RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Phase I Evaluation of the Safety and Immunogenicity of the Live Attenuated Zika Vaccine rZIKV/D4Δ30-713 in Flavivirus-naïve Adults

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 – your choice.
☐ If you join this study, you can still stop at any time.
☐ Nobody can promise that a study will help you.
☐ Do not join this study unless all of your questions are answered.

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
• What to do if you have problems or questions about this study.

Please read this consent form carefully.
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TITLE: Phase I Evaluation of the Safety and Immunogenicity of the Live Attenuated Zika Vaccine rZIKV/D4Δ30-713 in Flavivirus-naïve Adults

PROTOCOL NO.: CIR 318
Western Institutional Review Board (WIRB®)
Protocol #20181303

SPONSOR: Office of Clinical Research Policy and Regulatory Operations (OCRPRO)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

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410-340-6852 (cell-phone)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or discuss it with family or friends before making your decision.

PURPOSE OF THE STUDY:
You are being invited to take part in a research study to learn about the effects of an experimental live attenuated (weakened) vaccine to prevent Zika infection in people. This vaccine is named rZIKV/D4Δ30-713 but we will call it the Zika vaccine from now on. This
study will be used to evaluate the safety of this Zika vaccine in humans. We will also study how your immune system will respond to the Zika vaccine.

BACKGROUND INFORMATION:
Vaccines are medicines that are given to people to prevent diseases. It is hoped that this vaccine will help the body defend itself against the Zika virus, which would prevent a serious Zika infection. The Zika vaccine we are testing has never been studied in humans, but other vaccines for other flaviviruses (viruses related to the Zika virus) have been studied in humans. The people in whom we studied the other flavivirus vaccines tolerated the vaccine well. We will check you for side effects and we will see if the Zika vaccine helped your body make disease fighting antibodies in your blood.

This study is being conducted by the Center for Immunization Research at the Johns Hopkins Bloomberg School of Public Health. This study is sponsored by the National Institutes of Health (NIH), Office of Clinical Research Policy and Regulatory Operations (OCRPRO), and National Institute of Allergy and Infectious Diseases (NIAID).

We encourage you to ask questions about the study and to discuss the study with anyone you think can help you make a decision about participating in the study.

About Zika
Zika virus is a mosquito-borne flavivirus that was first isolated from the blood of a monkey in the Zika forest of Uganda in 1947. This virus can be found in warm places like the Caribbean, South America, Central America, Asia, Africa, and parts of Australia. The virus is not found very often in the United States. Countries and areas currently reporting Zika virus can be found on the CDC website.

Why Zika is Risky for Some People
In early 2015, Zika virus started spreading in Brazil. During the outbreak in Brazil, it was noticed that some babies whose mother got infected with Zika when she was pregnant were born with a serious birth defect called microcephaly. This means the baby had an abnormally small brain and head. We want to find a vaccine to prevent Zika infection and this serious birth defect linked to Zika infection during pregnancy.

In some countries that had Zika virus outbreaks, cases of an autoimmune disorder called Guillain-Barré syndrome (GBS) were reported. GBS is characterized by varying degrees of muscle weakness and nervous system abnormalities and has been seen with other infections like influenza (the flu). The risk of GBS appears to increase with older age, particularly older than 55. It also occurs more commonly in people with a history of GBS or autoimmune disease. The risk of GBS following Zika virus infection is not fully known, but it is estimated to be around 1-2 cases per 10,000 Zika virus infections. Most cases of GBS occurred within 5 - 6 days of having Zika virus symptoms.
Zika Symptoms
Most people who get Zika virus do not have serious complications. Zika virus can cause an itchy rash, low-grade fever, non-purulent conjunctivitis (redness in your eye with clear discharge), joint aches, and muscle aches. Only about 20% of those infected with Zika virus have symptoms. If a pregnant woman gets Zika virus, it can cause birth defects in her baby liked we have described above.

Information About our Zika Vaccine (rZIKV/D4Δ30-713)
We want to test the live vaccine to prevent Zika called rZIKV/D4Δ30-713. This vaccine is weakened by combining parts of the Zika virus with parts of an experimental dengue vaccine. Even though this vaccine contains parts of a dengue vaccine, it does not work against dengue. The vaccine was made at the Laboratory of Infectious Disease (LID), NIAID, and NIH, and then produced for human administration by a commercial manufacturer. This vaccine has not previously been tested in humans. It is considered investigational or experimental, which means that it has not been approved by the U.S. Food and Drug Administration (FDA). Because it is investigational and is made from a live virus, it should not be given to pregnant women.

Previous Exposure to Flaviviruses
We want to study the effect of this Zika vaccine on people who have not had previous exposure to flaviviruses. Examples of flaviviruses include Zika virus, dengue viruses, West Nile virus, and yellow fever virus. If you already have antibodies to any of these viruses, then you may have been infected naturally or received a vaccine to protect you against one of these viruses. Testing positive for antibodies against any flavivirus will exclude you from this study.

It is up to you to decide whether you wish to take part in this study. Participation in this study is voluntary and you will be free to withdraw from the study at any time. Any decision you make will not affect the care that you receive or the benefits to which you would otherwise be entitled.

How Many People Will be in the Study?
There will be a total of up to 28 subjects, both male and female, who will be recruited for participation in this study. We will enroll 14 subjects here in Baltimore. The other 14 subjects will be enrolled in Vermont.

In total, 20 subjects will receive the live Zika virus vaccine and 8 subjects will receive the placebo. If you enroll in this study, you will be randomly assigned (that is, by chance) to receive either the Zika vaccine or a placebo and neither you nor the staff will know which you received. A placebo is a substance that looks like the vaccine but does not have any vaccine or virus product in it. This placebo is like salt-water. The vaccine or placebo will be given as a shot under the skin in your upper arm on Study Day 0 (the day of enrollment). Approximately 3 months after you received either the Zika vaccine or placebo, you will be told if you got the vaccine or if you got placebo. This information is available to the study doctor at
any time if needed in an emergency. The table below (Table 1) describes what the different groups will get. You will not know if you got the Zika vaccine or placebo until at least 3 months after you are vaccinated.

<table>
<thead>
<tr>
<th>Table 1. Study Assignments</th>
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</thead>
<tbody>
<tr>
<td># subjects</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>8</td>
</tr>
</tbody>
</table>

**PROCEDURES:**

**Entering the Study:**
There may be reasons why you cannot take part in this study. The staff will discuss these with you. Before entering the study, you will have blood and urine tests to see if you are in good health. This is called the "screening visit."

To find out about your health, you will have:
- A complete medical history
- A complete sexual history (Some of the questions may be sensitive and personal, but your answers will be kept confidential)
- A physical examination
- Several laboratory tests including:
  - Complete blood count (CBC)
  - Blood clotting test (PT/PTT)
  - Blood chemistry (including tests of your kidneys, liver, and muscles)
  - Pregnancy test (women only)
  - Follicle Stimulating Hormone Test (FSH) (menopausal women only)
  - Urine analysis
  - HIV test (a test for the virus that causes AIDS)
  - Hepatitis B test (a test for a virus that hurts the liver)
  - Hepatitis C test (a test for a virus that hurts the liver)
  - Blood tests to see if you have ever had or have ever been exposed to ZIKV or other flaviviruses

You will be told of any abnormal results that may require follow-up by your private physician. Based on the results of these screening tests, you may be invited to participate in the study.

**HIV, Hepatitis B, and Hepatitis C Tests:**
If your tests show that you have HIV, the study doctor must notify the local health department. A separate HIV testing education form explains how positive results are
reported to the local health department. Counseling will also be made available to you to discuss your positive HIV test.

If your tests show that you have hepatitis B or hepatitis C virus, the study doctor must notify the health department. The health department will be notified in writing of the following information: laboratory test date, type of test, result of test, your name, age, sex, and address.

**Women:** Women who are pregnant, who plan on becoming pregnant within 6 months, or are breast-feeding will not be able to take part in the study. The effects of Zika virus on the unborn fetus have been shown to cause microcephaly and/or other birth defects, and the effects of the vaccine on the unborn fetus and breastfeeding infant are unknown. All women who can become pregnant MUST agree to use at least one of the following methods of birth control during this study: hormonal birth control, condoms with spermicide, diaphragm with spermicide, surgical sterilization, or an intrauterine device. Females who have sex with females (exclusively) may not be required to use contraception.

All female subjects will be considered to have child-bearing potential except for those with hysterectomy, tubal ligation, tubal coil (at least 3 months prior to getting the vaccine), or post-menopausal status documented as at least 1 year since last menstrual period and an FSH in the menopausal range, or at least 24 consecutive months of no menstrual period (not on any medication known to cause this). You may discuss what birth control method is right for you with the study clinician while in the study. We may ask for a copy of your medical records (after you sign a medical release) to confirm the type of birth control you are using. A pregnancy test will be done during the screening visit and on the day of vaccination. This test must be negative for the staff to give you the vaccine. A pregnancy test will also be done on several visits after you receive the vaccine.

**Transgender men:** Men who have internal female organs must agree to use one of the effective contraception methods listed above.

**Males:** Males should be willing to use barrier contraception for the duration of the study and agree to not donate sperm for the duration of the study.

If you become pregnant during the study, tell the staff right away. We may ask you to continue to come in for regular study visits and/or ask you to agree to let us keep checking on you until the end of your pregnancy. We will ask you to sign a medical information release form so that we can learn about your pregnancy and, if applicable, your baby's health at birth.

**Length of Study:**
You will take part in this study for about 6 months. In the event that a health problem develops related to the vaccine and it has not resolved by the end of the study, you may be followed longer, typically until it is resolved or stabilized.
It is very important for you to come to all your study visits. If you are unable to return to the center for study visits, you may be asked to have blood drawn at a local Quest Lab so that we can follow you for safety. It is very important that you understand the requirements of the study before you decide to sign this consent form and join the study.

**Study Visits:**

**Vaccination Day (Study Day 0):**
On this day you will get the vaccine or placebo and your visit will last about 3 hours. You will have your blood drawn, have a urine sample collected, have oral fluid collected, collect semen or vaginal fluid sample (may be done at home ahead of time), and receive a physical examination. If you are a female of child bearing potential, we will do a pregnancy test. We will make sure the test is negative before we give you the vaccine or placebo; a positive test will exclude you from getting vaccinated. We will discuss ways to prevent pregnancy and ways to prevent being bitten by a mosquito.

You will be asked to stay at least 30 minutes after the vaccination to check to see if you feel sick or have any side effects. We will give you a thermometer and a card to write down your temperatures. You will be told how to take your temperature and how often to write it down for record-keeping purposes. You will also be given a card to write down the dates and times you inserted your vaginal cup (for females) and dates and times of semen collection (for males).

**Follow-up Visits:**
You will be asked to come to the clinic on the days shown in the following table.

<table>
<thead>
<tr>
<th>Study Day</th>
<th>0</th>
<th>4</th>
<th>6</th>
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<th>10</th>
<th>12</th>
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<th>16</th>
<th>21</th>
<th>28</th>
<th>56</th>
<th>90</th>
<th>150</th>
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<tbody>
<tr>
<td>Vaccination</td>
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<td>Physical exam</td>
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<tr>
<td>Medical history</td>
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<td>Vital signs</td>
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<td>Pregnancy test</td>
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<td>Temperature review</td>
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<td>Blood Draw</td>
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<tr>
<td>Urine sample</td>
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<tr>
<td>Oral Fluid Collection</td>
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<td>Vaginal secretion or semen sample</td>
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[X] Physical exam may be performed but is not required.
[X] Samples for virology will be collected on Study Day if virus was recovered from the sample collected at the previous time-point or if virology results are not available.
Each follow-up visit will take about 30-60 minutes. At each visit we will perform some or all of the following:

- Ask you questions about how you are feeling
- Do a pregnancy test and/or provide pregnancy prevention counseling (for women)
- Review your temperatures
- Draw your blood
- Collect a urine sample
- Collect a semen sample (if male)
- Collect a vaginal secretion sample, if female (using a vaginal cup or vaginal swab)
- Collect an oral fluid sample
- Give you a physical examination

You will have blood drawn at each study visit. Each time we will take less than 5 tablespoons of blood. The total amount of blood to be taken from you during the 6-month study is a little more than 1 pint. We will not take more blood over the 6-month period than what the Red Cross recommends.

The blood we draw at your visits will be tested to:

- Check on your health after vaccination
- Look for vaccine virus in your blood
- See if your body has made antibodies (germ fighters) against the vaccine virus
- Test markers on your white blood cells and genes and look for proteins in your blood that may be important for your body to fight Zika infection

While you are in the study we will ask you to:

