INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**National Institutes of Health (NIH) / Division of Microbiologyand Infectious Diseases (DMID) / "A Phase 1, Open-Label, Dose-Escalation Trial to Evaluate the Safety, Reactogenicity,and Immunogenicity of the Sm-p80 + GLA-SE (SchistoShield®) Vaccine in Healthy Adults"**
Protocol Number:	**18-0018**
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We are asking you to be in a research study. This form gives you information to help you decide whether to be in the study. Being in the study is voluntary. Please read this form carefully. You may ask any questions about the study. Then you can decide whether you want to be in the study.

Key Information about This Research

The purpose of this research is to test an experimental vaccine for schistosomiasis. An experimental vaccine is one that is not approved by the United States Food and Drug Administration (FDA). This study vaccine, called Sm-p80 + GLA-SE, or trade name SchistoShield®, has not been given to humans before. Schistosomiasis is a disease caused by a worm-like parasite. Globally more than 200 million people are infected worldwide, most commonly in sub-Saharan Africa, leading to hundreds of thousands of deaths each year. There is currently no approved vaccine for schistosomiasis. The study vaccine contains a synthetic protein made in a laboratory that is designed to trigger immune responses against the schistosomiasis parasite.

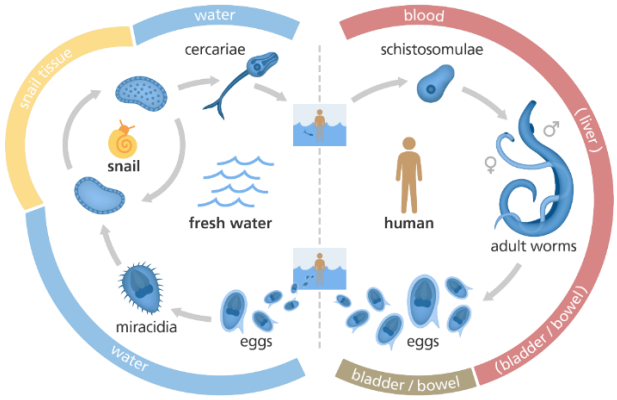
If you participate, you will be assigned to one of five study groups, each of which will include nine people, who will receive three study vaccinations. You will be in the study for approximately 15 or 19 months, depending on your study group. You will have 12 or 13 in-person visits at the research clinic, including a screening visit and three study vaccination visits, as well as 10 or 11 follow-up visits. Additionally, a re-screening visit may be done if you were eligible for the study but were not enrolled within 30 days of your original screening visit. Visits

may include physical exams, blood draws, and lab tests.

Purpose of This Research Study

Schistosomiasis is a serious infection caused by a parasite that has different life stages (Figure 1). One life form, called cercariae, is released from freshwater snails. When people are in a freshwater source (such as a lake) that contains infected snails, the cercariae in the water can penetrate the skin and enter the body. It then changes to another life form (larvae or schistosomulae) that invades the person's blood vessels, and then develops into the adult form, which multiplies into male and female worms. The females release eggs, that can be excreted in the person's stool or urine, which can then contaminate freshwater sources. When hatched, the next life form can penetrate snail tissue, completing the life cycle. If the eggs are not excreted, they lodge in the person's body and lead to scarring and inflammation of organs such as the liver and bladder, which can lead to organ dysfunction and cancer. Researchers are looking for new ways to prevent or minimize the consequences of schistosomiasis through the use of a vaccine.

Figure 1. Life cycle of the schistosome.



The main purpose of this research is to assess the safety of the Sm-p80 + GLA-SE (SchistoShield®) study vaccine. Another purpose is to assess whether the study vaccine prompts an immuneresponse, leading to the generation of antibodies, which are proteins that can prevent infection, and other immune system products. The study vaccine contains a synthetic protein (Sm-p80) made in a laboratory that cannot cause schistosomiasis infection or its consequences.

GLA-SE is an adjuvant, which is a substance that increases the body's immune responses to vaccines. This adjuvant is not licensed and is experimental. It has been used in other experimental vaccines against a wide variety of diseases including influenza, tuberculosis, and malaria and has been given to over 1100 people.

If you participate in this trial, you will be assigned to one of five study groups, each of which will include nine participants, who will receive three injections of the assigned study vaccine (Table 1). Group A will receive the study vaccine without the adjuvant, at a dose of 100 micrograms (µg) of Sm-p80, to test whether the adjuvant acts to increase immune responses.

