APPENDIX 5 B: ASSENT AGE 12-17 YEARS
Investigational New Drug (IND) BB 11184 IRB # 4167
Protocol #4167 BB IND 11184

ASSENT FOR ADDITIONAL BLOOD DRAWS WITH THE USE OF DIPHTHERIA ANTITOXIN (DAT) FOR SUSPECTED DIPHTHERIA CASES AGED 12-17 YEARS OLD

Flesch-Kincaid: 6.5

BACKGROUND

Your doctor suspects that you have a disease known as diphtheria. The disease is treated with a drug known as diphtheria antitoxin (DAT). Your doctor decided that you need this medicine for your treatment. This medicine is being given to you by The Centers for Disease Control and Prevention (CDC) and your State Health Department. You have already agreed to get this treatment and your parents have given permission. This medicine that you will get is made from horse blood. There is a risk for an allergic reaction to horse blood after receiving it.

Scientists are working to make the medicine from human blood instead of horse blood. If they can make this medicine from humans, then there will be no need to make it from horse blood in the future. We want to test your blood before and after you receive DAT to see how much medicine is in your blood. This will help scientists to decide the best dose for the medicine that is made from humans. This information is not available now. We would like your agreement to collect blood samples to measure the drug. It is up to you to decide to take part in this research part of the treatment. Whatever you decide will not affect your getting DAT for treatment.

WHAT IS THE PURPOSE OF THE BLOOD DRAWS?

DAT is being given to you because your doctor suspects you have diphtheria. Measuring antibodies in your blood before and after DAT treatment will tell us how much antitoxin is in your blood and how long it remains in your body. A blood sample (1 teaspoonful or 5 mL each time) will be taken before the DAT treatment is given; one hour after treatment is completed; then on days 1, 3 and 7 after treatment. A final blood sample (1 teaspoon) will be collected on day 28 or the day of discharge from the hospital whichever is earlier. The total amount of blood collected will be 2 tablespoons (or 30mL) in 6 blood samples. These samples will be sent to CDC with some information about you. The information includes your name, initials, age, sex, weight, dose, date and time of day when DAT was given.

ARE THERE ANY BENEFITS FROM THE BLOOD DRAWS?

There is no gain to you from the blood draws. Taking part in the blood draws will help to find the best dose of human antitoxin to treat diphtheria in the future.

ARE THERE ANY RISKS WITH BLOOD DRAWS?

Drawing blood may hurt a little. Redness, bruising, swelling, bleeding, and discomfort, or rarely, infection can occur where the needle enters your vein. Staff will try to draw blood for this purpose at the time you are having blood drawn for another reason due to your illness.

IS THIS PROTOCOL VOLUNTARY?

It is your choice to have your blood drawn for this research purpose. You may refuse at any time and not lose your right to other health care or services. You are not giving up any of your legal rights by signing this form. We will give you a copy of this form.

WHAT ARE THE COSTS?
There is no cost for supplies for blood draws, blood sample storage, or sending blood samples to CDC. CDC does not pay for medical care. Your parents (or your parent's health insurer, Medicare, or Medicaid) will have to pay for any other care that is needed.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS PROTOCOL?
You may choose not to have your blood drawn. This does not affect your receiving DAT.

WHAT HAPPENS IF I AM HARMED?
If you are is harmed because of the blood draws, medical care is available. But, the treatment will not be provided by CDC. Therefore, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this form, you will not give up any of your rights.

ASSENT STATEMENT
I have read and understood the above information or had it read to me, and have had all my questions answered. I agree to let the local/state health department, CDC, and the FDA see my medical records. I agree to blood collection from me before and after DAT treatment.

_____ _____
Signature of patient: Date:

_____
Type/Print name of patient: