UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: A Phase 1, Open-Label, Dose-Ranging Study to Evaluate the Safety, Tolerability and Immunogenicity of GLS-5700 Administered ID Followed by Electroporation in Dengue Virus-Naïve Adults

Principal Investigator: Pablo Tebas
3400 Spruce St., 3 Silverstein Building
Philadelphia, PA 19104
(215) 615-4321

Emergency Contact: 24 Hour Emergency Number (215) 662-6059
*** Ask for the Immunodeficiency Program doctor on call**

Why am I being asked to volunteer?

You are being invited to participate in a research study of a vaccine called GLS-5700 for the prevention of infection from the Zika virus. This study is a clinical research trial to find out whether an investigational (not approved by the US Food and Drug Administration (FDA) or Health Canada) vaccine is safe, tolerated, and can cause an immune response that may indicate the ability to prevent infection with Zika virus.

Zika virus infection is a disease that was relatively unknown prior to 2014. Zika virus was discovered in Africa and in 2015 spread into and across South America, Central America, and the Caribbean. Zika has been linked to congenital malformations in newborns of mothers who are infected during pregnancy, causing conditions such as microcephaly (small head and brains), retinal calcifications and blindness. Zika can also cause a condition of a temporary paralyzing illness called Guillain Barré syndrome (GBS).

At present, there are no therapies that have been tested in humans to treat or prevent Zika virus infection. Some vaccines and a few drugs have been tested in animal studies. The vaccine was able to show formation of immune response in all of the animals. The vaccine did not cause any safety concerns in any of the animals. This clinical trial would represent the first vaccine developed for Zika virus to be tested in humans.

Vaccines are medicines given to create resistance or immunity against a disease. The GLS-5700 vaccine used in this study is a relatively new type of vaccine called a DNA vaccine. DNA vaccines are not derived from live viruses or bacteria and contain no elements taken from a virus or bacteria. The GLS-5700 vaccine contains DNA that codes for proteins normally found on the surface of Zika virus. The DNA included in GLS-5700 was made in a laboratory, and was not made from Zika virus nor was there ever the use of any Zika virus to generate the DNA. The DNA is entirely synthetic – meaning it can be thought of as having been made in a test tube. There is no risk of getting Zika virus infection from GLS-5700.

The Study Team will monitor the safety, side effects, and immune system response of GLS-5700, the experimental vaccine against Zika virus infection. The vaccine will be given with an investigational device (called CELLECTRA®) that will deliver a small electric charge through 3 needles. This is called electroporation and is used to increase the amount of vaccine taken up by your skin cells. This investigational device has also not been approved for sale by the U.S. Food and Drug Administration (FDA) for use in this country but has been used in over 25 clinical studies like this one.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to evaluate the safety of the GLS-5700 vaccine and to help determine which dose of GLS-5700 should be used in future studies to test the vaccine in those who are at risk for Zika virus infection.

How long will I be in the study? How many other people will be in the study?

A total of approximately 40 subjects will be included in this study at 3 study locations in the US and Canada. The length of your participation in the study will be about 15 months and will include 10 study visits.

What am I being asked to do?

Pre-entry screening: Before you can start the study, the study doctor or study staff with talk to you about the study. Then you will have to read and sign this consent form before the study doctor or study staff can begin the screening period. These screening procedures will be performed to determine if you are eligible to participate in this study. These procedures include:

Health and medication questionnaire: You will answer questions about your health, your medical history, and the medications you take. You will also be asked specific questions about infections in the past and travel over the past 3 years.

Physical Assessment: The study doctor will do a physical exam.

Weight and Height: Study staff will see how much you weigh and how tall you are.

Vital signs: Study staff will check your blood pressure, your pulse, listen to you breathe in and out, and take your temperature. **Electrocardiograms (ECGs):** Study staff will attach leads (electrical sensing devices) to your chest to measure the electrical activity of your heart.

Collect blood for safety testing of your blood counts, chemistry, liver and kidney functions, antibody testing for Human Immunodeficiency Virus (HIV, the virus that causes AIDS), hepatitis B and C (viruses that affect the liver), and mosquito borne viruses (dengue, West Nile, and chikungunya).

Pregnancy testing (blood) on women who are able to have children.

You will be permitted to enter the study if you meet the study criteria and if study related test results are satisfactory which will be decided by the study investigator.

YOU MUST TELL THE MEDICAL STAFF ALL ABOUT YOUR PREVIOUS AND CURRENT MEDICAL CONDITIONS AND ANY DRUGS (LEGAL AND ILLEGAL) OR HEALTH SUPPLEMENTS YOU ARE TAKING. FAILURE TO DO SO MAY PUT YOUR HEALTH AT RISK.

If you qualify to be in this study, you will be assigned to receive vaccination (immunization) with GLS-5700 on Day 0, Week 4, and Week 12 at one of the following two doses given with the CELLECTRA® device:

- 1 mg (1 injection)
- 2 mg (2 separate 1 mg injections; this may be one injection in each arm or 2 injections in different areas of the same arm)

The first 5 subjects at each center will be assigned to the 1 mg dosing group. The next 5 subjects at each center will be assigned to the 2 mg dosing group. After 10 subjects have been enrolled at UPenn, the study sponsor will alternate even distribution of 1 mg/2mg dosing to the remainder of subjects enrolled.

Day 0 of study (Immunization #1): you will be asked about changes in your health since the last visit, have a physical examination, have your blood collected for monitoring lab tests, and have a urine pregnancy test if you are a woman who can become pregnant. You will receive your first immunization (1 or 2 injections, depending on which dosing group you have been assigned to) and electroporation (electroporation procedure is described below). You will stay in the Clinical Trials Research Center for a minimum of half an hour to be monitored closely for any side effects. You will be given a checklist to take home and write down any symptoms or reactions that you notice.

24 hrs after immunization#1: a member of the Study Team will call you to check on how you have felt since the injection and to describe the injection sites (where you got the vaccine).

Week 1: you will return for a brief physical exam, and to give blood samples to monitor the safety of the vaccine and your immune responses. You will discuss your checklist with the study staff.

Week 4 (Immunization #2): you will return for a physical exam, give a report of how you have felt since the last visit, and give blood samples for safety monitoring and immune responses. If you are a woman who could become pregnant, you will also have a urine pregnancy test. If your overall condition is unchanged (stable), you will receive your second immunization and electroporation, and will be watched for a minimum of half hour as was done for your first immunization. You will be provided a 2nd checklist to record any symptoms or reactions that you notice.

Week 6: you will return for a brief physical exam, and give blood samples to monitor the safety of the vaccine and your immune responses. You will discuss your checklist with the study staff.

Week 12 (Immunization #3): you will return for a physical exam, give a report of how you have felt since the last visit, and give blood samples for monitoring immune responses. If you are a woman who could become pregnant, you will also have a urine pregnancy test. If your overall condition is unchanged (stable), you will receive your third immunization and electroporation, and will be watched for a minimum of half an hour as was done for your first immunizations. You will be provided a 3rd checklist.

Week 14: you will return for a brief physical exam and to give blood samples to monitor the safety of the vaccine and your immune responses. You will discuss your checklist with the study staff.

Week 20 (2 months after the last immunization): you will return for a brief physical exam, discuss any reactions with study staff and to give blood samples for tests of immune responses.

Week 36 (6 months after the last immunization): you will return for a brief physical exam, discuss any reactions with study staff and to give blood samples for tests of immune responses.

Week 60 (12 months after the last immunization): you will return for a brief physical exam, discuss any reactions with study staff and to give blood samples for tests of immune responses.

Between 60-90 ml (3-4 ounces or 4-6 tablespoons) of blood will be taken at most of the study visits. The screening visit will require less blood, between 3 and 5 tablespoons. The total blood collected over the course of the study is approximately 675 ml (about 46 tablespoons).

You must agree not to engage in any high-risk behavior including intravenous drug use and unprotected sexual intercourse.

If for any reason you discontinue the study (and refuse to get more vaccinations) you will be asked to continue the study visits, or at least come to our clinic to complete the final visit, which is exactly as the Week 64 visit (see above).

CELLECTRA® Procedure:

This study procedure will occur with each administration of vaccine: at Day 0, Week 4, and Week 12. The study personnel will insert the needles from the CELLECTRA® device into a skin on your arm after injection of the study vaccine. Then there will be 4 short pulses from the CELLECTRA® device lasting less than 1 second each. Your arm may move slightly as a result of the pulse delivered into the skin. The CELLECTRA® device will be used to get the study medication into the skin cells. In addition, you may be offered Tylenol (acetaminophen) or Motrin (Ibuprofen) to help with pain related to the injection. The study staff will help you decide which medications you need, if any.

Pain Evaluation:
Immediately after and 30 minutes following each injection, you will rate the amount of discomfort you experienced during the injection

What are the possible risks or discomforts?

The vaccine used in this study may have side effects, some of which are discussed below. Please note that these lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning additional study vaccine side effects, please ask the medical staff at your site.

Risks of vaccine injections in the skin

- Injection site reactions such as redness, pain, swelling, bleeding, bruising, a warm feeling, or in rare cases infection.
- Flu-like symptoms such as fever, chills, muscle aches and pains, headaches, nausea, dizziness, and fatigue.
- Allergic reactions including itchy rash, hives, low blood pressure, sudden body swelling, breathing difficulty; in very rare cases, reactions can lead to death. Other immune reactions could occur such as serum sickness (fever, abdominal pain, diarrhea, joint pain and swelling). Therefore, clinic staff will watch you for a minimum of 30 minutes after each vaccination.

