

APPENDIX 5A: INFORMED CONSENT Protocol #4167 BB IND 11184

INFORMED CONSENT/PARENTAL PERMISSION FORM FOR ADDITIONAL BLOOD DRAWS WITH THE USE OF DIPHTHERIA ANTITOXIN (DAT) FOR SUSPECTED DIPHTHERIA CASES

Investigational New Drug (IND) BB 11184 IRB # 4167

Flesch-Kincaid: 7.8

INFORMED CONSENT

Your doctor suspects that you/your child have diphtheria. Your doctor has decided that you need diphtheria antitoxin (DAT) to treat you/your child. You have signed an informed consent agreeing to this treatment and DAT is being provided to you/your child by The Centers for Disease Control and Prevention (CDC) and your State Health Department. Diphtheria antitoxin (DAT) is obtained from horse serum and there is a risk for an allergic reaction to horse proteins. A laboratory in the United States, called MassBiologics of the University of Massachusetts Medical School, is working to develop a human antitoxin to treat diphtheria so that a horse product does not have to be used. In order to determine the best dose of a human antitoxin to use to treat diphtheria, it would be helpful to know the amount of diphtheria antitoxin antibodies in the blood of persons treated with DAT and this information is currently not available. The purpose of this consent form is to get permission to collect blood samples to measure diphtheria antitoxin antibodies. Participation in this research component of DAT treatment is completely up to you and does not affect your ability to get DAT for you/your child.

WHAT IS THE PURPOSE OF THE BLOOD DRAWS?

DAT is being given to you/your child because your doctor suspects you/your child have diphtheria. Measuring antibodies in you/your child's blood before and after DAT treatment will tell us how much antitoxin is in you/your child's blood and how long it remains in your/your child's body. A blood sample (5 mL or about 1 teaspoon each time) will be taken before the DAT treatment is given, one hour after DAT 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 (about 30 mL) in 6 blood samples. These samples will be sent to the CDC and antibodies to diphtheria will be measured by the CDC and/or MassBiologics. The information about you/your child that will be sent along with the blood samples is you/your child's initials, age, whether you/your child is a male or female, weight, dose of DAT and date and time of day DAT was given.

ARE THERE ANY BENEFITS FROM THE BLOOD DRAWS?

There is no benefit to you/your child from the blood draws. You/your child's participation in the blood draws will help to determine what dose of a human diphtheria antitoxin being developed could be given to people in the future to treat diphtheria.

ARE THERE ANY RISKS WITH BLOOD DRAWS?

The risks involved in drawing blood from a vein may include, but are not limited to, momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of lightheadedness when the blood is drawn, and rarely, an infection at the site of the blood draw. Every attempt will be made to draw the blood sample for this purpose at the time you/your child are having blood drawn for another reason due to your/your child's illness, but this

can't be guaranteed.

WHAT ABOUT PRIVACY?

The medical records with this protocol are subject to the terms of the Privacy Act of 1974, 5 U.S.C. Section 552a. People who work for the local health department, the CDC, and the FDA may read your/your child's medical records. They may obtain personally identifying information from these records. MassBiologics will not have access to personal information that can identify you. All data we gather about you/your child will be kept private to the extent allowed by law. You/your child will not be named when we present the results.

IS THIS PROTOCOL VOLUNTARY?

It is your/your child's choice to have your blood drawn for this research purpose. You/your child may refuse at any time. If so, you/your child will not lose the right to other health care or services that you/your child might be due apart from this. You/your child 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?

Supplies for blood drawing, blood sample storage and shipment of blood samples to the CDC will be provided to your doctor and to you/your child at no cost. CDC does not pay for medical care. You (or your health insurer, Medicare, or Medicaid) will have to pay for any other care that is needed.

WHAT OTHER CHOICES DO YOU/YOUR CHILD HAVE BESIDES THIS PROTOCOL?

You/your child may choose not to have your blood drawn. This does not affect you/your child receiving DAT.

WHAT HAPPENS IF I OR MY CHILD IS HARMED?

If you are or your child is harmed because of the blood draws, medical care is available, but the treatment will not be provided by CDC. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this consent form, you are not giving up any of your or your child's rights.

WHO DO YOU CALL WITH PROBLEMS OR QUESTIONS?

You can ask your treating physician any question you have about these extra blood draws. If you/your child have questions about these blood draws or the DAT treatment or if you feel that you or your child have been harmed as a result of participation, please call Dr. Tejpratap Tiwari at (404) 639-8765 in the Meningitis and Vaccine Preventable Diseases Branch, National Center for Immunization and Respiratory Diseases, CDC. If you have questions about your rights as a participant in this research, please call **CDC's Human Research Protection Office** at 1-800-584-8814 and say you are calling about CDC Protocol # 4167. Leave a brief message with your name, area code, and phone number. Someone will call you back as soon as possible.

CONSENT 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 child's medical records.

I agree to blood collection from me/my child before and after DAT treatment.

Signature of patient or guardian:

Date:

Type/Print name of patient: