Informed Consent Form (ICF) for Study EBSI-CV-317-002: A phase 2 open-label study to assess the safety and immunogenicity of an alum-adjuvanted chikungunya virus-like particle vaccine (PXVX0317) in prior recipients of other alphavirus vaccines versus alphavirus naïve controls

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DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
[redacted]

WRAIR #2677
Version 3.0, [redacted] 2019

Walter Reed Army Institute of Research
Consent for Research Participation

Title:	A phase 2 open-label study to assess the safety and immunogenicity of an alum-adjuvanted chikungunya virus-like particle vaccine (PXVX0317) in prior recipients of other alphavirus vaccines versus alphavirus naïve controls
Sponsor:	Emergent Travel Health Inc. [redacted]
Funder:	U.S. Department of Defense and Emergent Travel Health Inc.
Principal Investigator (PI):	[redacted] Walter Reed Army Institute of Research
Contact Info:	[redacted]
IND Number:	17998

You are being asked to take part in a research study. This study is supported by the US Department of Defense and Emergent Travel Health Inc. The box below summarizes important things you should think about before deciding to participate. More detailed information is provided in the rest of the form. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Please contact the site principal investigator if you have any questions or concerns.

[redacted]

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if, after you join, you decide to quit.

- **Purpose**. We are doing this research to better understand the safety and immune response to PXVX0317, an experimental vaccine for chikungunya fever that Emergent Travel Health is developing. In particular, this study is looking at responses to this vaccine in adults who have and have not previously received vaccines for related ("alpha-") viruses.

- **Duration.** Your part of the study may last up to 242 days (about 8 months) which includes the screening period to confirm eligibility. If you consent and are eligible, you will receive a single dose of the PXVX0317 vaccine followed by observation and follow-up periods that will last another 26 weeks.

- **Procedures and Activities.** We will ask you questions about your medical history and draw blood to verify that you are healthy. Once we have confirmed you are eligible, you will be given one dose of vaccine in your shoulder muscle. You will be given a diary in which to record any symptoms that develop over the following week. Then we will ask you to return to clinic for follow-up visits over the next 26 weeks. At most of these follow-up visits we will draw blood for lab tests to study your response to the vaccine.

- **Risks.** This vaccine has been given to hundreds of volunteers and appears to be safe. Nevertheless, as with any vaccine, we expect some people will experience pain, redness, or swelling from the injection. Some volunteers may also report fever, chills, a general ill feeling, tiredness, headache, muscle aches, joint pains, or nausea. When these types of reactions occur, they usually occur within a day of injection and typically last 1 to 3 days. There may be other side effects from this vaccine (PXVX0317) that we do not yet know about. PXVX0317 does not contain any live viruses and cannot cause a chikungunya infection.

- **Benefits**. We do not expect you to personally benefit from being in this study. However, if we can understand how this vaccine works in people who have been exposed to other viruses, it can be studied and used in more places where people may be at risk for chikungunya infection.

- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Why are we doing this research?

The purpose of this study is to research how people respond to PXVX0317, an investigational vaccine for chikungunya fever that Emergent Travel Health is developing. "Investigational" means that the drug has not yet been approved or cleared by the Food & Drug Administration (FDA) for preventing chikungunya fever.

Participants are healthy adults between the ages 18 to 65 years (inclusive). In particular, this study will compare responses in those who have previously received vaccines for related alphaviruses versus those who have not. This information will help us design future studies of this vaccine in areas where other alphaviruses are transmitted.

The chikungunya virus (CHIKV) causes fever and joint pain. In severe cases, the joint pain can be debilitating and last for months or years. CHIKV occurs or has occurred in tropical countries in Africa, parts of Asia, South America, and the Caribbean. Cases have also occurred in Puerto Rico, Florida and Texas. Travelers to areas where CHIKV is spreading, including those participating in military operations, could be at risk. There are currently no approved vaccines to prevent CHIKV. Other alphaviruses are very rare in the United States. Some are associated with brain infections in horses, such as Venezuelan Equine Encephalitis Virus (VEEV) in South and Central America. Others are associated with fever and joint pain, similar to chikungunya such as Ross River Virus in Australia.

