



Consent/Parental Permission Form:
Puerto Rico Severe Neurologic Illness Case-Control Investigation
(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 Department of Health, the U.S. Centers for Disease Control and Prevention, and Puerto Rico Clinical and Translational Research Consortium. I'm talking with you because people have been getting sick with a severe neurologic diseases, including one 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. Some countries have recently reported that some patients of GBS and other severe neurologic illnesses may have been infected with Zika virus. We are investigating severe neurologic illnesses, including GBS, in Puerto Rico to find out what is causing it, including if it is associated with Zika virus. If we know why, we might be able to prevent other people from getting sick.

We are conducting an investigation about why some people get sick. By conducting interviews with those that got sick and those that are healthy, we can use this information to compare the differences and evaluate what is causing the illness.

We would like to ask you some questions. The questions will take about 30 minutes to answer. We will ask you about your food, water, activities, and travel during a given period of time. We would also like to take a blood sample, which will be used to test for infections with Zika virus, dengue virus, and chikungunya virus. Once all diagnostic testing has been performed, all diagnostic test results will be given to you by telephone or mail, as you prefer. If any of your sample is left over, we would like to store it for future studies on severe neurologic illnesses, including GBS.

All the information you give us will be confidential, and only the investigators working on the investigation will be able to see it. There is a slight risk though that non-investigation personnel could see your information, but we will work hard to protect your privacy. Reports of the investigation will be summaries, and no information will be shared with others that can identify you personally. Answering the questions is completely voluntary, and you can stop answering any time you want, or you can decide not to answer any particular question. The same applies to the blood samples.

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 remuneration. 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 try 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, we would like to ask you some questions about things that you were doing or were exposed to over the past few weeks. We would also like to take a small sample of blood. This would mean that a trained professional will 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



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PUERTO RICO
Departamento de Salud



Printed Name _____ Signature _____



Appendix C:

Consent Form / Assent Form:
Puerto Rico Severe Neurologic Illness 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 severe neurologic illnesses, including one 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 severe neurologic illnesses, including 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 remuneration. 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 _____