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SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	**A Phase 1 Trial to Evaluate the Safety and Immunogenicity of an Inactivated West Nile Virus Vaccine, HydroVax-001B WNV in Healthy Adults [DMID Protocol 24-0008]**
IRB	

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – it is <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

SAINT LOUIS UNIVERSITY
Center for Vaccine Development
Research Study Consent Form

Participant:		**IRB #:**	34395
	First Name / Last Name		
Principal Investigator (PI)	Sarah L. George, MD	**Contact Phone #**	314-977-6333
	First Name / Last Name Credentials		
Title of Project:	**A Phase 1 Trial to Evaluate the Safety and Immunogenicity of an Inactivated West Nile Virus Vaccine, HydroVax-001B WNV in Healthy Adults [DMID Protocol 24-0008]**		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study because you are in good health and between the ages of 18 to 49 years.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain anything you do not understand.

Key Information for You to Consider

- **Purpose**. The purpose of this study is to find out if two different dose levels of an investigational West Nile Virus (WNV) vaccine (HydroVax-001B) given on Day 1, 29 and 181 are safe and induce antibodies to WNV in healthy adult participants.
- **Duration.** It is expected that your participation will last about 13 months, including screening.
- **Study Procedures**.
    - A screening evaluation will be done to see if you are eligible prior to enrollment.
- Thirty eligible participants will be enrolled. Each of the two groups will include 15 participants of which 12 participants will receive WNV vaccine and 3 participants will receive placebo (salt water). The low vaccine dose (4 micrograms [mcg]) group will be enrolled first, and, if there are no safety concerns after they have received 2 of 3 doses, enrollment into the higher dose (10 mcg) group will begin.
    - All participants will receive 3 doses of either vaccine or placebo.
- There will be 15 in-person study visits (including screening) and 3 phone call visits during the study.
- **Risks.** Some of the most common side effects include tenderness at the vaccination site, fatigue, and headache. Other symptoms include pain, redness, swelling, and itching, induration (hardening of skin) at the vaccination site, body aches, muscle pain, influenza-like illness, nausea, and fever.
- **Benefits.** You will receive no direct benefit from taking part in this study. By participating in the study, you will help researchers learn if the vaccine is safe and may help protect people from WNV disease after more studies are done.
- **Alternatives.** Participation is voluntary and the alternative is to choose not to participate.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

West Nile Virus (WNV) is a virus primarily transmitted to people by the bite of an infected mosquito; however, WNV can also be transmitted through blood transfusion, organ transplant, and from mother to baby during pregnancy, delivery, or breast feeding. WNV disease was first reported in the U.S. in 1999 and cases occur every year. While most WNV infections cause no symptoms, nearly 25% of infected people develop a self-limiting, acute febrile illness (West Nile Fever). About 1 out of 150 to 250 WNV infected individuals develop severe neuroinvasive disease, including encephalitis (inflammation of the brain), meningitis (inflammation of the protective membranes covering the brain and spinal cord), and acute flaccid paralysis (sudden onset of muscle weakness). Most people who develop neuroinvasive disease are over 60 years old or have a weakened immune system. Between 1999-2022, there were 28,684 cases of WNV neuroinvasive disease and 2,641 deaths due to WNV disease in the U.S. However, the true burden of disease is believed to be much higher, with estimates of nearly 3 million WNV infections resulting in approximately 780,000 illnesses.

The purpose of this study is to evaluate the safety and immunogenicity of the HydroVax-001B WNV vaccine in healthy adult participants. This study is significant to public health as it seeks to study an investigational vaccine that may be able to protect both healthy and vulnerable populations from severe disease and death due to WNV infection. There are currently no licensed human vaccines for WNV, and prior vaccine approaches showed limited ability to induce a robust immune response. This study addresses the urgent need for a vaccine to prevent WNV disease.

This study will be done at one site in the United States at Saint Louis University. Up to 30 people will participate.