The vaccine we are evaluating in this research study, PXVX0317, is made from the outer shell of the CHIKV virus. To your immune system, these shells or "virus like-particles" (VLP) look just like CHIKV. But these VLP cannot multiply or cause infection. CHIKV-VLP vaccines have been given to over 600 adults in other clinical studies and have been well tolerated without serious side effects or discomfort.

There will be up to 60 people taking part in the study at the US Army Medical Research Institute for Infectious Diseases (USAMRIID) and at the Walter Reed Army Institute of Research (WRAIR). There will be about 30 participants at each site. Participants at USAMRIID will have previously received vaccines for other alphaviruses like VEEV. Participants at WRAIR will not have been vaccinated or exposed to alphaviruses, so their responses can be compared with those of the participants at USAMRIID.

How long will I be in this research study?

We expect that your participation will last up to 242 days. This includes a screening visit (the visit in which you first receive this consent form and the study team begins to determine if you are eligible), followed by the vaccination visit within 2 months and then six follow-up visits. The vaccination visit will last about two to two and a half hours. After that, the follow-up visits are scheduled for 1, 3, 4, 8, 16 and 26 weeks later and will each last about 1 hour.

What will happen if I decide to be in this research study?

There are eight visits scheduled for this study. The following table summarizes what will take place at each visit:

SCREENING PHASE	
Day	**What will take place?**
Screening up to two months before vaccination	• You will receive a briefing about the study and this consent form. • If you agree to participate and sign this consent form, a copy will be given to you and screening activities will begin. • You will be asked questions about your medical history including previous and current use of medications and a travel history. • Your vital signs will be taken and a study doctor will complete a physical examination. • Lab tests will be performed to make sure you are healthy. You will have about 30 mL (2 tablespoons) of blood drawn for lab tests (Hepatitis B & C, HIV) and routine health tests (blood count and blood chemistry) to evaluate overall health status. Women who could become pregnant will have a pregnancy test. • If you choose to participate, you will sign the required Maryland consent form for HIV testing. If all screening procedures and lab tests come back normal, and you are eligible to participate, you will be asked to return within 60 days from the time of this first visit. Subjects who are selected must: • Be between the ages of 18 and 65, • Be in good physical and mental health, • Be available to participate for the duration of the study (approximately 8 months), Subjects may not be selected if they: • Are pregnant, nursing, or planning to become pregnant during the study, • Are taking medicines that suppress their immune system, • Have had an acute allergic reaction to a vaccine in the past, • Are participating in another clinical trial, • Previously had chikungunya or have received an investigational vaccine for chikungunya. • Have gotten or will get another vaccine within 30 days of your dose of PXVX0317.
VACCINATION AND OBSERVATION PHASE	
Day	**What will take place?**
Day 1 Visit to Clinic	Before Vaccination: • Questions on your medical history and current use of medications will be reviewed. The study doctor may examine you depending on any changes to your medical history.

	• Vital signs will be taken and a urine pregnancy test performed (if you are a female who can get pregnant). • About 90 mL (6 tablespoons) of blood will be drawn for routine health tests to check overall health status, to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells, and for future use to help us study the vaccine. Vaccination: • You will be given an injection of PXVX0317 in your shoulder muscle. After Vaccination: • You will be observed in the clinic for 30 to 60 minutes for immediate side effects. • You will be given a diary, thermometer, ruler and an explanation of how to use these items to record symptoms, temperature and reactions at the injection site, and medications. You will need to bring the completed diary back in one week.
Day 8 Visit to Clinic	• Questions about your health and current medication use will be reviewed using your completed diary • Vital signs may be taken at the discretion of the study doctor. • Blood will be drawn (about 90 mL or 6 tablespoons) to check your blood counts and evaluate overall health status, detect antibodies (germ fighters) and germ fighting white blood cells that have responded to the vaccine, and for future use to help us study the vaccine.
Day 22 Visit to Clinic	• Questions about your health and current medication use will be reviewed. The study doctor may examine you depending on any symptoms you may have. • Vital signs may be taken at the discretion of the study doctor. • Blood draw (about 20 mL or 4 teaspoons) to detect antibodies (germ fighters) and germ fighting white blood cells that have responded to the vaccine, and for future use to help us study the vaccine.
Day 29 Visit to Clinic	• The study doctor may examine you depending on any symptoms you may have. • Vital signs will be taken at the discretion of the study doctor. • A urine pregnancy test will be repeated in women who might have gotten pregnant. • Blood draw (about 60 mL or 4 tablespoons) to detect antibodies (germ fighters) and germ fighting white blood cells that have responded to the vaccine, and for future use to help us study the vaccine.
FOLLOW UP PHASE	
Day 57 Visit to Clinic	• The study doctor may examine you depending on any symptoms you may have. • Vital signs may be taken at the discretion of the study doctor. • Blood draw (about 80 mL or 5.5 tablespoons) to detect antibodies (germ fighters) and germ fighting white blood cells that have responded to the vaccine, and for future use to help us study the vaccine.

