Appendix E:

**Consent Form / Assent Form:**

**Puerto Rico Guillain-Barré Syndrome Cluster Case Control Investigation, Second Collection of Specimen**

**(To be administered to adults, minors aged 13–20 years, and the parents of children aged 8–12 years)**

*Flesch-Kincaid Grade Level: 7.7*

Hello. My name is \_\_\_\_\_\_\_\_\_\_\_\_, and I am working with the Puerto Rico Ministry of Health, the U.S. Centers for Disease Control and Prevention, and the Puerto Rico Clinical and Translational Research Consortium. I’m talking with you because roughly one month ago you agreed to participate in an investigation of a disease called Guillain-Barré Syndrome, or GBS. This disease causes weakness of the arms and legs. It also sometimes causes weakness of the muscles used for breathing. We are trying to find out what is causing this disease in Puerto Rico so we can try to prevent other people from getting sick.

Because the diagnostics for infection with dengue virus and Zika virus are quite complicated, we would like to take a second blood sample to compare with the first sample you already provided. The second sample will help us say more confidently if you have been infected with either of these viruses. If any of your sample is left over, we would like to store it for further studying on infectious disease or GBS. Providing the second blood sample is completely voluntary, and you can stop at any time you want.

COMPENSATION IN CASE OF INJURY

In the case of physical or mental injury as a result of this investigation, you will receive medical care free of cost at Hospital Universitario/Hospital Pediátrico, or whichever other hospital that is designated by the Rector del Recinto de Ciencias Médicas of the University of Puerto Rico. The University of Puerto Rico will not offer any other form of compensation nor other form of direct compensation or renumeration. However, by signing this consent form you will not renounce any legal right that you could have.

Do you have any questions?

* I agree to answer questions and have my or my child’s blood drawn.
* I agree to allow my or my child’s blood or other body samples to be stored for additional testing.
* I agree to allow the records from any medical visits and remaining clinical specimens due to illness experienced in the two months before \_\_\_\_\_\_\_\_\_\_\_\_ to be reviewed and collected, respectively.
* I agree to be contacted in the future.

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness

Printed Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***ASSENT FOR CHILDREN AGED 8–12 YEARS***

We are working with the Puerto Rico Department of Health to investigate cases of neurologic illness on the island of Puerto Rico. Neurologic illness means an illness that affects the brain or the nerves. We are trying to find out why these cases are happening here in Puerto Rico. To do that, in addition to the specimen we previously collected, we would like to take another a small sample of blood. This would mean that we would put a small needle in your arm and take some of your blood. It might pinch a little at first, but should not be too painful. This is to test for things that might cause such neurologic illness. Your parent/guardian has said that it is ok for you to answer these questions and give some blood. Would that be ok with you?

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness

Printed Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_