Title: A Phase 2 Open-Label Study to Assess the Safety and Immunogenicity of PXVX0317 (Chikungunya Virus Virus-Like Particle Vaccine [CHIKV VLP], Aluminum Hydroxide Adjuvanted)

NCT number: NCT05065983

Document: EBSI-CV-317-010 Informed Consent Form

ICF Version: v4.0

ICF Version Date: 03-Dec-2021

ICF IRB Approval Date: 26-Dec-2021

IRB APPROVED
AS MODIFIED
[redacted] 2021

Consent Form to Take Part in a Clinical Research Study and Authorization to Disclose Health Information

TITLE: A Phase 2 Open-Label Study to Assess the Safety and Immunogenicity of PXVX0317 (Chikungunya Virus-Like Particle Vaccine [CHIKV VLP], alum-adjuvanted)

PROTOCOL NO.: EBSI-CV-317-010
WIRB® Protocol #20212791

SPONSOR: Emergent Travel Health, Inc.

SITE ID: 13

INVESTIGATOR: [redacted]

STUDY-RELATED PHONE NUMBER(S): [redacted] ([redacted] for Emergency)

What is a Clinical Research Study?

The purpose of a research study is to gather information about how safe a study drug is and how well it works. Participating in a research study is not the same as getting regular medical care. Being in this study does not replace your regular medical care.

You are being asked to take part in a research study. This consent form will tell you:

- Details about the study and what will happen to you as a research participant
- Possible benefits and risks to you if you choose to take part in the study
- Your rights as a research participant

Before you give your consent to take part in the study, please read this form carefully and ask as many questions as you need to be sure that you understand what taking part in this study means. If you agree to participate in this study, you must sign and date this Consent Form before you start anything having to do with this study. You will be given a signed copy of this Consent Form to keep. It is your choice to take part in this study because it is voluntary. There will be no penalty or changes to your medical treatment if you choose not to take part in the study. No promises can be made about the outcome of this study.

Any time you have questions about the study you may contact the Principal Investigator (also referred to as the "study doctor") at the phone number listed above.

You may choose not to participate or change your mind about participating at any time during the study without penalty or loss of benefits to which you are otherwise entitled. You may leave the study at any time, even if you have signed this form. You do not have to give a reason if you decide to leave the study.

1 WHAT YOU SHOULD KNOW ABOUT THIS STUDY

This is a research study of a study drug called PXVX0317. The use of this study drug is investigational, meaning the drug has not been approved by the United States of America (US) Food and Drug Administration (FDA). This study is funded by Emergent Travel Health Inc., which will be called "Sponsor" throughout the rest of this document.

PXVX0317 is being developed with the intention of being used as a vaccine to prevent disease caused by chikungunya virus.

The chikungunya virus is a germ that causes a disease with a high fever and pain in many joints. The knees, elbows, wrists, ankles, and/or fingers are generally affected. In bad cases, the joint pain can be severe and can last for a long time (months or even years). Chikungunya disease typically occurs in areas such as Africa and parts of Asia, South America, and the Caribbean. The virus is most often spread to a person by a mosquito bite that can result in illness and disease. The disease can affect travelers from the US who are visiting these areas that have mosquitoes with the virus, and since 2014 there have been local cases seen in Florida, Puerto Rico, and US Virgin Islands. Vaccines are developed to prevent diseases that can be dangerous, or even deadly. Vaccines may greatly reduce the risk of infection by working with the body's natural defenses to safely develop immunity to disease. There are currently no FDA-approved vaccines to prevent chikungunya disease.

1.1 What is the study drug?

PXVX0317 is a vaccine made from only specific parts of the chikungunya virus. These parts when put together are called virus-like particles (VLP), although they are not the whole virus. Chikungunya virus-like particles have been given to about 723 adults in other clinical studies and was generally well tolerated without serious side effects or deaths. PXVX0317 vaccine

containing chikungunya virus-like particles does not cause chikungunya disease.

1.2 Who can participate in this study?

To join the study, you must be between 18 and 45 years of age, in good health, and your body weight must be higher than 110 pounds. If you are pregnant or breastfeeding or planning to become pregnant during the study, you cannot take part in this study. If you have previously been infected with Chikungunya virus, or you have previously received another vaccine in a clinical trial for prevention of Chikungunya disease, you may not be eligible to participate in this study.

1.3 How long will I be in the study?

Your participation in this study may last up to 213 days.

1.4 How many people will be in the study?

You will be one of 25 people taking part in this study at one research site.

1.5 Why is this study being done?

The purpose of this study is to research the safety of, and the body's immune response to, PXVX0317, an investigational chikungunya vaccine that the sponsor is developing. Investigational means this is not approved by the FDA. This is an open label study, which means that you will receive only active vaccine and not a placebo. Extra plasma (which is the liquid portion of your blood) is also being collected during this study for additional research purposes.

2 WHAT ARE MY RESPONSIBILITIES DURING THE STUDY?

You will be expected to attend all planned visits as listed in the study visits below. You will have to tell the research staff about any illnesses or unusual changes in your mind or body (symptoms).

If you participate in this study, it is important that you:

- Tell the study doctor about your medical and medication history.
- Follow the study doctor's instructions at and between visits until the last study visit.
- Attend all visits scheduled with the study doctor. Call the study doctor to reschedule a missed visit.
- Report to the study doctor or research staff as soon as possible if you are hospitalized, have an emergency room visit, or become pregnant.

3 WHAT WILL HAPPEN IF I JOIN THE STUDY?

If you decide to be in this study, the study doctor and study staff will collect information about your full medical history. This includes any medication you currently take and any other information in your medical records related to your health that may be relevant to you being in the study. For this study, your study doctor will schedule at least 5 in-clinic visits (not including the screening visit) and 3 scheduled phone calls. You must make sure that you can come to each visit as scheduled.

If you are a female who is able to get pregnant, your urine will be tested to check if you are pregnant as part of the screening process. The result of the pregnancy test must be negative in order for you to be allowed to be in the study.

If you meet all criteria to be in the study, a urine pregnancy test will be performed on Day 1 (date of vaccination) to check again that you are not pregnant, before you receive the vaccination. You will also receive urine pregnancy tests throughout the study on visit #5 and visit #7. The study doctor will discuss with you which forms of birth control are acceptable.

A physical examination will be performed, and your vital signs will be taken which includes measuring height, weight, blood pressure, pulse, breathing rate, and temperature.

You will be given a 0.8 mL injection (shot) in the upper arm using a needle with syringe one time during the study.

After you receive the injection, you will be given a thermometer, ruler, and a form (called a "Memory Aid") to record your symptoms and medications you take for 8 days in a row, starting on the day you receive the injection. The study staff at the clinic will provide you instructions and training on how to complete the Memory Aid.

The study is divided into 3 phases:

Screening phase: is the phase when you are given information about the study and tests are done to see if you are eligible to join. More visits may be needed if any of your screening tests are not normal.

Vaccination and observation phase: begins when you are given an injection in the upper arm on Day 1. After the injection, you will receive your Memory Aid form. You will return to the study clinic around 7 days after the injection and you will need to bring your Memory Aid form to the clinic. You will then have study visits at about 14 days, (in-clinic) and 21 days (in-clinic) after vaccination so the study doctor and study staff can ask about your health and any new medications you may be taking. In addition, blood will be taken to measure your antibodies (germ fighters).

Follow-up phase: is the remaining time in the study. You will have study visits at about 28 days (by phone), 56 days (in-clinic), 63 days (by phone), and 182 days (by phone) after your vaccination date so that the study doctor and study staff can ask about your health and any issues you observed. During your in-clinic visit (Day 57), blood will be taken to measure your antibodies (germ fighters).

Additionally, you will be undergoing a procedure called plasmapheresis at Day 22 and Day 57 which will be conducted at a nearby blood bank. The lab personnel will be collecting approximately 600-900 mL of plasma (a yellowish liquid component of the blood), depending on your gender, weight and height and other considerations. The procedure involves removal of blood from a vein of one arm, passage of blood through a device where the plasma will be removed, and the remainder of the blood returned to your vein. While the blood is being drawn, a small amount of anticoagulant (citrate) is added to the blood to prevent clotting during the procedure. You will also receive a saline solution to assist your body in compensating for the fluids lost during the procedure. The collection process is continuous and usually takes between 30 minutes to 2 hours.

