INFORMED CONSENT FOR PARTICIPATION IN A CLINICAL RESEARCH STUDY	
Clinical Study Protocol Title	A Phase 2 Parallel-Group, Randomized, Double-Blind Study to Assess the Safety and Immunogenicity of PXVX0317 (Chikungunya Virus-Virus Like Particle Vaccine [CHIKV-VLP], unadjuvanted or alum-adjuvanted)
Clinical Study Protocol No.	PXVX-CV-317-001
Clinical Study Protocol Version	V 2.0
Sponsor/Local Sponsor	[redacted]
Investigator(s):	[redacted]
Clinical Site:	[redacted]
Informed Consent Form Version	3.0
This consent form contains important information to help you decide whether to participate in a clinical research study. The study staff will explain this study to you. Participation is completely voluntary. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think it over and discuss it with family or friends or your primary care physician before making your decision.	

Introduction:

The purpose of this consent form is to give you information about a clinical research study. This consent form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the research study. Before you decide whether to participate in the study, it is important for you to understand why this study is being done and what it will involve.

You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time. If you sign this consent form, you agree to participate in the study and you give permission to the study doctor and study staff to perform the study procedures on you.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information you do not clearly understand now or in the future.

Please take time to read the all information carefully. You should not make a decision about being in the study and you should not sign this consent form until all of your questions have been answered and you understand all the information. You will be given a copy of this consent form for your own information.

What you should know about this study:

- This consent form explains the research study and your part in the study.
- You will be a research participant. If you join the study and you later change your mind, you may quit at any time without fear of penalty or loss of benefits up to the day you decide to leave this study.
- While you are in this study, the study team will keep you informed of any new information that might change your decision to be in the study.

Who is paying for the study?

[redacted] The study doctor will receive payment from the Sponsor for work involved in collecting study data and managing the study at their clinic.

Why is this research being done?

The purpose of this study is to research the safety and effectiveness of PXVX0317, a chikungunya vaccine that PaxVax is developing, in adults 18 to 45 years of age.

The Chikungunya virus (CHIKV) is a germ that causes a disease with a high fever and pain in multiple joints. In severe cases, the joint pain can be debilitating and last for months or years. CHIKV typically occurs in countries with mosquito-borne disease such as Africa and parts of Asia, South America, and the Caribbean. Although mosquitoes are the primary way this disease is transmitted, blood transmission by a needle stick is possible. The disease can affect travelers from the United States who are visiting these countries and since 2014 there were cases seen in Florida, Puerto Rico and U.S. Virgin Islands. Vaccines are given to people in order to keep them from getting sick in the future. There are currently no approved vaccines to prevent CHIKV infection or disease.

PXVX0317 is made from specific parts of the CHIKV germ. These parts are called CHIKV-VLP. CHIKV-VLP has been given to about 225 adults in other clinical studies and was well tolerated without serious side effects or discomfort. It has also previously been given to about 400 adults in this study, and the early results also show that it is well tolerated. PXVX0317 does not contain any CHIKV germs and does not cause chikungunya disease.

Why am I being asked to be in this study?
You are being asked to be in a clinical research study of PXVX0317 because you expressed interest in volunteering for research and, based on the information you previously shared, you are between the ages of 18 and 45 years. Being in this study is voluntary.

Please read this form carefully and ask your doctor if you have any questions. After reading this form and asking any questions you have, if you decide to continue being in this study, you must sign and date the last page(s) of this form.

Who can participate?
Healthy adults between the ages of 18 and 45 and who have not previously been infected with CHIKV may be eligible to participate in this study.

How long will I be in the study? How many people will be in the study?
About 420 individuals will be in this study in the U.S. Your participation in the study may last between 212 days or 7 months if you are participating in Group 9 (open label - you will receive active vaccine) and 760 days or 25 months if you are participating in Groups 1 through 8 (blinded - you will not know if you receive active vaccine or placebo), including the time allowed for screening (the process of determining if an individual is eligible to participate in a study). The entire study is expected to last a total of about 7 months to 2 years depending on if you are in Groups 1 through 8 or Group 9.

What are my responsibilities during the study?
If you participate in this study, it is important that you:
- Tell the study doctor about your travel, medical and medication history.
- Attend all visits scheduled with the study doctor.
- Follow the study doctor's instructions in between visits.
- Call the study doctor's office to reschedule a missed visit.
- Ensure that you do not get pregnant during the study. If you are of childbearing potential (a female who can get pregnant), you must avoid sex or use contraception for the duration of the study.
- Report to the study doctor or nurse as soon as possible if you are hospitalized, have an emergency room visit, or become pregnant.

What will happen if I join in this study?
If you decide to be in this study, the study doctor and study staff will collect information about your recent travel and 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 a maximum of 12 in-clinic visits and 1 scheduled phone call. You must make sure that you can come to each visit as scheduled.

There is a "double-blind" (Groups 1 through 8) and an "open-label" (Group 9) part of the study.