Groups B, C, D, and E will receive the study vaccine with adjuvant. The dose of the Sm-p80

protein will be 10 µg in Group B, 30 µg in Groups C and D, and 100 µg in Group E, to find out what dose leads to the best immune responses and side effect profile.

Participants in all five Groups will receive the second study vaccination about 28 days after the first study vaccination and those in Groups A, B, D, and E will receive the third study vaccination about 28 days after the second study vaccination. Participants in Group C will receive the third study vaccination about 150 days after the second study vaccination, to test whether a longer interval between the second and third study vaccination improves immune responses. Groups A and B will be enrolled together at the beginning of the study, followed by Groups C and D, and then Group E. The Group you are assigned to will depend on when you enroll in the study.

Table 1. Study Groups

Study Group	Number of Participants	Study Vaccine	Study Vaccinations
A	9	100 µg Sm-p80 (no adjuvant)	Day 1, 29, 57
B	9	10 µg Sm-p80 + 5 µg GLA-SE	Day 1, 29, 57
C	9	30 µg Sm-p80 + 5 µg GLA-SE	Day 1, 29, 180
D	9	30 µg Sm-p80 + 5 µg GLA-SE	Day 1, 29, 57
E	9	100 µg Sm-p80 + 5 µg GLA-SE	Day 1, 29, 57

At most of the in-person study visits (study vaccination visits, 7 days after study vaccinations, and 28 and 124 days after the third study vaccination) we will take blood from you to measure immune responses. At some of the visits we will also take blood from you to send to a medical laboratory for tests of blood counts, kidney and liver function, and other tests as detailed in the following sections.

Selection of Study Population

Only healthy people age 18 through 55 years old may enroll in this study. 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 received an experimental vaccine or drug in the past 30 days, OR plan to receive one during your study participation
- You have any serious chronic medical or psychiatric condition
- You are on certain medications
- You have a body mass index (BMI) of 35 kg/m^2 or higher, or weigh less than 50 kilograms (about 110 pounds)
- You are pregnant or breastfeeding a child

- You have any medical condition the study doctor feels would make your participation unsafe
- You have ever had or been treated for schistosomiasis infection

There are other factors that may make you not eligible to participate.

Procedures

If you agree to take part in this study, your involvement is expected to last for about 15 months if you are assigned to Groups A, B, D, or E and about 19 months if you are assigned to Group C.

Screening

You will first have a Screening Visit to check if you are eligible to enroll in this study. This screening visit must take place within 30 days prior to the enrollment visit, should you be eligible for enrollment. You may be re-screened if you were eligible but were not enrolled within the 30-day window to refresh the window. The Screening Visit will take about 90 minutes and will include:

- Reviewing, signing and dating the consent form
- Collecting information about your medical and mental health history, medications (and birth control if applicable), vaccination history, and drug or alcohol use
- Having a physical exam
- Collecting vital signs (heart rate, blood pressure, and temperature) and height and weight
- Blood sampling to check your kidney and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may berequired by law to report the result of the HIV and hepatitis tests to the local health authority.
- If you can become pregnant, a blood pregnancy test

If your lab results are not within standard, normal ranges, we may ask to redo the blood collection and check the lab results again for eligibility. If your lab results are still not within standard, normal ranges at that time, you will not be able to participate in the study, and the study doctor may refer you to your regular medical provider.

If you can become pregnant, you must agree to use an acceptable method of birth control from at least 30 days before the first study vaccination through at least 30 days following the last study vaccination. Acceptable birth control methods include abstinence from sexual activity that could lead to pregnancy, monogamous relationship with a partner who has had a vasectomy at least six months ago, successful Essure® placement (permanent, non-surgical, non-hormonal sterilization), intrauterine devices, and hormonal methods, including the birth control patch, shot (Depo-Provera), pills, the vaginal ring (NuvaRing), and the contraceptive implant (Nexplanon). Acceptable barrier methods include diaphragm or cervical cap with spermicide and the contraceptive sponge.

General Study Visit Procedures

Study visits that include a study vaccination will generally last about 2-3 hours and other visits will generally last about 30 minutes. Visits may include:

- Questions about your recent medical history and medications, illnesses or symptoms, andside effects or reactions
- Collecting vital signs (heart rate, blood pressure, and temperature)
- If applicable, reviewing use of birth control methods and pregnancy status
- Having a physical exam if needed
- Collection of blood samples at most of the study clinic visits (and, if you can become pregnant, urine for pregnancy testing at each of the three study vaccination visits)
- Study vaccination or assessment of the site of a previous study vaccination
- Review of the memory aid during telephone visits

Study Vaccination Visits

At the three study vaccination visits, we will review your lab test results and medical history to confirm that you are eligible for the study vaccination. If you are eligible, you will receive an injection of your assigned study vaccine in the muscle of your upper arm, below your shoulder. You will stay in the clinic for at least 30 minutes after the injection for study staff to check for any side effects.

Near the end of your study vaccination visit, we will give you instructions on how to use an electronic memory aid (eMemory Aid) via the internet as well as a thermometer, with instructions to record your temperature and any side effects. At home, you will complete the eMemory Aid daily, beginning on the evening after the study vaccination and continuing daily for the next seven days. If you do not have internet access we can give you a backup paper memory aid.

Follow Up Visits

In addition to the three study vaccination visits, you will also come to the clinic for eight or nine follow-up visits, which will take about 30 minutes. In addition, there will be a phone visit on the day after the first study vaccination and for the final study contact, one year after the third study vaccination, to identify any new illnesses or medications.

The study staff will also call you periodically during your study participation to check on your health status or to remind you of an upcoming visit or for other reasons. You may also be asked to come to the research clinic for an additional visit if there is a need to evaluate you for an illness or possible study vaccine side effect, which may include a blood draw.

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. Many side effects go away quickly if treated, but in some cases, side effects can be serious, long lasting, or permanent. The study vaccine is experimental and there may be risks that we do not know about right now. Side effects may occur more frequently with higher doses of the study vaccine or when the study vaccine is given with the GLA-SE adjuvant.

The possible risks of participating in this study include those associated with having blood drawn, adverse effects (side effects) of the study vaccine, and the possibility of a breach of

confidentiality.

Risks and side effects you may experience with the study vaccine

After a study vaccine injection, a person might experience:

Minor to moderate events:

- Sore arm from the injection
- Redness, swelling, hardness, or itching at injection site
- Fever, chills, or fatigue (feeling tired)
- Flu-like illness, runny nose, or cough
- Headache, muscle aches, pain and stiffness in the joints
- Nausea or vomiting
- Lack or loss of appetite for food
- Swelling of glands in the cheeks or neck
- Temporary abnormal lab test results
- Fainting

Severe events could occur very rarely:

- Any reaction above could be severe.
- A small number of people (about 1 in 4 million people) have an immediate allergic reaction called anaphylaxis (also known as allergic shock) after receiving vaccines or medications. This type of reaction may include symptoms such 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 a drop in blood pressure
    - Inability to breathe without assistance

If these reactions occur, emergency medications administered by study personnel can usually stop them. Most people who experience anaphylaxis recover completely. Rarely, people can die.

It is possible that receiving the study vaccine may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

If you stop or change the dose of your regular medication, therapy, or supplements to be in the study, your health might get worse. Please tell the study doctor or study staff right away if you have any problems when you stop or change your regular medication, therapy, or supplements.

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, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

Throughout this study, the amount of blood collected will be less than 36 tablespoons (525 mL) in any 8-week period (which is the amount of blood allowed to be drawn under the American Association of Blood Banks standards).

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study vaccine.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

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 in this study if you are:

- Pregnant
- Planning to become pregnant during the study
- Nursing a child

If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child. Nobody knows what all of these risks are right now. Some vaccines and drugs could cause babies to be born prematurely (early) or with birth defects.

If you are able to become pregnant, you must use an acceptable method of birth control, as previously described, from 30 days before your first study injection until at least 30 days after your last study injection. You should not participate in this study if you can become pregnant but cannot use one of these birth control methods. Some methods of birth control will not work when you are taking certain drugs. Be aware that you can still become pregnant even if using an acceptable birth control method. You must have a negative urine pregnancy test before each study injection. You should not plan to breast feed a child from the time of your first study injection through 30 days after the last study injection.

