HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

TITLE:	Zika virus sero-prevalence and assessment of the Dual Path Platform® Zika IgM assay to detect incident Zika virus infection, ARBO-004 substudy of ZIKA-002, Version 1.0, 25 July 2018
SPONSOR:	GeneOne Life Science, Inc.
SITE PI:	Pablo Tebas, MD
Clinic Location:	Perelman Center for Advanced Medicine 3400 Civic Center Blvd Philadelphia
STUDY-RELATED PHONE NUMBER(S):	214 349-8092 (during business hours) 215 662-6059 (outside of business hours)

Introduction:

You are being invited to participate in a research study to study the immune reactions that occur after natural infection with Zika virus and how many have been infected with Zika in a region.

The doctor in charge of this study at this site is Dr. Pablo Tebas. Before you decide if you want to be a part of this study, we want you to know about the study. This study is sponsored by the pharmaceutical company named GeneOne Life Science Inc. Funding for this research study comes from Chembio, Inc., the maker of one of the tests for Zika being used in this study, and Biomedical Advanced Research and Development Authority **(**BARDA**).**

As part of this study, you will be asked to donate a small quantity of blood and urine and to answer some questions including questions about prior infection with Zika and other similar viruses. The blood will be tested for antibodies to Zika virus and other viruses that are also transmitted by mosquitoes and the blood and urine may also be tested for presence of Zika virus RNA (to see if the virus is actually present). The primary use of the samples is to assist in developing a test to diagnose recent Zika virus infection. The blood collected may also be used to help to understand immune reactions to the Zika virus and to assist in future studies of Zika virus.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Please note that your participation in this study is entirely voluntary. If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

Why Is This Study Being Done?

Zika virus infection is currently widespread in Puerto Rico, throughout the Caribbean, and throughout Central and South America. Cases of Zika virus infection have also been documented in Florida. This study is being conducted to better understand the immune reactions of those who have been diagnosed with Zika virus infection either recently or in the past. The results of this study will also help studies of Zika virus vaccines.

What Do You Have To Do If You Are In This Study?

Procedures:

The exact schedule and procedures are as follows:

Screening and Enrollment Visit: If you agree to participate in this study, you will be asked questions to determine if you are eligible and then to read through and sign this consent form after all of your questions are answered. Once enrolled, you will complete a short questionnaire with the study staff and then to donate a small quantity of blood and a small amount of urine:

Demographic and flavivirus infection questionnaire: All study participants will answer questions about demographics such as age, gender, and race and whether you have ever been diagnosed with Zika, Dengue, West Nile, or Yellow Fever virus infection or whether you have ever received a vaccine against one of these viruses.

Viral and Arboviral symptom questionnaire: All study participants will answer questions about symptoms that may have occurred over the past 4 weeks that some individuals may experience with viral infections or arboviral infections such as Zika, Dengue, or Chikungunya.

Travel history: All study participants will be asked about travel to countries other than where you live, specifically to areas where Zika, Dengue, or Chikungunya may be found.

Collect blood and urine: A fingerstick will be performed for a small drop of blood. Additionally, blood will be collected by venipuncture for Zika, Dengue, and Chikunguna virus testing. A total of 50 ml of blood (approximately 3.5 tablespoons) will be collected. You will also be asked to provide a small amount of urine into a cup for Zika virus testing.

Results: No results will be given to you as part of this study.

Other: As part of this study, some of your blood that is left over after all required study testing is done will be stored (with usual protections of your identity) and used for future Arbovirus research that is separate from this study. Genetic testing will not be done on these blood samples. These samples may be stored for an indefinite period. Results of testing performed on these samples will not be given to you. You may withdraw your consent for research on stored specimens at any time and they will be destroyed. It is possible, however, that samples from the repository may have been distributed to a testing lab and the specimens cannot be discarded.

How Many People Will Take Part in This Study?

Overall, 500 persons will take part in this study. At the University of Pennsylvania, about 100 persons will be enrolled in the control group, ie. an area where Zika virus is not commonly found.

How Long Will You Be in This Study?

You will be seen only once for this study.

What Are the Risks Of The Study?

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

Are There Risks Related To Pregnancy?

There is no known risk to you should you be pregnant except related to blood draw of approximately 50 mL of blood (approximately 3.5 tablespoons). There are no known risks to your fetus from having a blood draw of this volume.

Are There Benefits to Taking Part in This 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 in the future.

What Other Choices Do I Have Besides This Study?

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

- Not participating

Privacy and Confidentiality

Except for the Informed Consent, you will be identified on study documents by a unique code (Participant Identification Number). The study site will maintain a record to be able to connect your Identification Number to your name, but this will not be provided to the study sponsor or any others outside of your study site. This information will be kept confidential and secure.

Your personal health information will be kept as confidential as possible under the law and safeguarded as per the United States Health Insurance Portability and Accountability Act (HIPAA).

Results of questionnaires and results of tests of samples collected will be entered into an Electronic Data Capture (EDC) system. No personal information will be entered into the EDC.

The sponsor may also wish to use your information and the blood and urine samples taken during this study for future research on the prevention, treatment or diagnosis of Zika. The sponsor will take all reasonable steps to ensure that in any future research, your privacy will be protected.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The study will be reviewed by local Institutional Review Boards (IRB) who perform independent review of research as required by regulations.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

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:

- Name, address, telephone number, email address, social security number, medical record number, dates directly related to you such as date of birth and clinic visits.
- Information from questionnaires administered in the study.
- Results of blood tests from this study

Why is my information being used?

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

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

Who may use and share information about me?

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need access to 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.)
- Authorized members at the University of Pennsylvania, School of Medicine who coordinate this study and support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

Who, outside 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:

<u>Individuals or organizations responsible for administering the study:</u>

- GeneOne Life Science Inc., the study sponsor.
- ChemBio, study sponsor collaborator

<u>Regulatory and safety oversight organizations</u>

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

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

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 must do so in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary 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. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

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.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

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.

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 Are the Costs To You?
There is no cost to you to participate in this study.

Will You Receive Any Payment?
To compensate you for your time, transportation or other expenses you may incur as a participant you will receive $50 dollars participation to include the completion of the questionnaire and donation of blood. Compensation will be paid via Clincard (a secure, reloadable debit card).

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide a Individual Tax Identification number or Social Security Number for tax purposes.

What Are My Rights as a Research Participant?

Taking part in this study is completely voluntary. You may choose not to take part in this study. There will be no penalty to you if you decide not to participate. Your healthcare provider will treat you the same no matter what you decide.

What Do You Do If You Have Questions Or Problems?

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

CONSENT

When you sign this form, you are agreeing to take part in this research study, which includes storage of leftover blood for future research. This means that you have read the consent form or it has been read to you, your questions have been answered, and you have decided to volunteer. You understand you rights as a research volunteer and freely consent to participate in this research study. You authorize the use and disclosure of your health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form, you has not given up any of your legal rights

A copy of this consent form will be given to you and copy kept with your study information.

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