Groups 1 through 8 - Double-blind means that neither you, the study doctor nor the study staff will know under which schedule you received the PXVX0317 study vaccine or a substitute mixture of sugar water with no active effect known as a "placebo". However, this information is available if needed in an emergency. You will be assigned randomly to 1 of the 8 study groups. You have an even chance of being in each group. Neither you, nor the study doctor will choose or know which group you will be in.
When the entire study is done, you will be informed as to which group you are in and under which schedule you received the vaccine or placebo.

Group 9 - Open-label means that you and the study doctor and study staff will know you are receiving the PXVX0317 study vaccine.

First, the study nurse (or delegated study staff) will draw 6mL (about one teaspoon) of blood to screen for infectious diseases such as HIV (virus that causes AIDS), and Hepatitis B and C (viruses that infect the liver). If required by state law, the results of a positive test for HIV or Hepatitis will be reported to a local health agency. If any screening tests are abnormal, the study staff will tell you. You will be referred to your primary medical provider for follow up care. Counseling will also be made available to you to discuss positive results.

The study nurse (or delegated study staff) will then draw from:
Groups 1 through 8 (Blinded study participants):

- 6mL (about one teaspoon) or 12mL (about two teaspoons) of blood will be drawn during the study to check your immune response (ability to fight the chikungunya virus) by measuring your antibodies (germ fighters in the blood). A total of 84 mL (about 5 and ½ tablespoons) will be drawn during the study.

Group 9 (Open-label study participants):

- 6mL (about one teaspoon) or 37mL (about six teaspoons) of blood will be drawn during the study to check your immune response (ability to fight the chikungunya virus) by measuring your antibodies (germ fighters in the blood) and certain kinds of your white blood cells (germ-fighting cells).
- You will be undergoing a procedure called plasmapheresis at Day 57 which will be conducted at a nearby blood bank. The lab personnel will be collecting approximately 600-800mL 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.
- You may also be undergoing a procedure called leukapheresis at Day 182 (only if you provide consent for this procedure), which will also be conducted at a nearby blood bank.

- The procedure is the same as that explained above for the plasmapheresis, however the lab personnel will be collecting approximately 250mL of lymphocytes (one of the subtypes of white blood cells in your blood), depending on your gender, weight and height and other considerations. The collection process takes usually between 1 to 4 hours.

The quantity of blood collected depends on the visit. If you are a female who is able to get pregnant, you will need to urinate in a cup for a pregnancy test to be performed as part of the screening process. The result of the pregnancy test must be negative in order for you to be eligible to be in the study.

If you meet all criteria to be in the study, a urine pregnancy test will be performed at specific visits during the study. If you join this study, you must ensure that you do not get pregnant during the entire study. For example, you must exercise abstinence or use a form of birth control.

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, respiration (your breathing), and temperature.

Groups 1 through 8 will receive the PXVX0317 study vaccine (with or without Alhydrogel® adjuvant) in a combination of four different strengths and a placebo on a pre-defined schedule. Alhydrogel® adjuvant is referred to as “alum” and is a commercial and FDA approved product that contains aluminum hydroxide which is to enhance the PXVX0317 study vaccine, so your body builds more antibodies to protect from chikungunya disease. You will receive 1 of 8 possible combinations, 1 or 2 injections of PXVX0317, with or without alum, and 1 or 2 injections of placebo.

Groups 1 through 8 will be given an injection in the muscle of your arm using a needle with syringe (shot in the arm), at three (3) different times in the study about 2 weeks apart, and a 4th injection after 1 and ½ years from the time you entered into this research study.

Group 9 will receive a dose of 20/300 mcg of PXVX0317 study vaccine in combination with the Alhydrogel® adjuvant. From our early look at the results of this study, this dose appears to be safe and causes a strong immune response (germ-fighting response).

Group 9 will be given an injection in the muscle of your arm using a needle with syringe (shot in the arm), at two (2) different times in the study about 4 weeks apart,

Immediately after each injection, you will need to wait in the clinic for 30 to 60 minutes for the study doctor and study staff to observe your health for any side effects and take your vital signs.

After you receive the first injection, you will be given a diary, thermometer, and ruler to record any specific or other symptoms you experience (and new medications or changes to medications), your temperature will be taken, and your skin will be measured for any reactions from the injection. Groups 1 through 8 will record this information in a diary after each injection (total 4 times) for 7 consecutive days after the injection. Group 9 will record this information in a diary after each injection (total 2 times) for 7 consecutive days after the injection. Instructions and training will be given to you on how to complete the diary, take your oral temperature, and measure any skin reaction at the injection site.

The study is divided into 4 phases:
Groups 1 through 8 - Screening, Vaccination and Observation, Follow-Up, and Booster.
Group 9 - Screening, Vaccination and Observation, Follow-Up

Screening phase: is the phase when you are given information about the study to see if you are eligible to join. More visits may be necessary if any of your screening tests are abnormal.

Vaccination and Observation phase:
For Groups 1 through 8 - is the phase when you are given an injection in the arm at 3 different visits, about 2 weeks apart. At 7 and 28 days after the 3rd injection, you will return to the study clinic, so the study doctor and study staff can ask about your health and any new medications you may be taking.

For Group 9 - is the phase when you are given an injection in the arm at 2 different visits, about 4 weeks apart. At 7 and 28 days after the 2nd injection, you will return to the study clinic, so the study doctor and study staff can ask about your health and any new medications you may be taking.

After each injection, you will need to write down in a diary provided by the site staff any symptoms you feel, take your temperature, and measure any reactions on your skin from the injection for 7 days after the visit. Instructions will be given to you on how to record this information in a diary. You will return to the study clinic around 7 days after each injection and you will need to bring your diary. At 7 and 28 days after the 3rd injection (Groups 1 through 8) and at 7 and 28 days after the 2nd injection (Group 9) you will return to the study clinic, 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) at all of these visits.

Follow-Up phase: is the phase at 5 and 11 months after the 3rd injection (Groups 1 through 8) and 5 months after the 2nd injection (Group 9) when you will return to the study clinic 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) at each of these visits.

Booster phase: (Groups 1 through 8 only): is the phase after 18 months (or 1.5 years) after the 3rd injection (or 6 months after your last visit to the clinic) when you will be given a booster injection.

After the injection, you will need to write down in a diary provided by the site staff any symptoms you feel, take your temperature, and measure any reactions on your skin from the injection for 7 days after the visit. At 28 days after the booster injection, you will return for 1 clinic visit and also have 1 scheduled phone call, so the study doctor and study staff can ask about your health and any new medications you may be taking. During the clinic visit, blood will be taken to measure your antibodies (germ fighters).

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 to Clinic	All Groups • You will receive this description of the study and consent form before any screening activities, including taking a medical history. • 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 a medical history including previous and current use of medications. • You will be given a physical examination, vital signs taken, and a urine pregnancy test (if you are a female who can get pregnant).
	• You will have 6 mL (about 1 teaspoon) of blood drawn for lab tests (Hepatitis B & C, HIV) 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 to Clinic	All Groups Before Vaccination: • Questions on your medical history and current use of medications. The study doctor may give you a physical exam depending on changes to your medical history. • Vital signs will be taken and a urine pregnancy test (if you are a female who can get pregnant). • Groups 1 through 8 - You will have 12 mL (about 2 and ½ teaspoon) of blood drawn in order to evaluate your blood for antibodies (germ fighters). • Group 9 - You will have 37 mL (about 6 teaspoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells. Vaccination: • Groups 1 through 8, if you are eligible for the study, you will be randomized to a study group and then given an injection of vaccine or placebo in the muscle of your arm. • Group 9, if you are eligible for the study, you will be given an injection of vaccine in the muscle of your arm. After Vaccination: • You will be observed in the clinic for at least 30 up to 60 minutes after the injection for immediate side effects. • You will be given a diary, thermometer, ruler and training on how to use these items to record symptoms, temperature and skin reactions at the injection site, and medications. You will need to return to the clinic with your completed diary after 7 days from this visit.
Day 8 Visit to Clinic	All Groups • Questions about your health and current medication use. • Diary review. • Blood draw (about 1 teaspoon or 6mL) to evaluate the antibodies (germ fighters). Groups 1 through 8 will need to return to the clinic after 7 days from this visit. Group 9 will need to return to the clinic after 21 days (3 weeks) from this visit.

Day 15 Visit to Clinic	Groups 1 through 8 only Before Vaccination: • Questions about your health and current use of medications. • Vital signs will be taken and a urine pregnancy test (if you are a female who can get pregnant). • You will have 6 mL (about 1 teaspoon) of blood drawn in order to evaluate your blood for antibodies (germ fighters). Vaccination: • You will be given the second injection of vaccine or placebo in the muscle of your arm (the alternate arm from the first injection). After Vaccination: • You will be observed in the clinic for at least 30 to 60 minutes after the injection for immediate side effects. • You will be given a new diary (and will use the thermometer and ruler you were previously given) and reminders on how to use these items to record symptoms, temperature and skin reactions at the injection site, and medications. You will need to return to the clinic with your completed diary after 7 days from this visit.
Day 22 Visit to Clinic	Groups 1 through 8 only • Questions about your health and current medication use. • Diary review. • Blood draw (about 1 teaspoon or 6mL) to evaluate the antibodies (germ fighters). You will need to return to the clinic after 7 days from this visit.

Day 29 Visit to Clinic	All Groups Before Vaccination: • Questions about your health and current use of medications. • Vital signs will be taken and a urine pregnancy test (if you are a female who can get pregnant). • Groups 1 through 8 - You will have 6 mL (about 1 teaspoon) of blood drawn in order to evaluate your blood for antibodies (germ fighters). • Group 9 - You will have 31 mL (about 5 teaspoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters) and germ-fighting white blood cells. Vaccination: • You will be given the third injection of vaccine or placebo (Groups 1 through 8) and 2nd injection of vaccination (Group 9) in the muscle of your arm (the alternate arm from the second injection). After Vaccination: • You will be observed in the clinic for at least 30 to 60 minutes after the injection for immediate side effects. • You will be given a new diary (and will use the thermometer and ruler you were previously given) and reminders on how to use these items to record symptoms, temperature and skin reactions at the injection site, and medications. You will need to return to the clinic with your completed diary after 7 days from this visit.
Day 36 Visit to Clinic	All Groups • Questions about your health and current medication use. • Diary review. • Blood draw (about 1 teaspoon or 6mL) to evaluate the antibodies (germ fighters). You will need to return to the clinic after 21 days from this visit.

Day 57 Visit to Clinic	All Groups • Questions about your health and current medication use. • Group 9 - A urine pregnancy test (if you are a female who can get pregnant). • Groups 1 through 8 - You will have 12 mL (about 2 and ½ teaspoons) of blood drawn in order to evaluate your blood for antibodies (germ fighters). • Group 9 - Blood draw (about 6 teaspoons or 37mL) to evaluate the antibodies (germ fighters) and germ-fighting white blood cells. • Group 9 subjects will undergo plasmapheresis procedure at a nearby blood bank. 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 You will need to return to the clinic after about 4 months from this visit.
FOLLOW UP PHASE	
Day	**What will take place?**
Day 182 Visit to Clinic	All Groups • Questions about your health and current medication use. • Group 9 - A urine pregnancy test (if you are a female who can get pregnant). • Groups 1 through 8 - You will have 6 mL (about 1 teaspoon) of blood drawn in order to evaluate your blood for antibodies (germ fighters). • Group 9 - Blood draw (about 5 teaspoons or 31mL) to evaluate the antibodies (germ fighters) and germ-fighting white blood cells. • Group 9 subjects who consented, will undergo leukapheresis (optional) procedure at a nearby blood bank. Vital signs will be taken before, and after the leukapheresis procedure. • After the procedure, you will be observed in the blood bank for 30 minutes to monitor for immediate side effects You will need to return to the clinic after 6 months from this visit. (only Groups 1 through 8).
Day 365 Visit to Clinic	Groups 1 through 8 only • Questions about your health and current medication use. • Blood draw (about 1 teaspoon or 6mL) to evaluate the antibodies (germ fighters). You will need to return to the clinic after 6 months from this visit.

BOOSTER PHASE	
Day 547 Visit to Clinic	Groups 1 through 8 only Before Vaccination: • Questions about your health and current use of medications. • Vital signs will be taken and a urine pregnancy test (if you are a female who can get pregnant). • You will have 6 mL (about 1 teaspoon) of blood drawn in order to evaluate your blood for antibodies (germ fighters). Booster Vaccination: • You will be given the 4th (and last) injection of vaccine or placebo in the muscle of your arm (the alternate arm from the third injection). After Vaccination: • You will be observed in the clinic for at least 30 to 60 minutes after the injection for immediate side effects. • You will be given a new diary, new ruler, new thermometer and training on how to use these items to record symptoms, temperature and skin reactions at the injection site, and medications. You will need to return to the clinic with your completed diary after 28 days from this visit.
Day 575 Visit to Clinic	Groups 1 through 8 only • Questions about your health and current medication use. • Diary review. • Blood draw (about 1 teaspoon or 6mL) to evaluate the antibodies (germ fighters). You will need to schedule a phone call with the study staff for about 5 months from this visit.
Day 730 Phone Call	Groups 1 through 8 only • Questions about your health and current medication use.

What are the potential risks, side-effects and discomfort?
Risks with PXVX0317:

PXVX0317 may cause the following reactions:
Very Common (occurred in >10% to <50% of people receiving the vaccine): injection site pain, a general ill feeling, nausea, headache, tiredness and muscle aches.

Common (occurred in 0.5% to 10% of people receiving the vaccine): injection site redness and swelling, joint pain, chills and fever.

In an earlier study, the majority of these reactions were mild or moderate.

The worst severity for any type of reaction in a subject was mild (29.6% of subjects) or moderate (21%) and rarely severe (7.2%). 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:

There is a risk of severe allergic reaction to an ingredient of PXVX0317 (including Alhydrogel®). Symptoms of allergic reaction include:

- Rash
- Wheezing and difficulty breathing or 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 with Apheresis (plasmapheresis and leukapheresis):

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. Also, very rarely, a machine malfunction may occur, resulting in the loss of about one unit of blood. 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. The long-term effect of the reduction of lymphocytes is not clear. If, for any reason the red blood cell loss during the procedure exceeds current CBC standards, the procedure may be terminated.

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 a 8-week deferral, or a 16-week deferral for a double red blood donation.

Risks with Questionnaire
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

Are there pregnancy risks?
If you are a female who is able to become pregnant, you will be required to use highly effective contraception throughout the study. 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 vaccination 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. If you become pregnant, you will have to leave the study. The Sponsor will ask permission to follow the pregnancy and ask about information of the birth of the baby.

Risks to Confidentiality:
Efforts will be made to keep your personal health information confidential. In order to maintain confidentiality, your study records will be stored in a secure location such as a locked office or 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. 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.

Other ways the study doctors and other supporting people will try to 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; and
3. Sponsor-designated study monitors: these are people affiliated with the Sponsor who will be visiting the study clinic to look over all of your medical records related to this study.

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.

What are the possible benefits of the study?
If you participate in this study, it is possible that you may not have any direct medical benefits. The study may provide information that would benefit others.

If you receive the first 3 injections in the study, you will have received at least one injection of PXVX0317 vaccine (Groups 1 through 8). Group 9 subjects receive 2 injections of the PXVX0317 vaccine. However, we do not yet know whether PXVX0317 may prevent a chikungunya infection when you travel to an area affected by chikungunya, or how long the protection may last. There is no guarantee that the study vaccine will protect you in the event you are exposed to chikungunya in the future.

What if I want to stop the study early?
If at any time during the study you, your study doctor, or the Sponsor feels it is not in your best interest to be in the study, or the Sponsor stops the study early, you may be asked to return to the clinic for a final visit.

If you decide you do not want to be in this study anymore, you are encouraged to let the study doctor or other research staff member know right away. You may be asked to come back to the study clinic for a final visit.

At that final visit, you will be asked about any changes to your health or medications, and you may be asked to have some blood drawn. You may voluntarily discontinue from participating in the study at any time.

What if there are new findings?
You will be informed of any important new findings that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

Will I receive any money or other compensation for taking part in this research study?
You will be paid for the visits and phone call follow-ups if you are enrolled in the study. You will be enrolled in the study when you are randomized into a study group and receive your first injection. [redacted]

Group (9)
[redacted].

[redacted]

If you do not complete all study procedures, do not follow study rules, or miss visits, your compensation will be reduced.

Will it cost me anything to be in this study?
The study procedures will be provided at no cost to you or your insurance company.

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.

What if I get hurt or sick while in the study?
If you feel that you have had a research-related injury as a result of being in this study, inform the study doctor.

If you suffer any complications, injury or illness requiring emergency medical treatment resulting directly from the study or procedures involved in the study, treatment will be provided, and the study staff will assist you in obtaining such treatment. The Sponsor will provide reimbursement for the reasonable costs of medical treatment of such complications to the extent such costs are not covered by your medical or hospital insurance, or by third party or governmental programs providing such coverage.

The Sponsor will not be responsible for deductibles and co-pays. The Sponsor has no plan to pay you for lost wages, disability or discomfort due to any injuries, side effects or illnesses you may suffer from. If you would like further information about compensation for your injuries related to the study, please contact the study doctor.

By signing this consent form, you will not give up any of your legal rights. You do not release the Sponsor, study doctors or the clinic from responsibility for their negligence.

What if I decide not to participate?
- Your participation in this study is voluntary. You may decide not to participate. You may leave this study at any time. Your decision to leave the study at any time will not result in any penalty or loss of benefits up to the day you decide to leave this study.
- If you decide to leave the study, please tell your study doctor or other research staff member right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave this study early, information collected up to the date you leave this study can be used only according to the confidentiality rules outlined below.
- If you leave this study after receiving the first injection, you will be given contact information to reach the study doctor and staff if you develop any study-related illness.

If you are an employee or a family member of an employee, if you participate or decide not to participate, your or your family member's benefits and position at the company will in no way be affected or influenced by your participation, your refusal to participate, or your withdrawal from this research.

You may be taken out of the study by the study doctor or the Sponsor at any time without your consent for any of the following reasons:

- Staying in the study would be harmful to you (based on the study doctor's evaluation, regardless of your consent).
- You need treatment not allowed in this study.
- You fail to follow the study procedures or instructions, or miss study visits.
- You become pregnant.
- You are taking a medication that is not allowed.
- You do not consent to continue in the study after being told of changes in the research that may affect you.
- The study is cancelled.
- It is otherwise in your best interest as determined by the study doctor.
- Any other reason determined by the Sponsor.

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 about any changes to your health and you may be asked to have blood taken.

What other treatment choices do I have if I am not in the study (Alternatives to Participation)?

You do not have to be in this study. If you do not participate, your care will not be affected. This is not a treatment study. The alternative is not to join this study.

Confidentiality: What privacy and confidentiality rights do I have?

Your participation in this study is entirely confidential to the extent allowed by law.

We understand that information about your health is personal. We are committed to protecting the privacy of that information.

Special authorization must be obtained before we may use or disclose your protected health information (PHI) for the research purposes described in this Informed Consent. This form provides that authorization and helps us make sure that you are properly informed of how the information will be used or disclosed.

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)
- Medical and health data from your medical records
- Data on your ethnic origins, or living habits
- Areas you have traveled to
- Identifying biological samples taken from you

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.

There will be people working on the study who need to see your health information. These people may include the researchers and study doctor and other study staff. Others who may see your information are the groups of people who make sure that the study is being done as it should be. These groups may include:

- The Sponsor
- Audit and compliance officers and legal counsel of the Sponsor.
- The U.S. Food and Drug Administration.
- Study support groups such as the study monitors and medical monitors.
- [redacted] Independent Review Board, which is a group of people who perform independent review of the study plan and approve its use as required by applicable regulations.

These people are required to keep your identity private. Applicable law requires the study doctor to report some diseases and information about you. If reported, this information may not remain confidential. 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.

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 give out 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?
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 do this by sending written notice to the study doctor or informing the study doctor during a 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 that point in time may still be used and given to others for the purpose of analyzing the data already collected.

What happens to the biological samples (any blood, urine, or other biological samples) taken from me?
Any biological samples taken from you become the property of the Sponsor. Any unused biological samples will be stored indefinitely once this study is completed. 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 studied, tested and used by medical scientists. Biological samples will be coded so that your name cannot be identified with a sample. There are not many risks to you from future use of your samples. Reports about research done with your samples will not be put in 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.

Results from future research using your samples will not be shared with you directly because you will not be contacted after completion of the study. You will not receive any compensation in any manner for future research using your samples.

Where can I find out about the study results?
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.

Who can I call with questions, complaints or if I'm concerned about my rights as a participant?
For questions, concerns or complaints or information about the study or a research-related injury, contact the study doctor at the number on page 1.

This research is being overseen by [redacted] Independent Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at [redacted] if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Although [redacted] 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 [redacted] 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.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions and you agree to participate in this study.

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

Optional Leukapheresis Procedure Consent (Group 9 Only):
You are being asked to take part in a procedure (leukapheresis) at Day 182, which will be conducted at a nearby blood bank. The procedure involves collecting approximately 250mL of lymphocytes, one of the subtypes of white blood cells in your blood.

You can decide to withdraw your consent for this procedure at any point during the study.

Carefully read the sentences below and think about your choice(s).
Check the "Yes" or "No" box and initial next to your choice.

I agree to participate in the leukapheresis procedure at Day 182.

☐ Yes - I consent to participate in the leukapheresis procedure

☐ No - I do NOT consent to participate in the leukapheresis procedure

_____	_____:_____
Printed Name of Subject	Time (HH:MM)
_____	_____/____/_____
Signature of Subject	Date (MM/DD/YYYY)

Informed Consent for PaxVax, Inc. A Phase 2 Parallel-Group, Randomized, Double-Blind Study to Assess the Safety and Immunogenicity of PXVX0317 (Chikungunya Virus-Virus Like Particle Vaccine [CHIKV-VLP], unadjuvanted or alum-adjuvanted)

SIGNATURE SHEET

- I have read the information in this consent form.
- All my questions about the study and my participation in the study have been answered.
- I agree to participate in this study.
- I authorize the use and disclosure of my health information to the parties listed in the Confidentiality section of this consent for the purposes described in the Confidentiality section.
- By signing this consent form, I have not given up any of my legal rights.

_____	_____:_____
Printed Name of Subject	Time (HH:MM)
_____	_____/____/_____
Signature of Subject	Date (MM/DD/YYYY)

I confirm that a copy of this signed and dated consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person and I have made every effort to answer all questions to his or her satisfaction. I have watched this person sign the consent form.

_____	_____:_____
Printed Name of Person Obtaining Consent	Time (HH:MM
_____	_____/____/_____
Signature of Person Obtaining Consent	Date (MM/DD/YYYY)

Please Use the Following Information When Completing Your Donor History Form.

Medication Deferral List: *(Question #4)*

SOME MEDICATIONS MAY AFFECT YOUR ELIBILITY TO DONATE BLOOD. PLEASE TELL US IF YOU...