Day 113 Visit to Clinic	• The study doctor may examine you depending on any symptoms you may have. • Vital signs may be taken at the discretion of the study doctor.
Day 182 Visit to Clinic	• The study doctor may examine you depending on any symptoms you may have. • Vital signs may be taken at the discretion of the study doctor. • Blood draw (about 80 mL or 5.5 tablespoons) to detect antibodies (germ fighters) and germ fighting white blood cells that have responded to the vaccine, and for future use to help us study the vaccine. This will be your last study visit.

What are my responsibilities as a participant in this research study?

If you agree to be in this research, you will be expected to:

- Tell the study doctor about your travel, medical and medication history.
- Attend all scheduled study visits.
- Follow the study team's instructions in between visits.
- Call the study team to reschedule any missed visits.
- Ensure that you do not get pregnant during the study. If you are female and able to conceive, you must use a highly effective method of birth control for the duration of the study.
- Notify the study team as soon as possible if you are hospitalized, have an emergency room visit, or become pregnant.

What happens to the information and specimens collected for this research?

Information and specimens collected from you for this research will become the property of WRAIR, USAMRIID and Emergent Travel Health and will be used to answer specific questions about this vaccine. Biological specimens will be coded so that your name cannot be identified with a sample. Reports about research done with your specimens will not be put in your health record. Results from this and future research using your specimens may be presented in publications and meetings, but your name will not be identified.

Your information, including information which can be used to identify you, may be used and shared with these people for the following purposes:

- The study doctor and staff will use your information to conduct this research study.
- A Research Monitor, a physician who is not part of the study team, has been assigned to this study in order to review serious side effects that are reported and ensure that the study is as safe as possible. This research monitor may stop the study if they decide that the vaccine is unsafe.
- The Sponsor, Emergent Travel Health; people who work with or for the sponsor, including the companies that are managing this study and other researchers

will use your information to review the study, to check the safety and results of the study and to someday seek government (FDA) approval of PXVX0317.

- Others required by law to review the quality and safety of research are the US Food and Drug Administration (FDA), government agencies in other countries who may consider licensure of this vaccine, representatives of the WRAIR Institutional Review Board, U.S. Army Medical Research and Development Command (USAMRDC) and other DoD offices who oversee research studies to protect the rights and welfare of research participants.
- Government agencies and public health authorities to whom certain diseases must be reported by law (reportable diseases) if the study team incidentally discovers that you have such a disease.

The results and findings from this study or future research with your samples will not be shared with you directly. A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. It is also expected that this study will be presented at scientific meetings and/or published in a scientific journal.

Any unused blood (including cells and serum isolated from your blood) will be stored a minimum of five years at WRAIR, USAMRIID, or Emergent Travel Health so it can be used in the future for other research studies. You should not participate in the study if you do not want your biological specimens stored. Some of your specimens may be shared with investigators at other institutions. Future research will most likely focus on the immune response generated by this vaccine and may further contribute to its further improvement and/or eventual licensure. You will not be informed of the results of any future research studies.

Though not currently planned, some future research studies may include genetic testing of your samples. This means that some of your DNA may be sequenced in order to, for example, learn how our DNA influences how we respond to vaccines. Using new technology, information about your DNA structure (genetic information) gained from your samples could be used to indicate your risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. There is growing concern that such information could be used by employers or insurance companies to discriminate against you. However, if we do this sort of testing, we will not share the results with you or knowingly make your samples available to your future employers or insurance companies. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233) also known as “GINA” is a federal law that prohibits discrimination in health insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or

the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

What are the risks if I participate in this research?

