Appendix 6. Consent to Take Part in a Research Study

For non-emancipated minors age 14-20 y, assent and parental permission may be documented on the same form, or separate forms may be used.

1. Title of Research: Communities Organized to Prevent Arboviruses: Assessment of Knowledge, Attitudes, and Vector Control Practices and Sero-Prevalence and Incidence of Arboviral Infection in Ponce, Puerto Rico

1. **Purpose of Research**: Ponce Health Sciences University/Ponce Research Institute, in collaboration with the Centers for Disease Control and Prevention, CDC, is doing a research study about diseases transmitted by mosquitoes. These diseases include dengue, Zika and chikungunya. The purpose of this study is to understand how you and people in the community protect yourselves from mosquitoes. This will help us learn how to better prevent the diseases caused by mosquitoes.

2. **Procedures and Duration:**
   a. We would like you to take part in this study. If you agree, we will ask you some questions about your practices to protect yourself from mosquitoes. We will also invite all members of your household age 1 year and older, including you, to answer a survey about your thoughts and practices to avoid getting sick from mosquitoes and illnesses in the last year. We will ask you to answer the questionnaire for children under 7 years old. Each household member would be free to agree to take part or not, or to stop at any time. The household may still take part in the study, even if some members choose not to take part.

   b. We would like to collect a small amount of blood (about 1 tablespoon) from each household member that agrees to take part in the study. Blood will be collected through a vein in the arm, using a small needle. This may cause minor pain or bruising. Each household member will be tested to see if he/she has been infected with the virus that causes Zika, dengue and chikungunya. We will send individual test results in about 3–6 months. If any blood is left over after we finish this testing, we would like to store what is left for future testing related to infectious diseases. We will not perform human genetic testing or HIV testing. We will send the results of any future tests that may be important for that person's health. We would like to collect your mailing address to send your test results, as well as your phone number and/or email address so that we may contact you for annual follow up or future studies. If you permit us, we will take a low-resolution photo of your house from the street so that we can more easily identify your household in follow up.

   c. Study staff will contact you once per week (by phone call, text message, phone app, or in person) to ask you if any household member participating in the study has had fever in the past 7 days. If the answer is yes, study staff will schedule a visit to make some questions related with the fever, and to take blood samples to test for dengue, zika, and chikungunya. You can decide not to participate in this section of the study and still can participate in the other sections.

3. **Risks and Discomforts:** The procedures (questionnaires and blood draw) are part of the procedures performed routinely during your visit to the clinic or reference laboratory. We do not expect major changes or discomforts to be associated with this study.

   Blood collection: Blood samples for analysis will be taken using a needle the same way blood is collected in a clinical laboratory. While the blood is being drawn you may feel dizzy, experience redness and swelling of the vein, pain, bruising or bleeding from the site of the needle puncture. Very few people also get an infection. Trained personnel will be in charge of this procedure to minimize your discomfort.

4. **Benefits:** This study will provide information about the epidemiology of DENV, CHIKV or ZIKV infection and the burden of diseases transmitted by mosquitoes (arboviruses) in Southern Puerto Rico. Results of this study may be used to design future vector control efforts or vaccine efficacy trials in Puerto Rico. Development of an intervention to prevent arboviruses would benefit not only citizens of Puerto Rico, but residents of and travelers to the tropics. There may be benefit to society if knowledge gained by participating in this study leads to increased awareness of arboviral disease by study participants, their families, and health-care providers. Increased knowledge may result in better vector control in the community, more timely diagnosis, and/or better treatment of cases, resulting in better health outcomes.

5. **Reasons for Removal from Study:** Study participants may withdraw from the study at any time. It is highly unlikely that the investigator will have to remove any participants from the study because of safety concerns. We expect to repeat this study periodically over the next several years. We may invite you to take part one or more times in the future. However, if you do not want us to invite you to take part in this study again, please let us know, and we will remove you from our list.

6. **Voluntary Participation:** Participation in this study is voluntary, and you can refuse to be in the study,stop at any time, or decline to answer a particular questions. You may decline some parts of the study and still take part in others. Participantsare free to refuse storage of samples for future testing. Those who do not want their blood stored may still take part in the rest of the study. Those who agree to storage of the remaining sample may contact the study investigator at the number listed below if they change their minds and want to withdraw their consent for storage.

7. **Responsibility for Cost:** The tests that will be done for the study are free of charge. You do not have to pay for the tests. However, your participation does not include additional testing or treatment for problems that might be identified as part of the study. Participation in the study also does not include treatment for any complication or illness that might occur during this study. In case they occur, you will be referred to medical services that will be offered at the usual charge.

8. **Confidentiality:** All data obtained in this study will be kept confidential to the extent allowed by law. In any publication or presentation of research results your identity will be kept confidential but there is a possibility that records which identify you may be inspected by authorized individuals such as representatives of the Food and Drug Administration, CDC and Ponce Medical School Foundation, Inc. or employees conducting peer review activities. I consent to such inspections and to the copying of excerpts from my records, if required by any of these representatives. If you have records from other studies or surveillance conducted by the investigating organizations, these may be linked to data from this study.

9. **Other Considerations:** We will give you a copy of this consent for you to keep. If you have questions, doubts or believe that you were harmed by being in this study, you can contact Dr. Vanessa Rivera-Amill at (787) 840-2575 Ext 2158. If you have questions regarding your rights as a participant in this study, you should contact Dr. Simón Carlo, Chairman, Institutional Review Board of the Ponce Medical School Foundation, Inc. at (787) 840-2575 Ext 2158.

Please take a moment to decide. Feel free to ask as many questions as you need. When you have decided, please check the boxes below to indicate your choice

FOR HOUSEHOLD REPRESENTATIVE ONLY: Permission for household participation

I agree for my household to join this study. This includes answering a brief survey (~15 minutes) about household practices, permission to invite all household members, including myself, to take part in individual surveys and give a small sample of blood.

- ☐ **Yes**, I agree to participate.
- ☐ **NO**, I do not agree to participate.
- ☐ Please exclude my household from future rounds of this study.

I authorize to take a picture of my house.

- ☐ **Yes**
- ☐ **NO**

I authorize to be contacted weekly to monitor cases of fever in the household.

- ☐ **Yes**
- ☐ **NO**

FOR ALL ADULTS AND EMANCIPATED MINORS- Individual consent

I give consent to take part in this study. I have been given the opportunity to ask questions, and all of my questions have been answered. I have been told that my participation includes answering a brief survey and giving a small sample of blood.

- ☐ **Yes**
- ☐ **NO**

Consent for storage of specimens

I give permission for study investigators to store my leftover samples for future research related to infectious diseases. If I am the parent or guardian of any child in this household ≥5 years of age, my permission to store or not store my child's/children's leftover specimens is indicated in the next section.

- ☐ **Yes**
- ☐ **NO**

Consent to be contacted for annual follow up of this study and for other future studies

I give permission for study investigators to contact me in the future for annual follow up of this study and for other future studies.

- ☐ **Yes**
- ☐ **NO**

Permission to include children aged 1–20 years

I am the parent or legal guardian of the children listed below. I give permission for the following children to take part in the survey and/or blood draw, and for leftover samples to be stored for future testing related to infectious diseases, as indicated below.

Child's Name	Survey and blood draw	Storage of leftover samples
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No

ASSENT FOR NON-EMANCIPATED MINORS 14-20

Please remember:

- You do not have to be in this study if you do not want to. You won't get into any trouble with *anyone* if you say no.
- You may stop being in the study at any time. *(If there is a question you don't want to answer, that is OK)*
- Your parent(s)/guardian(s) were asked if it is OK for you to be in this study. Even if they say it's OK, it is still your choice whether or not to take part.

FOR NON-EMANCIPATED MINORS 14-20 – Assent

I give assent to take part in this study. I have been given the opportunity to ask questions, and all of my questions have been answered. I have been told that my participation includes answering a brief survey and giving a small sample of blood.

☐ **Yes**
☐ **NO**

Consent for storage of specimens

I give permission for study investigators to store my leftover samples for future research related to infectious diseases.

☐ **Yes**
☐ **NO**

Signatures

My signature below indicates that I give consent/assent/permission for the activities indicated above. I have had the chance to ask questions, and all of my questions have been answered. My consent is given freely.

ADULTS, EMANCIPATED MINORS, AND ADULTS SIGNING FOR MINORS

Name (printed): _____

Signature: _____ Date: _____

NON-EMANCIPATED MINORS

Name (printed): _____

Signature: _____ Date: _____

Parent or Legal Guardian Signature: _____ Date: _____

_____

Investigator or Individual obtaining this consent
Date: _____

(Flesch-Kincaid grade level – English: 7.7)

Consent Summary for Communities Organized to Prevent Arboviruses

- Ponce Health Sciences University in collaboration with the Centers for Disease Control and Prevention is conducting a research study about disease transmitted by mosquitoes, including dengue, Zika, and chikungunya. The purpose of the study is to understand how you and others in the community protect yourselves from mosquitoes and we are inviting you to take part.

- The results of this study can help you and your community as it can improve the understanding of different ways to control mosquitoes and learn how to better prevent diseases transmitted by mosquitos in Puerto Rico and possibly other places.

- It is your decision to take part or not in this study. Feel free to ask any questions. You can stop at any time or refuse to answer any questions.

- The study consists of completing a survey about household characteristics, basic demographic information, medical history, and mosquito control methods. Also, our certified phlebotomist will take a small blood sample of two tubes from you.

- The blood sample will be tested for dengue, Zika, and chikungunya and we would like to store any remaining sample for future testing related to infectious diseases. But we will never do genetic or HIV testing with this sample.

- In the coming months we would like to contact you weekly to see if any household member participating in the study has had fever during the previous week. If someone has had a fever in the past week, study staff will schedule a visit to complete a short survey and collect additional blood samples to see if the illness is related to dengue, Zika, o chikungunya. You can opt out of this part of this study if you want to.

- The risks of this study are no greater than when a nurse draws your blood at a laboratory or doctor's office, and you could experience some minor pain or bruising at the site of the needle stick.

- This study is completely confidential. We maintain your information on a secured computer and server that only study staff has access to.

- Your blood will be tested for dengue, Zika, and chikungunya at no cost to you and you will receive the results in 3–6 months.

- Do you have any questions about the study at this time?