Are being treated with the following types of medications....	or have taken...	anytime in the last...	These medications affect your eligibility for the following reasons:
Anti-platelet agents (usually taken to prevent stroke or heart attack)	**Feldene** (piroxicam) 11-3	2 days	**Anti-platelet agents affect platelet function,** so people taking these drugs should not donate platelets for the indicated time; however, you may still be able to donate whole blood.
	Effient (prasugrel) **Brilinta** (ticagrelor) 11-19	7 days	
	Plavix (clopidogrel) **Ticlid**(ticlopidine) **Zontivity** (vorapaxar) 11-12	14 days	
Anticoagulants or "blood thinners" (usually to prevent blood clots in the legs and lungs and to prevent strokes)	**Xarelto** (rivaroxaban) **Fragmin** (dalteparin) **Lovenox** (enoxaparin) **Pradaxa** (dabigatran) **Eliquis** (apixaban) **Savaysa** (edoxaban) 11-22	2 days	**Anticoagulants or "blood thinners"** are used to treat or prevent blood clots in the legs, lungs, or other parts of the body, and to prevent strokes. These medications affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate.
	Coumadin, Warfilone, or **Jantoven** (warfarin) **Heparin,** low molecular weight heparin - unless listed separately (heparin) **Arixtra** (fondaparinux) 11-11	7 days	
Acne treatment	**Accutane, Amnesteem Absorica, Claravis, Myorisan, Sotret, Zenatane** (isotretinoin) 11-1	1 Month	**Isotretinoin, finasteride, dutasteride acitretin and etretinate** can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman. Once the medication has been cleared from your blood, you may donate again.
Hair loss remedy	**Propecia** (finasteride) 11-6		
Prostate symptoms	**Proscar** (finasteride) 11-6		
	Avodart, Jalyn (dutasteride) 11-4	6 Months	
Psoriasis	**Soriatane** (acitretin) 11-7	3 Years	
	Tegison (etretinate) 996	Ever	
Basal cell skin cancer	**Erivedge** (vismodegib) **Odomzo** (sonidegib) 11-24	2 Years	**Erivedge (Vismodegib), Odomzo (sonidegib), and Aubagio (teriflunomide)** can cause birth defects or the death of an unborn baby if transfused to a pregnant woman. Once the medication has been cleared from your blood, you may donate again.
Relapsing multiple sclerosis	**Aubagio** (teriflunomide) 11-25	2 Years	
Hepatitis Exposure	**Hepatitis B Immune Globulin** HBIG) 10-5	12 Months	**Hepatitis B Immune Globulin (HBIG)** is an injected material used to prevent hepatitis B infection following a possible or known exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case, therefore, persons who have received HBIG must wait to donate blood.
Experiment Medication or Unlicensed (experimental Vaccine 10-13		12 Months	**Experimental Medication or Unlicensed (Experimental) Vaccine** is usually associated with a research study, and the effect on the safety of transfused blood is unknown.
Growth hormone from human pituitary glands (No longer available in the US) 965-2		Ever	**Growth hormone from human pituitary glands** was prescribed for children with delayed or impaired growth. The hormone was obtained from human pituitary glands, which are in the brain. Some people who took this hormone developed a rare nervous system condition called Creutzfeldt-Jakob Disease (CJD, for short).
Insulin from Cows (Bovine or Beef Insulin) manufactured in the United Kingdom (No longer available in the US) 10-5		Ever	**Insulin from cows (bovine, or beef, insulin)** is injected material used to treat diabetes. If this insulin was imported into the US from countries in which "Mad Cow Disease" has been found, it could contain material from infected cattle. There is concern the "Mad Cow Disease" is transmitted by transfusion.

Donors SHOULD NOT discontinue medications prescribed or recommended by their physician in order to donate blood.

[redacted]

APPROVED

JUN 06 2019

[redacted]RB

Received

JUN 04 2019

[redacted]IRB

Ethnic Origin (Select One/Optional):

- ☐ (W) White
- ☐ (I) American Indian or Alaskan Native
- ☐ (H) Hispanic
- ☐ (2) Two or More Races (Not Hispanic or Latino)
- ☐ (B) Black
- ☐ (P) Native Hawaiian or Other Pacific Islande
- ☐ (A) Asian
- ☐ (O) Other

Physical Examination

Code	Acceptable Value	Value		
47	Arm Appearance	Y / N		
48	Weight: ≥ 110 lbs		Height	
49	Temperature: 96-99.5			
50	BP: S 90-180 D 50-100			
51	Pulse: 50-100 bpm			
52	Hgb F: ≥ 12.5 M: ≥ 13.0			
38	Hgb: ≤ 20.0			

Deferrals – Initial when donor informed

Code	Effective Date	Eligible Date	Staff Initials

Collection Procedure

(1) Arm	L / R	Phleb	Init / ID #	Dc'd by	Init / ID #	Vol Suf?	Y / N	
Lot #				Start		Stop		
(2) Arm	L / R	Phleb	Init / ID #	Dc'd by	Init / ID #	Vol Suf?	Y / N	
Lot #				Start		Stop		

MILD Reaction - 541

Time of Onset	
Check all that apply	
Pallor (skin color change)	
Feeling faint, lightheaded or dizzy, sweating	
Hyperventilating (rapid breathing)	
Nauseated/Stomach Cramps	
Vomiting	
RCI Given	
Symptoms resolved at site	

Initials_____

***** Document Moderate or Severe Reaction on KC-FORM-0503*****

Comments:

☐ Manual

☐ ASA

HF #
(1)
(2)

[redacted]

[redacted]

PLEASE READ CAREFULLY! - PAGES 2 TO BE COMPLETED BY DONOR.
(CIRCLE "Y" FOR YES OR "N" FOR NO TO EACH QUESTION)