2. WHAT AM I BEING ASKED TO DO?

Screening Visit Day -45 to -1

You will have a screening visit you are eligible to enroll in this study. Prior to the screening visit, you will be given information about the study and asked to read this informed consent. At the screening visit, we will review this consent form with you and answer your questions. After you have had time to think about whether to participate in the study and have discussed it with your family, friends, or doctor, if you wish to continue, you will be asked to sign this consent form agreeing to take part in the study.

The following will be done by the study team at the screening visit after the consent form is signed:

- Collect demographic information (age, race, sex)
- Determine eligibility
- Collect information about your medical history and medications
- Check your vital signs (temperature, blood pressure, pulse)
- Measure your height and weight
- Review menstrual history and counsel you on pregnancy prevention if you are a female of childbearing potential
- Perform a physical examination
- Females of childbearing potential will have a serum pregnancy test
- Collect a urine sample to check for protein and glucose

- Collect your blood for safety and HIV, Hepatitis B and Hepatitis C testing

Study Vaccinations on Day 1, Day 29, and Day 181

The following activities will be done by the study team on Day 1, Day 29, and Day 181:

- The eligibility criteria (Day 1), criteria for second (Day 29) and third (Day 181) vaccination will be reviewed with you
- An interim medical history and review of medications will be completed
- Review menstrual history and counsel you on pregnancy prevention if you are a female of childbearing potential
- A focused physical examination will be performed
- Your vital signs (blood pressure, pulse, and oral temperature) will be obtained prior to vaccination.
- You will have your blood and urine collected for safety and immune studies.

If you are a female of childbearing potential, you will have a urine pregnancy test.

- You will be randomized on Day 1 to receive either WNV vaccine or placebo (salt water). You will receive the same product on Day 29 and 181.
- You will remain in clinic for at least 30 minutes after receiving the vaccine or placebo to assess for any immediate reactions and injection site evaluation.
- Prior to clinic discharge, you will be provided with a thermometer, instructions for Memory Aid, ruler, and instructions as to how to contact study personnel at any time.
    - You will complete the Memory Aid for the next 7 days including all symptoms and medications used.
    - Study staff will contact you to discuss symptoms and/or medications that you record.

Study Day 2+1 after 1st, 2nd, and 3rd Vaccination

A follow-up phone call will be made to collect your interim medical history, record medications you have taken, and review your Memory Aid.

Study Day 8+3 and 15±2 after 1st, 2nd, and 3rd Vaccination

The following activities will be done by the study team on Day 8 and 15 after each vaccination:

- You will have an interim medical history and review medications taken since your last visit.
- You may have a targeted physical exam (if needed) based on your medical history.
- Your vaccination site will be evaluated.
- Your memory aid will be reviewed with you (Day 8 after each vaccination).
- If you are a female of childbearing potential, you will be counseled on pregnancy prevention.
- You will have blood and urine collected for safety (Day 15 after each vaccination only).
- You will have blood collected for immune studies (Day 15 after each vaccination only).

Study Day 29±4 days after 2nd or 3rd Vaccination

The following activities will be done by the study team on Day 29 after second and third vaccination:

- You will have an interim medical history and review of medications taken since your last visit.

- You may have a targeted physical exam (if needed) based on your medical history.
- Your blood will be collected for immune studies.

Study Day 57±4 days after 2nd Vaccination

The following activities will be done by the study team on Day 57 after the second vaccination:

- You will have an interim medical history and review of medications taken since your last visit.
- You may have a targeted physical exam (if needed) based on your medical history.
- Your blood will be collected for immune studies.

Study Day 91±14 days and 181±14 days after 3rd Vaccination

The following activities will be done by study team on Day 91 and 181 after the third vaccination:

- You will have an interim medical history and review of medications taken if needed since your last visit.
- You may have a targeted physical exam (if needed) based on your medical history.
- Your blood will be collected for immune studies.

Early Termination Visit

If you withdraw from the study before completion, we will ask you to come in for an early termination visit.

At this visit, the following will be done:

- You will have an interim medical history and any new medications since last visit.
- You may have a targeted physical exam (if needed) based on your medical history.
- Your vital signs will be collected.
- Depending on when the visit occurs, we may ask your permission to collect blood for safety laboratories, virus, or immunity studies.

3. HOW MUCH BLOOD WILL BE TAKEN?

In this study, we will collect 325 milliliters (mL) or about 22 tablespoons (tbsp) of blood from every participant over about 13 months. For comparison, when you donate a unit of blood, they collect about 450 mL of blood in a single day.

Amount of Blood Collected	
Screening	29.5 mL or about 6 tsp
Vaccination #1	32.5 mL or 6.5 tsp
Day 15 after Vaccination #1	32.5mL or about 6 tsp
Vaccination #2	32.5 mL or 6.5 tsp
Day 15 after Vaccination #2	32.5 mL or about 6 tsp
Day 29 after Vaccination #2	20 mL or 4 tsp
Day 57 after Vaccination #2	20 mL or 4 tsp
Vaccination #3	32.5 mL or 6.5 tsp

Day 15 after Vaccination #3	32.5 mL or about 6 tsp
Day 29 after Vaccination #3	20 mL or 4 tsp
Day 91 after Vaccination #3	20 mL or 4 tsp
Day 181 after Vaccination #3	20 mL or 4 tsp
Total Amount of Blood Collected = 325 mL or about 22 Tablespoons	

Blood Storage for Secondary Research

As part of this study, we are obtaining blood samples from you. However, we may not use all the blood that we collect for this research study. We plan to store the extra blood collected during this study and information about whether you received the 4 or 10 mcg dose of vaccine or placebo for use in future research. Types of research include development of immune laboratory tests to provide information for the development of new WNV vaccines, or to better understand WNV or other infections. The tests we might use to study your blood samples may not exist now.

The excess/leftover blood samples for future research will be stored indefinitely at a site determined by the study sponsor, the National Institutes of Health (NIH). Each blood sample will be labeled only with a barcode and a unique tracking number to protect your confidentiality. No testing of your DNA (genetic material) will be performed. Personnel at the storage facility and testing lab will not know your identity, or the volunteer ID code assigned to you for the study. However, the researchers who enrolled you will keep a code key in a secure area that could connect barcodes or tracking numbers to identify your blood samples, if needed.

Stored excess/leftover blood samples will be used only for research purposes. At any time during this study or after this study is over, stored excess/leftover blood samples may be shared with other investigators, institutions, or drug companies. The samples will not be sold or used directly for production of any commercial product. There are no benefits to you in the collection, storage, and future use of your blood samples. The results of any future testing will be kept confidential in the same way as the results of other testing done for this study. If you decide, after the end of the study, that you do not want your blood samples to be used for future research, you will need to contact Dr. George or a research team member at 314-977-6333 so that your samples can be destroyed after all study specified tests have been done.

Please feel free to ask the study staff any questions you may have about how your blood samples may be used.

4. WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to do the following:

- You will come to all study visits as scheduled.
- You will complete the Memory Aid after each vaccination visit.
- You will avoid eating or drinking anything hot or cold within 10 minutes prior to oral temperature being taken.
- You will not donate blood for 60 days before enrollment and for the duration of the study.
- You will avoid new strenuous exercise within 3 days before each vaccination and 3 days before Day 15 after each vaccination (e.g., Days 12-15 after each vaccination).

- You will not travel to areas where other related viruses (such as dengue, Zika, Yellow Fever virus) are circulating. Please discuss any plans you make for travel outside the United States during the study with the study team.
- You will not get any inactivated vaccines (such as flu shots or COVID boosters) or allergy desensitization shots within 14 days of a study vaccination or any live attenuated vaccines (such as an MMR booster) within 30 days of a study vaccination.
- You need to avoid taking medications that may affect your immune system, such as corticosteroids (example: prednisone). If you are prescribed these medications or any medications that could affect your immune system, please inform the study team.
- You will not participate in another research study without first discussing with the research team.
- If you are a female of childbearing potential, you will avoid becoming pregnant during the study.

5. HOW LONG WILL I BE IN THE RESEARCH STUDY?

You will be in this study for about 13 months, including screening. It is estimated that the study will be completed in 18 months.

6. WHAT ARE THE RISKS?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be risks in this study which are not yet known.

The potential risks of participating in this trial are those related to the investigational vaccine (HydroVax-001B), the blood draws, intramuscular injections, and breach of confidentiality.

Risks of HydroVax-001B WNV

This is the first time that the HydroVax-001B vaccine is being given to people. A closely related vaccine, HydroVax-001A was given to people in an earlier study with no safety issues. However, 66% of participants had a side effect (mostly mild). These were mainly headache, fatigue, and tenderness at the injection site. There was no difference in the rate of side effects between people who received vaccine vs. placebo. Potential risks related to vaccination with HydroVax-001B may be like those of other inactivated flavivirus vaccines that are adjuvanted with aluminum hydroxide (alum). An adjuvant is a chemical which is used to boost your body's immune response to the vaccine. The use of alum as an adjuvant is generally well-tolerated and is part of many licensed vaccines including Tetanus, Hepatitis A and B vaccines and HPV vaccine.

There is a first-generation vaccine that is related to HydroVax-001B called HydroVax-001. HydroVax-001 was evaluated in a Phase 1 randomized, double-blind, placebo-controlled trial, like this one, that showed that two doses of the vaccine given 28 days apart were well tolerated and had an acceptable safety profile. The most reported reactions after HydroVax-001 vaccination were fatigue and headache, but these were seen at equal rates in the 1 and 4 mcg dose groups and placebo groups. The most common local reaction was tenderness, which also occurred similarly among active and placebo groups. Importantly, there were no severe systemic reactions, or moderate or severe local reactions reported after either vaccination with HydroVax-001 or placebo. There were no differences between people who received vaccine or placebo in the severity of adverse events (AEs). Overall, none of the reactions were severe and most (80%) were mild.

There were no serious adverse events (SAE) reported during the study, and no significant vaccine-related safety laboratory abnormalities.

Other inactivated flavivirus vaccines (same family of viruses as WNV) appear to be reasonably well tolerated. This includes licensed vaccines for Japanese encephalitis and tick-borne encephalitis. However, typical reactions reported after getting an inactivated flavivirus vaccine includes local reactions at the injection site including pain, tenderness, redness, swelling, and itching, and mild to moderate systemic reactions including headache, muscle aches, fatigue, influenza-like-illness, nausea, and fever. If you develop side effects, you can take Tylenol or NSAIDS (ibuprofen) if needed.

Risks Related to Blood Draws and Intramuscular (IM) Injections

Having blood taken from your arm and IM injections can cause temporary discomfort and fainting. Fainting is treated by having the participant lie down. Bruising at the blood draw site may occur but can be prevented or lessened by applying pressure to the site for several minutes after blood is drawn. Drawing blood and IM injections may also cause discomfort, fainting and possible infection. However, the use of aseptic technique will make infection at the site where blood will be drawn or where the IM injection is given extremely unlikely. A possible risk of having blood drawn may be a low blood count (anemia), however, the total amount of blood drawn for this study is much less than donating a unit of blood, so the risk of anemia is low.

HIV/Hepatitis Reportable Disease Testing

At the Screening visit, you will be tested for hepatitis B and C, and HIV. Positive tests will be reported to the Missouri Public Health Department along with your name (for hepatitis) or a code number for HIV. Receiving information that any abnormal health screening tests or positive HIV and hepatitis B or C tests may be upsetting. The study doctors will discuss your results with you face-to-face (and notify your primary doctor at your request). Counseling will be available to you on an as needed basis.

Risks of Allergic Reaction

Acute and potentially life-threatening allergic reactions are possible with receipt of any vaccine. A severe, vaccine-related allergic reaction occurs in about 1 in 4 million people who are vaccinated. Symptoms include skin rash (hives), swelling around the mouth, throat or eyes, difficulty breathing, fast heartbeat, or loss of blood pressure. If these reactions occur, they can usually be stopped by the study staff giving emergency medications and by sending the person to the local emergency department for treatment, if medically necessary. As with any vaccine, there is a small chance of fatal reaction, although it is unlikely to occur as we evaluate this second generation, inactivated, alum-adjuvanted vaccine.

