to come into the clinic for an unscheduled visit, you will be compensated [redacted] for each visit. There will be no payment for the telephone call on Day 2.

If you do not complete the study, for any reason, you will be paid only for the study visits you do complete.

The study staff will need to take a photocopy of a government-issued photo ID (driver's license, state-issued ID card, military ID, or passport) at your first visit.

Payments will be made by electronic gift card. The gift cards will be emailed within 4 weeks after each study visit.

Federal tax law requires that you report your research payments when you file your taxes. If your total payments from [redacted] exceed the federal reporting threshold in a calendar year, [redacted] will report these payments to the Internal Revenue Service (IRS) and you will receive a 1099-MISC form from us. This form tells the IRS that payment was made to you, but it does not name the study or studies in which you participated. You will be

asked to provide your Social Security Number for tax reporting purposes. This information is stored confidentially and separate from research data. Parking in the study clinic building's garage will be paid for by the study clinic, and if you take a bus you will be given bus tickets at each study visit. Ask the study team for more information about this.

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 are not a part of this study.

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

COMPENSATION FOR INJURY

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. Tell the study staff if you think you have been injured.

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 may need to pay for that care. The study site will provide short-term medical care for any injury resulting from your participation in research here. Still, you might not be reimbursed for care 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.

If you are a [redacted] member and you are injured or harmed by this study, [redacted] will provide necessary medical treatment as covered by your usual health benefits. If your injury is directly caused by the product being studied, your medical treatment will be provided at no cost to you.

[redacted] does not offer any other financial compensation if you are injured or harmed as a result of participating in this research.

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

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 vaccine, Boost-2867. 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.

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;
- 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 collected for the study, 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 regular doctor or other healthcare workers.

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

- Laboratory test results, electrocardiogram results, diagnoses, 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
- The Office for Human Research Protections (OHRP)

- Additional governmental agencies in the United States
- Advarra (the Institutional Review Board for this study)
- Your primary care provider (if you are a [redacted])
- Representatives of [redacted]
- The Food and Drug Administration (FDA) and other US federal and state agencies
- Boost Biopharma, Inc. (the vaccine developer)
- 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.

Your permission to use and share health data about you will expire 50 years after the date on which this form is signed.

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, 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.

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: Pro00090304.

You may also contact the [redacted] about your rights as a [redacted] research participant.

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.

If you are a [redacted] member and you choose not to be in the study, you will not lose any [redacted] benefits. If you are not a [redacted] member and you choose not to be in the study, you may continue to receive your usual medical care.

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 anytime. 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 AND AUTHORIZATION

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 authorize my personal information to be collected, used, and disclosed as described above. I will receive a copy of this signed and dated consent document. I am not giving up any of my legal rights by signing this form.

_____

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