ARE YOU :			
Feeling healthy and well today?	Y	1	N
Currently taking an antibiotic?	Y	2	N
Currently taking any other medication for an infection?	Y	3	N
(Please read the Medication Deferral List on Page 4) Have you taken any medication on the Medication Deferral List in the time frames indicated?	Y	4	N
Have you read the educational materials today?	Y	5	N
IN THE PAST *48 HOURS*:			
Have you taken aspirin or anything that has aspirin in it?	Y	6	N
IN THE PAST *8 WEEKS*, HAVE YOU:			
Donated blood, platelets or plasma?	Y	7	N
Had any vaccinations or other shots?	Y	8	N
Had contact with someone who was vaccinated for smallpox in the past 8 weeks	Y	9	N
IN THE PAST *16 WEEKS*:			
Have you donated a double unit of red cells using an apheresis machine? 58-2	Y	10	N
IN THE PAST *12 MONTHS*, HAVE YOU:			
Had a blood transfusion? 2-3	Y	11	N
Had a transplant, such as organ, tissue, or bone marrow?	Y	12	N
Had a graft such as bone or skin?	Y	13	N
Come into contact with someone else's blood?	Y	14	N
Had an accidental needle stick?	Y	15	N
Had sexual contact with anyone who has HIV/AIDS or has had a positive test for HIV/AIDS virus? 77-1	Y	16	N
Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex? 77-2	Y	17	N
Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything **not** prescribed by their doctor? 77-3	Y	18	N
Male donors: Had sexual contact with another male? 77-8	Y	19	N
Female donors: Had sexual contact with a male who had sexual contact with another male in the past 12 months? 77-5	Y	20	N
Had sexual contact with a person who has hepatitis? 25-1	Y	21	N
Lived with a person who has hepatitis? 25-1	Y	22	N
Had a tattoo? 26-5	Y	23	N
Had ear or body piercing? 26-2	Y	24	N
Had or been treated for syphilis or gonorrhea? 32-1	Y	25	N

IN THE PAST *12 MONTHS*, HAVE YOU:			
Been in juvenile detention, lockup, jail, or prison for more than 72 consecutive hours? 77-6	Y	26	N
IN THE PAST *3 YEARS*, HAVE YOU:			
Been outside the United States or Canada?	Y	27	N
FROM *1980 THROUGH 1996*:			
Did you spend time that adds up to (3) months or more in the United Kingdom? **(Review list of countries in the UK on Page 3.)** 968	Y	28	N
Were you a member of the U.S. Military, a civilian military employee, or a dependent of a member of the U.S. military? 968	Y	29	N
FROM *1980 TO THE PRESENT*, DID YOU:			
Spend time that adds up to (5) years or more in Europe? **(Review list of countries in Europe on Page 3.)** 968	Y	30	N
Receive a blood transfusion in the United Kingdom or France? **(Review list of countries in the UK on Page 3.)** 968	Y	31	N
HAVE YOU *EVER*:			
Have you ever been pregnant or are you pregnant now?	Y	32	N
Had a positive test for the HIV/AIDS virus? 959-5	Y	33	N
Used needles to take drugs, steroids, or anything **not** prescribed by your doctor? 967	Y	34	N
Received money, drugs, or other payment for sex? 959-1	Y	35	N
Had malaria? 28-2	Y	36	N
		37	
Had babesiosis? 923	Y	38	N
Received a dura mater (or brain covering) graft or xenotransplantation product?	Y	39	N
Had any type of cancer, including leukemia?	Y	40	N
Had any problems with your heart or lungs?	Y	41	N
Had a bleeding condition or a blood disease?	Y	42	N
Have any of your relatives had Creutzfeldt-Jakob disease? 965-3	Y	43	N
Have you ever tested positive for hepatitis B or C?	Y	44	N

PLEASE NOTE: NEW OR REVISED QUESTIONS ARE HIGHLIGHTED IN YELLOW

Countries of Europe, including the United Kingdom: (Questions #28, 30, and 31)

Albania Austria Belgium Bosnia-Herzegovina Bulgaria Croatia Czech-Republic Denmark Finland	France ➢ including overseas dept. (e.g. French Guiana, Guadeloupe, Martinique, Mayotte, Reunion) Germany Greece Hungary Republic of Ireland Italy Kosovo	Liechtenstein Luxembourg Macedonia Montenegro Netherlands Norway Poland Portugal ➢ including the Azores Romania Serbia Slovak Republic	Slovenia Spain ➢ including Canary Islands and Spanish North African territories (Ceuta, Melilla) Sweden Switzerland Yugoslavia (or the former Federal Republic of Yugoslavia)	United Kingdom Channel Islands England Falkland Islands Gibraltar Isle of Man Northern Ireland Scotland Wales

☞ FOR DS STAFF USE ONLY! ☜

Comments:

DONOR CONSENT

I have reviewed and understand the educational materials fully, including the risks of transfusion transmitted infections, and have answered all the questions on this form truthfully. I voluntarily donate approximately one pint of blood. I understand that my blood will be used for the treatment of patients, biomedical research, the study of new diagnostic tests or other uses at CBC's discretion. I understand that my blood will be tested for evidence of exposure to certain infections (including HIV) which might be transmitted by blood. I also understand that if for any reason I am ineligible to be a donor I will be informed, deferral information will be added to my record, and my name will be entered on a list of deferred donors. I agree not to donate blood for transfusion or further manufacture if my donation could result in a potential risk to recipients as described in the educational materials. I have been provided and reviewed information regarding the risks and hazards specific to my blood donation.

I have had the opportunity to ask questions and to withdraw from the blood donation procedure prior to signing this informed consent.

X_____

SIGNATURE

Interviewer	
Initials	ID #

Post-Collection Reviewer	
Initials	ID #

Auditor	
Initials	Date of Audit