The following tables summarize what will take place if you are eligible and agree to be in the study.

Screening Phase	
Day	**What will take place?**
Screening: Visit 1 (-30 days from Day 1) Visit to Clinic	• You will receive this description of the study and consent form before any screening activities. • If you agree to sign this consent form, a copy will be given to you and screening activities will begin. • You will be asked to provide your medical history including previous and current use of medications. • You will be given a physical examination (general examination of the body to check overall health), have vital signs taken (which includes measuring height, weight, blood pressure, pulse, breathing rate, and temperature), a urine pregnancy test given (if you are a female who can get pregnant), and urine drug test given (if your doctor thinks this is needed). • You will have about 15 mL (approximately 1 tablespoon) of blood drawn for lab tests (Hepatitis B & C, HIV, Chikungunya) to give the study doctor information to assess your prior exposure to these viruses. State law requires requires positive test results for certain communicable diseases, including HIV and hepatitis, to be reported to a local health agency. • If all screening procedures and lab tests come back normal,

	and you are eligible to participate, you will be asked to return within 30 days from the time of this first visit.
Vaccination and Observation phase	
Day	**What will take place?**
Day 1: Visit 2 Visit to Clinic	Before Vaccination: • The study doctor or staff will ask questions about your medical history and current use of medications. The study doctor may give you a physical exam (general examination of the body to check overall health) depending on changes to your medical history since the screening visit. • Vital signs (which includes your blood pressure, pulse, breathing rate, and temperature) will be taken and a urine pregnancy test given (if you are a female who can get pregnant). • You will have about 74 mL (about 5 tablespoons) of blood drawn in order to check your blood for levels of antibodies (germ fighters) and germ-fighting white blood cells. Vaccination: • If you are eligible for the study, you will be given an injection of PXVX0317 vaccine in the muscle of your upper arm. After Vaccination: • You will be observed in the clinic for at least 30 minutes after the injection for immediate side effects. • You will be given a Memory Aid, thermometer, ruler and training on how to use these items to record symptoms, temperature and skin reactions at the injection site. You will need to record this information for 8 days starting with Day 1 (the day you receive your injection). You will also need to record any medications you take during this time period. The study staff will train you on how to record your symptoms and fill out the Memory Aid.
Day 8: Visit 3 (+3 days) Visit to Clinic	• Questions about your health and current medication use. • Review Memory Aid. • You will have about 74 mL (about 5 tablespoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells.

Day 15: Visit 4 (± 2 days) Visit to Clinic	• Questions about your health and current use of medications. • You will have about 74 mL (about 5 tablespoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells.
Day 22: Visit 5 (+ 5 days) Visit to Clinic	• Questions about your health and current medication use. • You will have about 114 mL (about 8 tablespoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells. • You will have urine pregnancy test (if you are a female who can get pregnant). • You will undergo plasmapheresis procedure at a nearby blood bank. You will have about 690-900 mL of plasma drawn (exact amount is dependent on your body weight). To confirm eligibility for the plasmapheresis procedure, body weight, vital signs, finger stick to check red blood cell level, and a questionnaire regarding your health history will be conducted by the blood bank personnel. • After the procedure, you will be observed in the blood bank for 30 minutes to monitor for immediate side effects
Follow-up Phase	
Day 29: Visit 6 (-1/+5 days) Telephone	• The study staff will call you to ask questions about your health and current medication use.
Day 57: Visit 7 (+ 5 days) Visit to Clinic	• Questions about your health and current medication use. • You will have about 114 mL (about 8 tablespoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells. • You will have urine pregnancy test (if you are a female who can get pregnant). • You will undergo plasmapheresis procedure at a nearby blood bank. You will have about 690-900 mL of plasma drawn (exact amount is dependent on your body weight). To confirm eligibility for the plasmapheresis procedure, body weight, vital signs, finger stick to check red blood cell level, and a questionnaire regarding your health history will be conducted by the blood bank personnel. • After the procedure, you will be observed in the blood bank for 30 minutes to monitor for immediate side effects
Day 64: Visit 8 (-1/+5 days) Telephone	• The study staff will call you to ask questions about your health and current medication use.