- Take your temperature (check for a fever) two times a day, every day, for 16 days after the vaccination. We will ask you to write down these temperatures and bring them to your visits.
- Write down dates and times of semen collection (for males) and dates and times of vaginal cup insertion (for females)
- Contact the staff or study doctor before taking medications. This includes medicines that you buy without a prescription like herbal or over-the-counter medicines like Advil or Tylenol, and medicines that affect the immune system, such as prednisone.
- Wait to get routine licensed vaccines, like the flu shot (or nasal spray flu vaccine), until after study Day 28 (about 4 weeks after vaccination). This may put you at more risk for illness such as the flu. We will ask you to tell us if you do get a licensed vaccine during the study.
• Not join another clinical study. You may not receive any other experimental drugs or vaccines while you are in this study.
• Not donate any blood products.
• Not donate any sperm.
• Not get pregnant or receive IVF.
• Use barrier contraception (men)
• Not receive any other live vaccines 4 weeks before study vaccination or killed vaccines 2 weeks prior to study vaccination. You may need to get certain vaccines like a tetanus shot for emergency reasons. Please contact the contact the study staff right away if this happens.
• Avoid drinking large amounts of alcohol.
• Tell the staff if you receive any blood products.

We may take photographs of your skin or the injection site where you get the vaccination. These pictures will help us follow a skin rash and any other changes that may occur during the study. Your face or any other identifying marks will not be in the picture. You can refuse to have a photograph taken.

In addition:
• A study doctor will be available at all times to check on you and treat you during the study.
• It is important that you tell the staff if you become sick or feel bad. We may ask you to come to the clinic so that we can check on you, even if it is before your next scheduled visit.
• If you become ill during the study, some additional tests may be done (for example blood tests, nasal wash, or x-rays) to find out what is making you ill. You will not be charged for these tests. Any risks associated with these tests will be explained to you before they are performed. You may refuse to have these tests done if you do not want them.
• If we find the Zika vaccine in your blood, urine, vaginal secretions (women) or semen (men) at your last visit (6 months after you are vaccinated), we will ask you to come back for additional visit(s) until the Zika vaccine can't be found anymore. You will be compensated for any additional visits.
• Staff or the study doctor can be reached 24 hours a day, if needed, during the study.
• Because Zika virus may be spread by mosquitoes, we ask that you protect yourself from mosquitoes for at least 4 weeks after you have been vaccinated. We will give you bug spray during the spring, summer, and fall to help you protect yourself.
• We will contact you to remind you of study visits and to check on you if you miss a study visit.
• We may contact you by one or more of the following ways:
  o Telephone call
  o Text message
  o Email message
  o Electronic Media (twitter, Facebook, etc.)
  o Card mailed by US Postal Service
  o Ask one or more of the people you provided as a contact to remind you to come
to the clinic

RISKS AND DISCOMFORTS:
This is an experimental vaccine to prevent Zika. We do not know all the risks that may occur. We do know some risks that have been discovered in people infected with Zika virus. The effects of Zika virus on the unborn fetus have been shown to cause microcephaly and/or other birth defects and the effects of the vaccine on the unborn fetus and breastfeeding infant are unknown. **You should not become pregnant or breast-feed during this study.**

**Common side effects** that have been seen in people infected with Zika virus include rash, low-grade fever, red eyes, headache, joint aches, and muscle aches, with a majority of those infected not reporting symptoms.

The risks for the vaccine being used in this study (rZIKV/D4Δ30-713) are listed below.

**Immediate risks from vaccination:**
- You may have pain, redness, tenderness, itching, and/or swelling where we give you
  the shot.
- You may have a fever, headache, red eyes, bruising, muscle or joint aches, upset
  stomach, or not feel like eating.
- You may get a skin rash. This rash may be itchy.
- You could have an allergic reaction (a rash, hives, or trouble breathing) right after
  vaccination. Some allergic reactions can be life-threatening. We will watch you
  for at least 30 minutes after you are vaccinated to check for signs of an allergic
  reaction and will treat you immediately for any sign of an allergic reaction.

In addition, on the day of vaccination, you will be given a card that tells you in detail how to
avoid being bitten by mosquitoes.

There may be other side effects and risks that we don't know about yet. If we learn about any
new side effects or risks while you are in the study, we will tell you and you can decide if you
want to continue in the study.
Blood drawing:

- Blood drawing can cause pain, bruising, a lump called a hematoma, or infection at the place where blood is taken. To ease the discomfort, a topical anesthetic cream may be used during blood draw by request or at the phlebotomist’s discretion.
- Blood drawing can cause subjects to feel lightheaded or to faint.
- Bleeding may occur from the site of blood draw.
- There may be psychological or social risks that might result from taking part in the study such as testing for HIV.

Other risks:
Risks occasionally associated with the use of topical anesthetic cream include temporary skin discoloration, skin irritation, rash, hives, and rarely, dizziness or drowsiness.

The vaginal cup is a commercially-available product used during menstruation. It is contraindicated in women with an intrauterine device (IUD) in place. For women who have an IUD in place, vaginal secretion specimens will be collected by use of vaginal swab.

We will ask you to wait to get routine licensed vaccines like the flu shot (or nasal spray flu vaccine) until at least 4 weeks after you have joined the study. This may put you at more risk for illness such as the flu.

NEW FINDINGS:
The study doctor or staff will share with you any new findings that may develop while you are participating in this study that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS:
You will not receive any medical benefit from taking part in this study. We hope that the information we gather from this study will lead to a Zika vaccine that could help many people around the world.

COSTS:
There will be no costs to you for being in this study.

Ask your study doctor to discuss the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

PAYMENT FOR PARTICIPATION:
You will be paid for your screening only if you are enrolled in the study, unless you are an alternate on the day of vaccination. If you are an alternate on the day of vaccination and are not vaccinated, you will be paid $150.00 for your time. You will only be paid for the visits that
you complete. You will be paid $80.00 for screening and $80.00 for each completed follow-up visit. Because you must stay in the clinic for a longer amount of time on vaccination day, you will be paid $150.00 for the vaccination day visit.

After screening, there are 14 scheduled outpatient study visits, including the one vaccination day. You will also be paid a $250.00 bonus if you complete all study visits on time. You may only receive a portion of the bonus if not all study visits are completed on time. If we need you to come back because we need to collect blood, urine, vaginal secretions (women) or semen (men) after Study Day 180, you will be compensated an additional $80.00 for each visit. The total amount you will be paid if you complete all scheduled visits is $1,520.00. You may be compensated more than $1,520.00 if you have to come back after 6 months for one or more additional visits. To comply with federal law, this payment will be reported as income to the Internal Revenue Service (IRS).

If you choose to withdraw before the study is completed, you will only receive payment for the number of visits that you have completed.

ALTERNATIVE TREATMENT:
Since this is not a treatment study there are no alternative treatments, but you may choose not to be in this study.

CONFIDENTIALITY:
The National Institutes of Health has given us a Certificate of Confidentiality for this study. This Certificate does not mean that the government approves or disapproves of this study. This Certificate adds special protection for research information that identifies you. It allows us, in some circumstances, to refuse to give out study information about you without your consent when it is sought in a legal action. Still, we may disclose identifying information about you if, for example, you need medical help. We may also give out information about you if the government audits us. The research team will also give information to local or state authorities:

- if they suspect abuse or neglect of a child or dependent adult;
- if certain communicable diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

A description of this clinical trial will be available on https://ClinicalTrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information from this study will be given to the sponsor. The sponsor is the organization responsible for financing and overseeing this study. The sponsors of this study are the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Office of Clinical Research Policy and Regulatory Operations (OCRPRO). "Sponsor" includes any
persons or companies that are contracted by the sponsor to have access to the research information during and after the study. Information about side effects of the Zika vaccine (rZIKV/D4Δ30-713) will also be given to the US Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study vaccine may be considered for approval.

Medical records which identify you, including photographs, and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by the sponsor, and may be looked at and/or copied for research or regulatory purposes by:

- The FDA
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases must be reported
- Governmental agencies in other countries
- Johns Hopkins University
- The Johns Hopkins University Bloomberg School of Public Health
- The Western Institutional Review Board® (WIRB®)

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

**COMPENSATION FOR INJURY:**
A study doctor will be available at all times while you are in the study to check on you and treat you for any short-term medical care resulting from your taking part in this research study. The services at the Johns Hopkins Hospital or the Johns Hopkins Bayview Medical Center will be available to you in case of any such injury. This short-term medical care will be paid for through our contract with the NIH. Short-term medical care will be given at a facility determined by JHU and NIH. No long-term medical care or financial compensation for research-related injuries will be offered by the Johns Hopkins University, Johns Hopkins Hospital, the NIH, or the federal government. At your request, your insurance company will be billed for payment of any such long-term treatment or hospitalization. It is up to you to check with your insurance company before you start this study to find out what your insurance company will pay for.

You do not lose any legal rights by being in this study.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL:**
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. If you decide to withdraw from the study soon after you are
vaccinated, the study doctor may ask permission to follow you briefly for safety reasons. We may ask you to let us check on you or return for a follow up and/or final study visit.