If you become pregnant while you are in this study, you should report this immediately to the study staff. No further study vaccinations will be administered to pregnant participants. With your permission, the study doctor or study staff will ask about your health and the outcome of your pregnancy and will collect scheduled blood samples. The study doctor may share this information with the study sponsor and with the Advarra Institutional Review Board, a group of people who review research studies to protect the rights and welfare of research participants.

Benefits of Being in The Study

You will not benefit from being in this study. However, the results of this research might benefit others by contributing knowledge that could lead to development of a vaccine for schistosomiasis.

Alternatives to Participating in This Study

You can choose to not participate in this study.

Early Withdrawal from the Study and Follow -Up

Your participation in this study is completely voluntary. You can stop 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 staff 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 for the following reason(s):

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

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.

The 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.

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.

Laboratory Testing of Blood Specimens

The blood specimens collected from you will be used for two types of tests — clinical tests to assess your health and research tests of the immune response to the study vaccine. None of the study tests are a part of your regular medical care. The clinical tests will include measures of your blood counts and kidney and liver function. If you have any abnormal clinical test results that may require medical care, we will share these results with you. Information about your blood samples for clinical testing will be kept confidential to the best of the study staff's and sponsor's ability and as required by law.

The research tests will measure indicators of immunity to schistosomiasis. Giving blood samples for the research tests will not benefit you. The results of these tests are useful only for research purposes. Your individual results will not be available to you or your regular doctor.

Blood specimens for the research tests will not be identified by your name or other identifying information. They will be labeled only with a barcode and a unique tracking number in order to help protect your confidentiality.

A part of each coded blood sample may be stored indefinitely at a site or sites determined by the study sponsor, the NIH. The stored samples will be labeled only by study participant number and will not be labeled with your name or initials, or any other information that could readily identify you, and will be kept confidential to the best of the sponsor's ability within state and federal law.

Some of the specimens are being collected to store for possible secondary research. Secondary research is research that is not part of this study and is not planned yet. These samples might be used in new or different laboratory tests, to provide information for the development of new vaccines, or for studies of schistosomiasis. The samples may be shared with other researchers at other institutions. All blood samples will be used only for research purposes; the samples will not be sold or used directly for production of any commercial product.

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 secondary research **might include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

There are no benefits to you in the collection, storage, and secondary research use of specimens. The results of any secondary research testing will be kept confidential in the same way as the results of other testing done for this study.

We may remove the codes (so that we cannot identify you) from your information or samples and use these in secondary research. These samples and/or data may be shared with other researchers without your additional consent.

If you do not want your blood to be used as described in this section, you should not participate in this study.

If you change your mind and do not want us to store and use your specimens and data for secondary research, you should contact a research team member. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your samples. 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 the study doctor or study staff if you have questions about how your blood samples may be used.

Certificate of Confidentiality

To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) 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:

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 informationmust 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.

Compensation for Participation

You will receive compensation based on the number and type of study visits you complete. For your time and effort, you will receive a payment of $75 for each of the 12 or 13 scheduled in-person clinic visits that you attend. The payments will be made by mailed check and a single check may be issued for several closely spaced visits. Checks may take up to 6-8 weeks to arrive in the mail. The total payment will depend on the number of study visits you attend. If you are withdrawn from the study for any reason, or if the study is halted, you will be paid for the visits that you have completed. The study staff will need to collect your social security number in order to process these payments. We will also 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. You will be paid after each completed visit.

You will not be paid for phone visits.

You are responsible for paying any state, federal, Social Security, or other taxes on the payments you receive. If you receive more than $600 in a calendar year from Kaiser Permanente Washington, Kaiser Permanente Washington will file a 1099 tax report with the IRS with a copy to you. No taxes are kept from your payments.

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 doctor or study staff for more information about this.

You will not share in the commercial profit if this study leads to a licensed product.

Cost to the Participant

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.

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

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

Research-Related Injury

In the event that you are injured as a result of being in this study, you should notify the study doctor as soon as possible. If you are a Kaiser Permanente Washington member, medical treatment will be provided by Kaiser Permanente Washington. You will not be asked to pay for any of the costs of this care (such as co-pays or other costs). If you are not a Kaiser Permanente Washington member, you may choose to receive medical care for the research-related injury from Kaiser Permanente Washington at no cost to you. If you choose to receive medical care for the research-related injury outside of Kaiser Permanente Washington, Kaiser Permanente Washington does not plan to pay for that care.

If you are not a Kaiser Permanente Washington member, be aware that your health insurance, if you have health insurance, might not cover the costs of study-related injuries.

No long-term medical care or financial compensation for research-related injuries is planned to 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.

Study Information

When the results of this study are available, which will be at least several months and likely 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

Funding for this research study will be provided by the NIH, Division of Microbiology and Infectious Diseases, the sponsor of the study. NIH is paying the study doctor to do this study.

Participant's Rights

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:

- Reasons related to you (for example, if you move to another city or if you donot agree to receive your study injection)
- Reasons related to your health (for example, if you have a serious reaction to the study vaccine)
- Because the entire study is stopped (the sponsor may stop the study at anytime)
- If you do not later consent to any future changes that may be made to howthe study is done
- If you become pregnant
- Any other reason

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more telephone assessments or come into the research clinic for assessments or blood tests.

If you withdraw from the study, the study doctor or study staff can still use your information that they have already collected.

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

What if I am a study center employee?

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.

What if my family member is a study center employee?

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.

New Findings

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or might change your decision to be in this study. You may be asked to sign and date a revised consent form if this occurs.

Confidentiality

Paper documents containing personal information about you will be maintained in locked file

cabinets. 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.

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 Institutional Review Board (a group of people who review research studies to protect the rights and welfare of research participants), as well as the Investigator (study doctor) and other employees of Kaiser Permanente Washington 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.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCHPURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you (protected health information).

What information may be used and given to others?

If you choose to be in this study, the study doctor and study staff will get personal information about you. This will include information that might identify you, such as your name and address. The study staff will also get information about your health including:

- Past and present medical records. If you are a Kaiser Permanente Washington member, the study staff will periodically review your medical record to identify new health events, medications, or vaccinations. The information reviewed will include clinic visit notes, hospitalization records, email exchanges with providers, laboratory results, medication prescriptions,and vaccinations. If you are not a Kaiser Permanente Washington member, we may ask you for a release of information to obtain your medical records if you have a new health event or if we need additional information about your health, medications, or vaccinations.
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

- Information obtained during this research
- Records about any study injection you received

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor, the study staff, and the research center, both during and after the study.

Who might get this information?

Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. The sponsor of this research study is the NIH. For this study, "sponsor" also includes ICON, an agent for the sponsor.

Information about you and your health which might identify you may be given to:

- The FDA
- Department of Health and Human Services (DHHS) agencies
- The OHRP
- Additional governmental agencies in the United States or other countries
- The Advarra Institutional Review Board (a group of people who review research studies to protect the rights and welfare of research participants)
- Your regular doctor (if you are a Kaiser Permanente Washington member)
- 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.

If you sign and date this form, you allow the study doctor to share your records with your health care payer to resolve your claim if you are hurt because of being in this study. If this happens, the study doctor or the sponsor may share your records with their insurance carriers to resolve your insurance claim, and the study doctor may also request medical records from your other healthcare providers to learn more about your condition.

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, employees of the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to other governmental agencies in the United States or other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research and so these agencies can monitor the study. The information may also be used to meet the reporting requirements of governmental agencies. The Advarra Institutional Review Board may also use records to check how researchers are doing the study, the study information, and participants' safety.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

Please note that the study doctor or study staff may share personal information about you if required by law. (For example, if the study doctor or study staff suspects that you are going to

harm someone or yourself.) If you have questions about this, please ask the study doctor or study staff.

What if I decide not to give permission to use and give out my health information?

By signing and dating this authorization, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research study.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information as held by the study doctor and study staff. However, if you decide to be in this study and sign and date this authorization form, you will notbe allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2050 unless you cancel it before that time.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on the first page of this form. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to one of the entities listed above, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your study records will be kept at Kaiser Permanente Washington for at least 2 years after licensing (if granted) of the investigational vaccine or for at least 2 years after the end of research with this study vaccine.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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, 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,and/or concerns or complaints regarding this research study, 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: Pro00059240.

CONSENT AND AUTHORIZATION

Information describing this research study has been explained to me. I have read this consent form. All the questions that I have at this time have been answered by the study doctor or study staff to my satisfaction. I voluntarily consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described in this form.

By signing and dating this consent form, I have not given up any of my legal rights. I will get a signed and dated copy of this consent form for my records.

_____

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 Explaining Consent

_____ _____

Signature of Person Explaining Consent Date