Day 183: Visit 9 (-14/+7 days) Telephone	• The study staff will call you to ask questions about your health and current medication use.

3.1 Early Withdrawal/Termination Visit

If you or your study doctor decides that you should leave the study before the completion of all required visits, you will be asked to come back to the study clinic for a final visit. At the final visit:

- You will be asked questions about your health and current medication use.
- You will have about 74 mL (about 5 tablespoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells.
- You will have urine pregnancy test (if you are a female who can get pregnant).

4 WHAT ARE THE POTENTIAL RISKS, SIDE EFFECTS, AND DISCOMFORTS?

4.1 Risks with study drug

All medicines may cause side effects. There may be side effects of PXVX0317 that are not yet known. Tell the research staff right away if you have any problems or if you notice anything different about your emotional or physical health.

Based on earlier studies of people who received this dose of PXVX0317, about half (48%) reported side effects. The most common side effects of PXVX0317 were:

- Pain at the injection site (14%)
- Tiredness (4%)
- Nausea (4%)
- Joint pain (2%)
- Headache (8%)
- General ill feeling (4%)
- Muscle aches (12%)
- Injection site bruising (2%)

Most of these side effects were mild or moderate. Approximately 6% of these reactions were severe. No serious or life-threatening side effects to the vaccine occurred. Fever and injection site swelling/redness have been reported in other studies of PXVX0317. There may be other side effects from PXVX0317 vaccine that are not common or that we do not yet know about.

Talk to the study doctor about any side effects that concern you. You can ask the study doctor for additional information about PXVX0317 vaccine that is available to healthcare professionals.

4.2 Risk of Allergic Reaction(s)

There is a risk of severe allergic reaction to an ingredient of PXVX0317 vaccine components. Symptoms of allergic reaction may include (but are not limited to):

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

Talk to the study doctor about any side effects that concern you. During this study you will be observed for any bad or harmful effects. The study doctor will decide if it is safe for you to keep participating in the study.

4.3 Possible risks to pregnancy and unborn baby (fetus or embryo), reproduction, or nursing infant

If you are a female who is able to become pregnant, you will be required to use highly effective contraception throughout the study, up to 213 days. Please discuss the exact details with the study doctor in order to avoid an unintended pregnancy if you are sexually active.

If you become pregnant while participating in this research study, the study drug could be hazardous to the pregnancy and/or the developing baby. If you think you are pregnant during the study, you must tell the study doctor immediately. The sponsor will ask permission to follow the pregnancy and ask about information about the birth of the baby. You may choose to allow the sponsor to directly contact your health care provider to collect this information.

4.4 Risks from blood draws

Some people have discomfort or pain when blood is collected. Some people feel faint or pass out during or shortly after blood is drawn. If you feel faint, lie down right away so you don't get hurt from a fall and tell the research staff or study doctor right away. There is a risk of infection, bleeding and/or bruising at the spot where blood was taken or a clot may form when blood is collected, but these are unusual.

4.5 Risks with Apheresis (plasmapheresis):

Many of the potential risks of these procedures are the same as those associated with whole blood donations. Donations may cause pain, bruising, and discomfort in the arms where the needles are placed. It may also cause chills, nausea, heartburn, mild muscle cramps and tingling sensation around the mouth or in the fingers. However, this can usually be relieved by slowing or temporarily interrupting the apheresis or taking a calcium containing antacid, such as Tums. Other possible side effects are anxiety, vomiting and lightheadedness.

Temporary lowering of the blood pressure may develop. There is the rare possibility of infection, fainting or seizure. Very rarely a nerve problem at the needle placement site may occur. There may be additional risks of apheresis that are unknown as this time.

The white cell count, platelet counts, and /or plasma volume may decrease temporarily, and these levels should be back within normal range in several days.

You should not participate in any plasma collection for at least 28 days and understand that the donation of whole blood or red blood cells while participating in the apheresis procedures may result in an 8-week deferral, or a 16-week deferral for a double red blood donation.

4.6 Risks of physical injury resulting from participation

All forms of medical or mental health diagnosis and treatment, whether routine or experimental, involve some risk of injury. There may also be risks in this study that we do not know about. Even with all the care that is taken, you may still develop medical complications from participating in this study. If during the course of the study you get hurt or sick or experience any side effect to the study drug or study procedure, please contact the study doctor. If such complications arise, the study doctor will help you get the proper medical treatment.

In the event of an injury that occurs to you as a result of receiving PXVX0317 vaccine or undergoing study procedures, you will receive the necessary medical treatment. In the event that you suffer injury as a direct result of participating in this study, the sponsor will cover the costs of reasonably necessary medical treatment not covered by your medical or hospital insurance or by third-party or governmental programs providing such coverage. The sponsor or the study doctor will not cover costs for medical care for injuries or illnesses that are not a direct result of research activities. No other compensation is routinely available from sponsor or the study doctor.

By signing this Consent Form you do not give up your right to look for and receive required medical treatment.

4.7 Risks to confidentiality

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. In order to maintain confidentiality, your study records will be stored in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected. 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.

Some of the questions may seem personal and may make you uncomfortable. If you have any questions or concerns while answering these questions, please talk to your study doctor or study staff.

4.8 Risks related to COVID-19

The sponsor will monitor the situation related to the COVID-19 pandemic to ensure that potential risks to study participants and research staff are mitigated. The following strategies will be implemented:

- The conduct of the study will be in accordance with state and local travel limitations/restrictions.
- Research staff at the research site will take appropriate precautions to protect study participants.
- Safety assessments will be performed by telephone when appropriate.
- If travel restrictions or COVID-19 related illnesses impact the conduct of the study, specific measures will be taken to mitigate risk to research staff and participants.

5 WHAT ARE THE POSSIBLE BENEFITS TO BEING IN THE STUDY?

If you take part in this study, it is possible that you may not have any direct medical benefits. However, the results of this research may benefit others by guiding the future development of PXVX0317 vaccine. We do not yet know if PXVX0317 will prevent chikungunya disease if you travel to an area affected by chikungunya virus, or how long the immune protection may last.

6 WHAT ARE THE ALTERNATIVES

Your alternative is to not participate.

7 PRIVACY AND CONFIDENTIALITY

7.1 What are my Privacy and Confidentiality rights?

Privacy rights of subjects participating in clinical research studies are being protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your rights as a subject under this act include deciding who has access to your personal health information (called “Protected Health Information”).

Protected Health Information is medical information about you that includes your entire historical medical records, all study doctor visits, evaluations, biospecimens (e.g., blood samples), laboratory tests, diagnostic tests, procedures, treatments, medications taken, hospitalizations, etc. The study doctor may also get information about your past, present and/or future physical or mental health and/or condition from your primary care doctor.

Protected Health Information contains identifiers that can link your medical records specifically to you, such as:

- Your name and initials
- Your address
- Date of birth
- Social security/insurance number
- Dates and results of various tests and procedures
- Basic demographic information (such as age, gender, ethnicity/race)

Your written authorization is required before any information about you can be collected, shared, or stored.

7.2 What information will be collected for the study and why?

The study doctor and research staff will collect your medical history, blood samples, results from laboratory analyses and procedures, and results from physical examinations. Your study medical record will also contain personal information such as your name, address, telephone number, date of birth, social security/insurance number, or unique identifiers.

Information collected about you during this study will be used to better understand the safety of, and the body's immune response to, the dose of PXVX0317 that has been selected for further study, and the study information may be published in a scientific or medical article. You will not be personally identified in these instances. In addition, the sponsor may re-analyze the results at a later date and combine them with results of other studies.

7.3 How will my information be shared, protected, and stored?

Any information learned about you in this study will be treated as confidential.

The study doctor and study sponsor, the Institutional Review Board (IRB), and the proper national and international regulatory authorities such a FDA may be able to see your health and research records and test results. They may copy information from your health record for the purpose of this research study and to confirm your safety. Your records will be protected and kept as private as possible under local/national/international regulations. Total privacy cannot be guaranteed.

Copies of your medical records that are related to the research may be collected by the study sponsor after your name or initials, address, telephone number, date of birth, social security/insurance number, or unique identifiers have been removed, in order to review for your safety and to ensure the study data is recorded correctly. These copies may be transferred via encrypted email, secure fax line, or uploaded to a secure, password-protected website. These copies will be permanently destroyed at the end of the study unless required

by law for safety reporting.

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.
The study doctor will keep this personal health information in your study-related medical records (that we will refer to as "your records") during the study and for up to 2 years after the study is completed.

7.4 Sample Storage for Future Use

Any biological samples (such as blood) taken from you during the study become the property of the Sponsor. Any unused biological samples may be stored for at least two years after last approval of the vaccine. This is a requirement of the study..

You should not participate in the study if you do not want your biological samples stored. These biological samples may be used for future research to learn more about PXVX0317 vaccine, the body's response to it and responses to vaccines in general. No genetic testing will be performed on your biological samples. Your biological samples will only be used for studies and tests performed by medical scientists. Biological samples will be coded so that there is no identifiable information associated with your sample. Reports about research done with your samples will not be part of or entered into your health record. There will be no direct benefit to you, but from studying your samples the Sponsor may learn more about how to prevent and treat chikungunya. Results from future research using your samples may be presented in publications and meetings, but your name will not be identified.

7.5 Authorization to Use and Disclose Protected Health Information

By signing this Consent Form, you are allowing the study doctor to have direct access to your Protected Health Information collected in this study, and to receive your Protected Health Information from either your physician or facilities where you have received health care.

Your signature on this Consent Form authorizes:

- The research staff, study doctors, and/or institution to have access to your Protected Health Information collected as part of this study
- The study doctor and/or institution to receive your Protected Health Information from your physician and/or facilities where you have received any health care
- Your Protected Health Information to be shared with other persons or organizations involved in the conduct or oversight of this research study, including but not limited to: US Food and Drug Administration (FDA); US Centers for Disease Control and Prevention (CDC); the Institutional Review Board (IRB) used by your research site;

regulatory agencies in other countries; third parties working on behalf of the sponsor; and the laboratory(ies) handling the lab specimens for this study. The other persons and/or organizations need to see your personal health information so they can review the data and to make sure of the quality of the study conduct and/or the data collected. These other persons and/or organizations may or may not have the same obligations as the study doctor or institution to protect your Protected Health Information.

Your Protected Health Information will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study. Your Protected Health Information will be used for as long as the sponsor reports study information to the FDA or other countries' regulatory agencies.

You may cancel this authorization in writing at any time by contacting the study doctor listed on the first page of this Consent Form. If you cancel the authorization, continued use is permitted for the Protected Health Information obtained before the cancellation, if its use is necessary in completing the research, including samples collected for future research. However, Protected Health Information collected after your cancellation may not be used in the study.

If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study.

Finally, federal regulations allow you to obtain access to your Protected Health Information collected or used in this study. However, in order to complete the research study, your access to this Protected Health Information may be temporarily suspended while the research study is in progress. When the study is completed, your right of access to this information will be reinstated.

This authorization will expire once there is no longer a need to review and analyze the information related to this study.

8 WILL I RECEIVE ANY MONEY OR OTHER COMPENSATION FOR TAKING PART IN THIS RESEARCH STUDY?

If you are entered into the study, you may be compensated:

- $75.00 for the screening visit
- $300.00 for your vaccination visit (Day 1)
- $100.00 for your visits after the injection (Day 8 and Day 15)
- $150.00 for your visits after the injection (Day 22 and Day 57)
- $50.00 for the scheduled phone visits (Day 29 and Day 64, and Day 183)
- $50 for any unscheduled visits

In addition, you will be paid $350.00 for the Plasmapheresis procedure done few days after Days 22 and Day 57. The Plasmapheresis will be performed at the [redacted].

You will be paid after each completed study visit. If you do not complete all study procedures, do not follow study rules, or miss visits, your compensation will be reduced. If you complete all study visits and procedures, and follow all instructions provided by the research staff, you will be compensated a maximum of $1725.00 for taking part in this study.

There will be no expenses charged to you for taking part in the study. All tests, examinations, study drugs and medical care required as part of this study will be provided at no cost to you. You will be reimbursed for transportation to and from the research site.