Risks of DNA Vaccines

More than 1200 people have received various DNA vaccines other than those developed by Inovio and/or GeneOne and more than 700 individuals have received DNA vaccines that are similar to GLS-5700 developed by Inovio and/or GeneOne.

DNA vaccines have been given to animals and humans without any problems being found but it cannot be certain that they will continue to be safe for humans. The possible risks related to DNA vaccines - which are theoretical (a guess as to what could happen) and haven't been observed to date include: cell damage, antibodies to DNA, insertion of the vaccine DNA into the body's DNA, insertion of the vaccine DNA into bacteria leading to the formation of a new bacterium which might resist some antibiotics, or insertions of the vaccine into a virus leading to formation of a new virus. None of these possible risks of DNA vaccines has been seen in laboratory tests or in animals or humans so far.

Risks of GLS-5700: GLS-5700 is a DNA vaccine. While no other vaccine for Zika virus infection has been tested in humans, three other DNA vaccines against related viruses in the same virus family (one for Dengue virus and two for West Nile virus) have been tested for

safety in humans as part of clinical studies. People in DNA vaccine studies have experienced minimal bleeding, bruising, redness and swelling at the injection site. There have been no bad effects on the kidneys, liver, heart, or other organs.

Risks of CELLECTRA®

Reactions observed in patients who have received vaccination followed by the **CELLECTRA®** device are summarized below.

Common

- Mild to moderate administration site pain, redness, swelling, hardness
- Not feeling well, tiredness, or headache in the first few days following immunization
- Visible lesion, scar and or/discoloration at the injection site

Less Common

- Injection site bruising, redness, laceration, other transient lesions, or bleeding related to the injection procedure
- Bruising, redness, or itching at near the administration site
- Joint pain or nausea

Uncommon or Rare

- Laceration, other transient lesions, or bleeding related to the injection procedure
- Severe administration site pain or tenderness
- Rash
- Lightheadedness/dizziness related to the injection/EP procedure
- Transient changes in clinical laboratory values such as CPK (muscle enzyme) or the aspartate transaminase (AST, also released from muscle)

Other possible side effects

- Tylenol (acetaminophen): Rarely large doses or long term usage can cause liver damage, rash, itching, fever, lowered blood sugar. These side effects are unlikely at the doses being used for this study.
- Motrin (ibuprofen): large doses or long-term usage can cause kidney damage.

Risks of blood drawing

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body, and in rare cases, fainting or infection.

Other risks of being in this study

There may be risks or serious and/or life threatening side effects when other medications or herbal supplements are taken with the study vaccine. For your safety, you must tell the study doctor or nurse about all medications you are taking besides the study vaccine before you start the study, and also before starting any new medications while on the study. In addition, you must tell the doctor or nurse before enrolling in any other clinical trials while on this study.

Unknown/Unforeseeable Risks and Discomforts

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. The research may involve risks that are currently unknown. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side

effects. Many side effects go away. In some cases, side effects can be serious, long lasting, or may never go away.

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study medication, including severe or life-threatening allergic reactions or interactions with another medication. There also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Reproductive Risks

The vaccine has unknown effects for unborn babies. You must agree not to become pregnant or make a woman pregnant.

Because of the risk involved, you and your partner must use an acceptable method of birth control that you discuss with the study staff. You must continue to use birth control until three months after you have received all vaccines. Acceptable birth control methods are listed below:

- Birth control drugs that prevent pregnancy given by pills, shots or placed under the skin
- Male or female condoms with or without a cream or gel that kills sperm
- Diaphragm or cervical cap with a cream or gel that kills sperm
- Intrauterine device (IUD)

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. **If you think that you or your partner may have become pregnant during the study it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility, and may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB.** (An IRB is a committee responsible for making sure that the study follows the guidelines for the protection of human research subjects). You will not be allowed to breast-feed during this study. If you become pregnant, the health of your baby will be followed for a year after birth.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You may receive no benefit from being in this study. Information learned from this study may help those who are at risk for Zika virus infection.

What other choices do I have if I do not participate?

Instead of being in this study you have the choice of:

No participation in this study. Please talk to your doctor about this and other choices available to you. Your doctor will explain the risks and benefits of these choices.

Will I be paid for being in this study?

To compensate you for your time, transportation or other expenses you may incur as a participant you will receive $25 for the pre-entry screening visit, $150 dollars for each visit that has an injection (3 visits), $50 for other visits including the final study visit. You will receive the compensation either by check or a reloadable pre-paid card called ClinCard *after* the visit has occurred. There are 9 total visits in the study that include the 3 injection visits. Thus if you complete today's visit, all study visits, and the final visit, you will be compensated a total of $775 for the study. You will not be compensated for any screening visits or for telephone contact for follow up.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

Laboratory tests, clinical evaluations, study vaccines, and EP procedure will be provided by the study for free.