Your decision to withdraw or to not take part will not result in any penalty or loss of benefits to which you are entitled. If you decline to participate in this study, you will not put at risk any present or future employment at Johns Hopkins University, any access to care at Johns Hopkins hospital, or the quality of the medical care you may receive at Johns Hopkins.

If you decide to leave the study, the samples that have been collected will be used as described in this consent form. If you do not want us to use these samples after you leave the study, you may request that we destroy them and they will be destroyed. You should ask the study doctor listed below any questions you may have about this research study. You may ask questions in the future if you do not understand something that is being done.

You may be withdrawn from the study at any time by the study doctor or the sponsor without your consent if:

- The study sponsor decides to stop or cancel the study for any reason
- The study staff or the study sponsor decides to discontinue your participation for any reason
- The staff or your study doctor feels that staying in the study is harmful to your health
- You do not follow instructions from the staff or do not keep appointments
- The Data and Safety Monitoring Board (a scientific review board that monitors studies) feels the study should be stopped
- The FDA or Western Institutional Review Board® feel the study should be stopped
- If new information becomes available regarding the safety of the vaccine
- You do not consent to continue in the study after being told of changes in the research that may affect you
- For any other reason

STORAGE OF UNUSED SAMPLES:
We will store any unused blood and urine samples once this study is finished. Your samples will be used only for research. We may use these samples to learn more about Zika virus and other diseases. The samples may be used for tests to detect:

- Immune responses to the test vaccine (immunology)
- How antibodies to Zika virus react with other viruses
- How certain cells in your blood react to other viruses
- Genetic differences in responses to vaccines or Zika infection (samples will be used anonymously)
Your samples will not be sold. Your samples will not be used to make commercial products. We will label your stored samples with a code that only the study team can link to you. We will keep any information that can be traced back to you private to the extent permitted by law. In some cases, the Western Institutional Review Board® (WIRB®) will review new research proposals that would like to use your samples. WIRB is a group of people who perform independent review of research.

Reports about research with your samples will be kept with the study records only. There will be no direct benefit to you. From studying your samples, we may learn more about how to prevent, treat, or cure Zika virus or other diseases. Results from research using your samples may be presented in publications and meetings but your name will not be used.

The research tests we perform are not like routine medical tests and may not relate directly to your medical care, so we may not put future test results in your medical record. However, if you wish, someone on the study team will discuss the test results with you. We will not share these test results with your private doctor unless you ask us to do so.

There are risks associated with a loss of confidentiality of your health information and genetic testing results. Information about genetic test results may affect your employment, insurance, or family relationships. The sponsor cannot be certain that your genetic test results could never be linked to you.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) provides some protection for your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information collected in this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information collected in this research when making a decision about your employment.

However, this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**If you do not want your unused samples used for future research, you should not join this study.**

You can change your mind at any time about allowing your samples to be used for future research. If you do change your mind, call or write the study doctor or study staff and let them know. Your samples will then no longer be made available for research. Your samples
will be destroyed. However, information already obtained from your samples will continue to be used for research purposes.

**SOURCE OF FUNDING FOR THE STUDY/CONFLICT OF INTEREST:**
A conflict of interest occurs when a researcher or the University has a financial or other interest that might affect the researcher’s judgment when conducting a research study. The National Institutes of Health (NIH) pays for the conduct of this study through the NIH Contract No. HHSN272200900010C "Operation of a Facility for the Study of Infectious Agents, Vaccines and Antimicrobials in Adult and Pediatric Human Subjects" with Johns Hopkins University. Funding for this research study will be provided by Office of Clinical Research Policy and Regulatory Operations (OCRPRO)/National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH). Dr. Durbin is a faculty member at Johns Hopkins University.

**QUESTIONS:**
If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to the study vaccine, or if you have questions, concerns or complaints about the research, contact:

Dr. Anna P. Durbin: 410-614-4736 (office)
410-283-6522 (24-hour pager)
410-340-6852 (cell phone).

If you have questions about your rights as a research subject, or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE
Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions. If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.
CONSENT:
I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

I authorize the release of my medical records, including photos and the results of HIV and hepatitis testing, for research or regulatory purposes to the sponsor, the FDA, DHHS agencies, governmental agencies in other countries, and WIRB®.

By signing this consent form, I have not given up any of my legal rights.

Printed Name of Subject

CONSENT SIGNATURE:

Signature of Subject                                    Time                                    Date

Attestation Statement
I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject’s questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

Printed Name of Person Conducting the Informed Consent Discussion

Position

Signature of Person Conducting the Informed Consent Discussion                                    Date