Risks with PXVX0317:

The injection of PXVX0317, like other injections, can cause pain, redness, or swelling at the spot where you are injected. These types of reactions are generally mild. Less commonly, it can cause itching, bruising, or infection.

In an earlier study, symptoms reported after study injection included: injection site pain (41.4% subjects), injection site redness (1.0%), injection site swelling (0.5%), malaise (14.2%), nausea (13.0%), headache (27.2%), joint pain (9.6%), fatigue (19.5%), chills (6.5%), fever (1.7%), and muscle soreness (22.7%). The majority of symptoms reported were mild or moderate; 6% of subjects reported at least one symptom that was graded as severe. An example of this would be a headache so bad you could not go to work. No solicited events were potentially life threatening. These types of reactions usually happen within a day after injection and typically last 1 to 3 days. PXVX0317 does not contain any CHIKV virus and **cannot** give you CHIKV infection. There may be other side effects from PXVX0317 that are not common and that we do not yet know about. Please tell the study staff about any side effect you think you are having. This is important for your safety.

Risk of Allergic Reaction:

With any vaccine, there is a risk of severe allergic reaction. Although such reactions have not been reported with this vaccine, they have occurred with other vaccines containing some of the same ingredients. Symptoms of allergic reaction include:

- Rash
- Wheezing and difficulty breathing
- Difficulty swallowing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please inform the study staff immediately if you experience any of these symptoms.

Risks with Blood Draws:

Blood drawing may cause pain, bruising, feeling faint, fainting, needle site infections, swelling, and rarely other infections. Bruising at the site of blood drawing can be prevented by applying pressure for several minutes. To reduce the risk of infection, we will wipe the area clean with alcohol and use sterile (germ-free) equipment.

Risks of Positive Screening Test for HIV, Hepatitis B and C:

At the Screening visit, you will be tested for hepatitis B and C and HIV. If your blood tests show that you have HIV or hepatitis B or C, we are required by law to report this information to the Maryland Health Department. The test results reported to Maryland Health Department will contain your name, contact information, including address and telephone numbers, and the type of testing that was done on you. If you are in the military, we are required to report the same kind of information to military preventive medicine service. As a result, this information may end up in your military medical record and may be reported to your chain of command.

Receiving information that any health screening tests are abnormal or that tests for HIV and hepatitis B or C are positive may be upsetting. The study doctors will discuss your health results with you face-to-face (and notify your primary doctor at your request). Counseling will be available to you, if you wish. A positive HIV status could limit your ability to obtain future life and health insurance. In rare circumstances, a positive HIV test has led to discrimination in employment and housing, etc.

Are there pregnancy risks?

If you are a female who can become pregnant and want to take part in this study, you should know that PXVX0317 has not been thoroughly evaluated for potential risks to unborn or nursing children. You should not get pregnant or breastfeed while taking part in this study. You must have a negative pregnancy test at screening and again immediately before vaccination, however pregnancy tests are not 100% accurate. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed on the first page of this document. If you become pregnant, the study team will ask permission to contact you regarding the outcome of your pregnancy.

Risks to Confidentiality:

Efforts will be made to keep your personal health information confidential. In order to maintain confidentiality, paper study records will be stored in a secure location such as a locked office or locked cabinet. Electronic data will be password-protected. Electronic study records and samples taken from you will be coded with a number, not your name. Records will only be shared with authorized personnel and only in connection with carrying out the obligations relating to the study.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your research records or other information researchers have stored about you.

Other ways the study team will lessen the potential risks:
The safety of all volunteers will be monitored throughout the study. Research data or information related to the safety of the vaccine will be reviewed on an ongoing basis by the following people and groups:

1. The main study doctor and study staff;
2. A Sponsor medical monitor: this is a doctor affiliated with the Sponsor who will promptly review all medical events reported as "serious" by your study doctor and will also periodically review all other potential side-effects reported;
3. Sponsor-designated study monitors: these are people affiliated with the Sponsor who will be visiting the study clinic to look over all of the records related to this study;
4. An independent research monitor who is a physician independent of the sponsor and study team.

There may be risks in this study which are not yet known. You will be informed of any significant new findings in case they might change your decision to participate in this study.

How will my privacy and data confidentiality be protected?

Your participation in this study is entirely confidential to the extent allowed by law. We understand that information about your health is personal. We will take measures to protect your privacy. Even with these measures, we can never fully guarantee your privacy will be protected. We will try our best to protect your privacy by doing the following:

If you experience any adverse effects during the study which are treated by another doctor, we may request to see the records made by that doctor. You must agree to authorize the release of these medical records from the physician who treated you to the study doctor if requested.

If you are in this study, the following "personal data" will be collected by the study team:

- Identifying data (for example: name, address, date of birth)
- Race or ethnicity
- Information from your medical and vaccine records
- Areas you have traveled to
- Biological samples (blood) that contain your unique DNA

Your personal data will be processed at all times in accordance with applicable legal requirements. Your personal data are not given out to anyone unless required by law. All of the information you give during the study will be kept in locked areas and/or on password-protected computer files. The only people who will have access to your information are those involved in the study as listed above. Otherwise, the information that identifies you will not be given out to people who are not working on the study, unless you give us permission. Efforts will be made to keep the records as confidential as

possible, within the limits of the law. However, confidentiality cannot be assured as there is always some risk that an unauthorized person may view your records.

The study results and data may be published in scientific and medical journals; however, the identity of individual participants will not be disclosed. To help ensure this, your name and any identifiable information (for example, your address or date of birth) will be removed from study files and your lab samples and be replaced with an identification code that consists of numbers and letters. Different codes may be used for you during the course of the study. Only the study investigators, study coordinators, research monitor and representatives from certain agencies (described above) will be allowed to know which codes belong to you, and to have access to your study information.

Your study files will be kept in a safe, secure storage area at WRAIR for the duration of the study. While we will do our best to protect your information there are some cases where we cannot guarantee complete confidentiality.

What are the possible benefits from this research?

We do not expect that you will benefit directly from participating in this study. However, the information we learn may benefit others. We do not yet know whether PXVX0317 will prevent a chikungunya infection if you travel to an area affected by chikungunya, or how long the protection may last. If you ever travel to an area where chikungunya is being transmitted, you should follow that same preventive health advice as anyone who did not participate in this study. There is no guarantee that the study vaccine will protect you in the event you are exposed to chikungunya in the future.

What other choices do I have besides participation in this research?

It is your choice to participate or not to participate in this research.

Will I be paid to take part in this research study?

You will receive compensation at each visit for the time and effort involved in participating in this study. Subjects will receive $50 for the screening visit in the form of a Visa gift card that can be used as a debit card. Payments for all other visits will be given via debit card or by direct deposit at the preference of the volunteer. $200 will be given for the vaccination visit. Other scheduled visits will be compensated at $130. Unscheduled visits requested by study investigators will be compensated at least $50. You will not be compensated for missed visits.

If you make every follow-up visit during the study within the allowed window, an additional $200 will be provided at the last study visit (Day 182). The maximum compensation for completing the study is approximately $1,230.

Under 24 USC 30, payment to federal employees to include civilians and active-duty personnel for participation in research is limited to blood donation and may not exceed

$50 per blood draw, unless the individual takes part outside of duty hours; in that case, compensation is the same as that for non-federal subjects.

If you receive more than $600 in a calendar year, we are required to report this to the Internal Revenue Service and you may be required to report this on your income tax form.

Other than the medical care that may be provided and any other payment specifically stated in this consent form, there is no other compensation available for your participation in this research study; however, you should also understand that this is not a waiver or release of your legal rights.

Are there costs for participating in the research?

Ask your study doctor to discuss the costs that will or will not be covered by the Sponsor. This discussion should include the costs of treating possible side effects. Otherwise you might have unexpected expenses from being in this study.

Are there disclosures of financial interests or other personal arrangements from the research team?

Members of the clinical study team are employees or contractors of the US government and will not receive any additional benefit from participating in this study regardless of its outcome.

Data from this study and from the use of your samples collected as part of this study may result in new products, tests or discoveries which may have commercial value for Emergent Travel Health.

What happens if I am injured as a result of this research?