What happens if I am injured from being in the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

If during the course of this study any injury occurs to you as a direct result of the administration of the study medication or study procedures, the study sponsor, GeneOne Pharmaceuticals, agrees to pay any reasonable medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance, and (2) to the extent that such expenses are not attributable to any pre-existing abnormal medical condition or underlying disease.

Financial compensation for such things as lost wages, disability or discomfort due to injury is not available. But, you **DO NOT** waive your legal rights by signing this form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected.

The study doctor may need to take you off the study early without your permission if:

- The study is cancelled by the U.S. Food and Drug Administration (FDA), Health Canada, or the site's Institutional Review Board (IRB).
- The sponsor stops the study.
- You are not able to attend the study visits as required by the study**.**
- You become pregnant or begin breastfeeding.
- Continuing the study vaccinations may be harmful to you.
- You need a treatment that you may not take while on the study.
- You are not able to take the study vaccinations as required by the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal identifying and health information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal identifying and health information may also be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The personal health information that will be collected from you includes:

- Information that is created or collected from you while you are in the study, including test results and any procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

If you test positive for HIV, hepatitis B or C, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born. The purpose of reporting a positive HIV result is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV.

Your research records may be reviewed by employees from GeneOne, an agent, contractor or representative working on their behalf, representatives from the Food and Drug Administration or other governmental regulatory agencies, and the Institutional Review Board (IRB) at the University of Pennsylvania. Your research records remain part of this clinical study even if you withdraw from the clinical study.

The electrical output, in other words information on the current, voltage and resistance during each electroporation of the CELLECTRA® device, will be reported to Inovio Pharmaceuticals who makes the CELLECTRA® to ensure that the device works properly. Additionally, data from the study will be discussed with the scientists involved with this study at the University of Pennsylvania and Université Laval as well as Inovio Pharmaceuticals; however, such data will NOT have any personally identifying information to be able to link any information to a study participant. The Sponsor and its representatives will analyze and evaluate these results and information and may report them to the U.S. Food and Drug Administration (the FDA), other

Regulatory Agencies in the U.S. or similar agencies in foreign countries. Your study records will be assigned a code number by the study team and your name, social security number, and medical record number will not be used in the study records that are sent to the Sponsor and its representatives. However, the Sponsor and its representatives will have the right to see your complete study records, including your name, and might choose to do so. Records linking the study ID code with any personal identification information will be kept in a locked file.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Social security number.
- Medical record number.
- Any other unique identifying number (such as study ID number linked with your medical records in a separate research file).
- Personal medical history, including participation in research (past, present, and future).
- Current and past medications or therapies.
- Information from a physical examination.
- Results of tests and procedures you will undergo during this research study as described in the informed consent form.
- Basic information about you, such as your name, dates, address, email address, and telephone number may also be disclosed.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team.
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of the School of Medicine, might receive my information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- The sponsor of the study, GeneOneLife Science Inc., and its agents and representatives
- Labs performing analyses for the study
- All research centers participating in the study

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections
- Health Canada

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by the 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.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. 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 investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and that you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of the study.

Financial Disclosures

The doctor in charge of this study at this site is Dr. Pablo Tebas. The vaccine was developed by Dr. David Weiner, a researcher at the Wistar Institute. This study is sponsored by the pharmaceutical company named GeneOne Life Sciences Inc. The study was designed by

GeneOne in collaboration with researchers at Université Laval, University of Manitoba, and Dr. Pablo Tebas from University of Pennsylvania who is the Principal Investigator overseeing the entire study. Funding for this research study comes from GeneOne.

The treatment was licensed to Inovio Pharmaceuticals, Inc which sub-licensed the treatment to GeneOne Life Sciences. If the research shows the new treatment is safe and effective, UPENN would receive a part of the profits from any sales of this treatment.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

STORAGE OF SAMPLES FOR FUTURE USE (OPTIONAL)

As part of this clinical trial, your blood will be used for other studies to determine the best way to diagnose Zika virus infection. If additionally studies of the immunity generated against Zika virus are considered useful, the researchers would like to be able to use blood and serum that are left over from the blood draws during the study. Blood will be stored at Quest Diagnostics Research Division with all samples identified by a code but without any identifying information. Identifying information is stored separately by the study team but only has the Participant Identification Number. All Protected Information is stored at the University of Pennsylvania by the study team. Samples will be stored for up to 5 years for additional studies and destroyed at that time.

If at any time you change your mind about study participation or the storage of blood samples for future use, blood already collected and stored will be kept by the study team. If, however, you desire that any stored blood be destroyed and not kept, then please notify the study staff so that your blood can be removed from the storage facility.

Please indicate below whether you approve the use of your leftover blood.

_____ YES _____ NO _____ Initials