9 WHAT IF I WANT TO STOP THE STUDY EARLY?

Your participation in this study is completely voluntary. You may drop out of this study at any time without giving a reason. Your choice to drop out of this study will not in any way affect any necessary medical treatment.

Please ask questions about any and every part of this study you do not understand before you sign this Consent Form. If you drop out of the study you cannot re-enter, but this will not affect you in any other way.

If you decide to leave this study after taking the study drug, or are asked to leave by your doctor, you will be asked to come back to the research site for tests for your safety. These tests are to identify any unexpected side effects. The study doctor will record your condition at the time you leave the study.

10 WHAT IF THERE ARE NEW FINDINGS?

You will be told in a timely manner by your study doctor of any new important information about this study, PXVX0317, and other information that may affect your health, welfare, or willingness to stay in the study. You may be asked to sign a new (revised) Consent Form to show that you have been told of this new information. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

11 YOU MAY BE TAKEN OUT OF THE STUDY BY THE STUDY DOCTOR OR THE SPONSOR AT ANY TIME WITHOUT YOUR CONSENT

The study doctor, the study sponsor, or the regulatory authorities may decide to take you out of the study if:

- It is in your best interest
- The IRB suspends/terminates study approval
- You are unable to meet or follow the study requirements
- The study is cancelled
- The study shows signs of causing medical harm to you

The study sponsor may decide to end the study at any time.

12 WHO DO I CONTACT TO REPORT ANY PROBLEMS OR TO OBTAIN FURTHER INFORMATION?

If you experience a research-related injury or develop any problems at any time during the course of the study, or if you have any questions, concerns or complaints about this research study, or in case of emergency, you can contact:

[redacted] for Emergency)

This study has been reviewed by a central Institutional Review Board. An IRB is a group independent from Emergent Travel Health Inc. that reviews the details of the study to help ensure that your rights, safety and well-being as a study participant are protected.

If you have any questions about your rights as a research participant or questions, concerns or complaints about the study, you may contact:

WCG IRB at [redacted]

Study Number and Title: EBSI-CV-317-010 / A Phase 2 Open-Label Study to Assess the Safety and Immunogenicity of PXVX0317 (Chikungunya Virus-Like Particle Vaccine [CHIKV VLP], alum-adjuvanted)

This Consent Form contains important facts that will enable you to decide if you want to participate in this study. If you have any questions that are not answered in this form, please ask the research staff.

With your consent your primary physician will be told of your participation in the study.

I consent to having my family doctor or primary health care provider notified by the research

team of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ Yes (please complete the information below) ☐ No

Name and address of family doctor or primary health care provider:

Name: _____

Address: _____

Telephone: _____

STATEMENT OF INFORMED CONSENT

NOTE: This informed consent with the "original" signatures must be retained in the participant's file by the clinical study doctor. A signed copy must be given to the participant for their records.

By signing below, you (the participant) agree to the following:

- I confirm that I have read and understand this Consent Form for the above study.
- I confirm that the study has been explained to my satisfaction and I have had the time and opportunity to ask any questions. I know whom to contact if I think of more questions later.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected.
- I understand that sections of my medical notes may be looked at by responsible individuals appointed by sponsor, IRB, and regulatory authorities where it is relevant to my taking part in the study. I give permission for these individuals to have direct access to my records.
- By taking part in this study, I agree to the transfer of my personal data within Emergent Travel Health Inc. and to medicines regulatory authorities both within and outside North America.
- I have been given the information about the use and disclosure of my protected health information from this research.
- I have not given up any of my legal rights.
- I authorize the use and disclosures of my health information for the purposes described above to the parties listed in this Consent Form for this study.
- I understand and agree to my primary physician being notified of my participation in the study (if appropriate).
- All my questions have been answered.

- I agree to take part in the above study.

A copy of the signed Consent Form will be given to you to keep.

Signature of Participant

		:
Signature of Participant	Date (dd.mmm.yyyy)	Time (24hr clock)

Printed Name of Participant

Signature of Witness

I confirm that I was present for the oral presentation of the written summary presented to the research participant as well as the execution of this form. I agree that the information was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant.

		:
Signature of Witness	Date (dd.mmm.yyyy)	Time (24hr clock)

Printed Name of Witness