Pregnancy/Childbearing Potential for FEMALES ONLY

If you are a female of childbearing potential, please read and sign below.

Some research medications or procedures can cause severe birth defects, mental disability in an unborn baby, or loss of the unborn baby. If you take part in a research study that includes a drug or medical procedure, you must be willing to have a pregnancy test done before beginning your participation and before each vaccination and you must avoid becoming pregnant while you take part in the research study.

If you are pregnant or breast-feeding a baby, you cannot take part in this research study. If you are pregnant or think you are pregnant, it is important for you to tell the study doctor immediately. You will not be able to receive any more vaccinations in the WNV vaccine study if you become pregnant.

If you are sexually active during your participation in the research, you must use one acceptable primary measure (chosen in consultation with your health care provider) to avoid becoming pregnant for the duration of the study.

☐ Check this box if you are not a female of childbearing potential (no signature needed).

Your signature below indicates you agree to these requirements.

Signature Date

If you become pregnant while in this study, the sponsor may ask to follow the outcome of the pregnancy. If you agree to allow the study doctor to follow your pregnancy, you will be asked to read and sign a separate consent form for permission to follow the outcome of your pregnancy.

Confidentiality

As a participant in this study, you will be asked to provide us with personal health information. We will try to keep your personal health information confidential within the limits of the law. However, there is a chance that someone unauthorized will see your personal health information. Your records will be kept in a locked file or maintained in a locked room in the research areas. Electronic files will be password protected. Only people involved in the conduct, oversight, or auditing of this study will be allowed access to the personal health information we collect. Any publications describing findings from this study will not use information that will identify you by name. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups, such as the National Institute of Allergy and Infectious Diseases (NIAID), the Food and Drug Administration (FDA), and the Saint Louis University Institutional Review Board (IRB).

Unknown risks

There is a small risk that you may have an unknown health problem that is not identified at the screening visit but may become apparent during the study.
The research team is willing to discuss any questions you might have about these risks and discomforts.

If side effects or discomforts do occur, one of the study doctors will try to help these by using medically appropriate treatment, if indicated.

7. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

As the ability of the investigational vaccine (HydroVax-001B) to protect against WNV disease has not been proven, there are no benefits to participants in this trial who will receive HydroVax-001B. Society will benefit if HydroVax-001B is eventually found to protect people against WNV disease because of this and other future trials.

8. WHAT OTHER OPTIONS ARE THERE?

You do not have to take part in this study. Instead of being in this study you may choose not to take part in this study.

9. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed, and your record will remain private. During this study, your individual study record will contain your photo identification, social security number, date of birth, information on how to contact you, and other information that could identify you personally. To maintain confidentiality, Dr. George and the other study doctors will keep your study record locked in a secured area; only the study team will have access and your electronic data will be stored on password protected computers on a secured network. Your reported study data and any samples will not contain your personal identifiable information. The study data and samples will be labeled with an assigned code consisting of a unique number.

The results from this research study may be published. However, your name and identity will not be revealed in the publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

Your study records are confidential unless the law requires certain people to see them. For example, the Saint Louis University Institutional Review Board (IRB) (the Board that is responsible for protecting the welfare of persons who take part in research) and other University officials may review your research study records. Organizations that may inspect and/or copy your study records, including your medical records, for quality assurance and data analysis include groups such as the sponsor, NIAID, and its affiliates, including monitors, and auditors, and the Saint Louis University IRB to carry out their obligations. Federal agencies such as the FDA, the Office for Human Research Protections (OHRP) and accrediting agencies will have access to your study records with identifiers. The purpose of these reviews is to make sure the study is being conducted properly and that the data are being collected correctly, or for other purposes allowed by law. State laws or court orders may also require that information from your research records be released.

To help us protect your privacy, we have received a Certificate of Confidentiality from the NIH. The certificate says that the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this certificate cannot be disclosed to anyone else who is not connected with the research unless:

- There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

- You have consented to the disclosure, including for your medical treatment; or
- The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

As noted above, disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As this research study involves medical tests for safety, the research team could find information that affects your health during the study. The researchers plan to provide you with information regarding any abnormal safety lab 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 web site will include a summary of the results. You can search this web site at any time.

If we need to contact you for any reason during the study and attempts to contact you at all the telephone numbers you provide are not successful, we will try to contact you via the secondary contact(s) provided by you. Providing us with a secondary contact may mean that a person could learn that you are in a clinical trial. We would not provide the secondary contact(s) with any other information other than the fact that we were trying to reach you. We recommend that you let any secondary contact(s) you provide know that you are/may be in a clinical trial.

10. WHAT ARE THE COSTS AND PAYMENTS?

Costs

There will be no costs to you for being in this study and there are no anticipated expenses related to your participation. You will not have to pay to receive study product (the vaccine or placebo). There are no costs for the physical examinations, laboratory testing, or clinic visits. They will be included as part of the study.

Compensation

You will be compensated for your time and participation in this study. You will be paid $100.00 for each scheduled clinic visit you attend and $25.00 for each scheduled phone call. You will also be compensated $100.00 if we ask you to come in for extra clinic visits during the study because of symptoms that need to be assessed by study staff.

Payments for taking part in this research study will be put onto a participant payment card. The participant payment card is managed by an external company. Your personal information, such as your name, date of birth, and social security number will be shared with this company to put study payments onto the card. While the participant payment card is not a credit card, the company may use your information like a credit card company would. You should review the terms and conditions of the participant payment card when deciding whether to take part in this study.

To receive payment for participation in this study, you will be asked to provide your home address and social security number. If you receive $600 or more for participation in this research study, or a combination of studies at Saint Louis University in one tax year, you will be sent an IRS Form 1099 for tax purposes.

11. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you have been injured due to your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment if an injury results because of your participation in this research. The University will have the right to determine whether an injury is related or not to your participation in this study. If the injury is due to participation in the study, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. Saint Louis University has no plans to pay for additional care. You have not waived your legal rights by signing this form. If you have any questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

12. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call the Principal Investigator Dr. George or the other study doctors and appropriate Vaccine Center personnel who can be reached during normal business hours at 314-977-6333. After hours, if you have any study related medical concerns, you can reach the Vaccine Center nurse on call at 314-486-1288.

If you have any questions, concerns or complaints about your rights as a research participant and would like to talk with someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

13. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part or if you decide to withdraw from the study. You may leave the research study at any time. If you do decide to withdraw from the study after you receive a dose of vaccine, we will ask to remain in contact with you for safety follow-up and, with your permission, collect blood samples to measure immune response to the vaccine. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

The study doctor or sponsor may decide to stop you from taking part in this study at any time, without your consent. You could be removed from this study for any of the following reasons:

- Reasons related to you (for example, if you move to another city or do not agree to get your study drug).

- Reasons related to your health (for example, if you have a serious reaction to your study drug).
- Because this entire study is stopped (the sponsor may stop this study at any time).
- If you do not later consent to any future changes that may be made to how this study is done.
- If you become pregnant you will not receive any more vaccinations, but we will follow you for safety.

If you stop taking part in this study, we may ask you some questions about taking part in this study. To help you leave this study safely, we may ask you to take part in more tests, such as blood tests to confirm safety if you agree.

Although the results from this study may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research.

The use of your samples and/or data may result in commercial profit, such as a product, material, or process. You will not be compensated for the use of your samples and/or data other than what is described in this consent form.

Saint Louis University is receiving financial support from the NIH to assist in the conduct of this research study. The amount of payment is enough to cover the research study doctor's and/or institution's expenses to perform the research study.

14. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____ _____

Consent Signature of Research Participant Date

_____

Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP **This form is valid only if the IRB's approval stamp is shown below.**

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the participant has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**

First Name / Last Name *Credentials*
Printed Name of Consenting Research Team Member

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.