If you are injured because of your participation in this research and you are a Department of Defense (DoD) healthcare beneficiary (e.g. active duty in the military, military spouse or dependent, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to medical care for your injury at an Army hospital or clinic; medical care charges for care at an Army hospital or clinic will be waived for your research-related injury. You are also entitled to care for your injury at other DoD (non-Army) hospitals, but such care for your injury at other DoD (non-Army) hospitals or clinics may be time-limited, and your insurance may be billed. It cannot be determined in advance which Army or DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of an Army or DoD hospital or clinic, you or your insurance will be responsible for medical expenses.

Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical expenses to treat research-related injuries. No

compensation is available for research-related injuries. You are not waiving any legal rights.

If you believe that you have sustained a research-related injury, please contact the investigator or other member of the study team.

What happens if I withdraw from this research?

You may withdraw from this study at any time. If you choose to leave the study, data and specimens collected prior to your withdrawal may still be used by the study team.

You may withdraw your consent at any time and stop participating in this research study. Leaving the study will not impact your ability to receive care or any other benefits that you would have received otherwise. If you leave this study, you will be given contact information to reach the study doctor and staff if you develop and study-related illness.

Please note that withdrawing your consent to participate in this research does not fully revoke your authorization to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator.

Could my participation in the study end earlier than expected?

Once you receive the study vaccine at the beginning of the study the only risks to your health are those associated with blood draws. Even if you become pregnant or develop a new health condition, you will most likely be asked to continue in the study. If there is some reason to think it would be harmful to your health to continue, you may be removed from the study. If there are safety concerns that lead to cancellation of further vaccination of other volunteers, or if we discover any new information during the study that may affect your health and willingness to continue participation, you will be informed.

Your individual participation may be terminated if you do not follow the instructions of the study team or if it is otherwise felt that your continued participation would pose a risk to you or the study team.

Can I access my personal health records from this research study?

You will be permitted to access your personal health information as it pertains to this study only after the entire study has been completed, all the data from all participants have been analyzed, and the results of the study have been published.

Any published information including reports and articles about the study will not include your name or any information that could personally identify you. Information received during the study will not be used to market to you; your name will not be placed on any mailing lists or sold to anyone for marketing purposes.

What if I decide not to share my health information?

By signing this consent form, you are giving permission to use and give out your health information noted above for the purposes described above. If you refuse to give permission, you will not be able to participate in this study.

Can I withdraw or revoke (cancel) my permission to access my health information?

Your permission to use and share your health information will continue indefinitely (it does not expire), but that use and sharing will only be for the purposes described in this consent form. You may withdraw or take away your permission to use and disclose your health information at any time. You can do this by informing a study team member in writing or in person during a study visit. If you withdraw your permission, you will not be able to continue being in this study. Information that has already been gathered up to the point you withdraw permission may still be used and given to others for the purpose of analyzing the data already collected.

Who can I contact if I have questions about my rights as a research participant?

If you have questions about your rights as a research volunteer in this study, you may contact the Human Subjects Protection Branch, Walter Reed Army Institute of Research [redacted]

What is the volunteer registry?

It is the policy of the US Army Medical Research and Development Command (USAMRDC) that data sheets are to be completed on all volunteers participating in this type of research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRDC; and second, to ensure that the USAMRDC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRDC for a minimum of 75 years. The Volunteer Registry Data Base is separate from and not linked to the treatment protocol database.

Your Consent

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

Although the WRAIR IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean WRAIR has approved your being part of the study. You need to read the

information in this informed consent form for yourself and decide whether or not you want to be in this study.

If there is any portion of this document that you do not understand, ask the investigator before signing the form. Signing this form means that you consent to participate in this research at this time.

A signed and dated copy of this document will be given to you.

Please initial the sentences that reflect your choices, and then sign below:

_____ I have read the information in this consent form.

_____ All of my questions about the study and my participation have been answered.

_____ I agree to participate in this study.

_____ I do not authorize the storage of my biological specimens for future use in research studies.

_____ I authorize the storage of my biological specimens for future use in research studies.

_____ I do not authorize the storage of data collected as a part of this study for future use in research studies.

_____ I authorize the storage of data collected as a part of this study for future use in research studies.

_____ I agree to be contacted in the future about other research studies.

_____ I do not agree to be contacted in the future about other research studies.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date