

APPENDIX 8C: ASSENT AGE 7 –11 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 7–11 YEARS OLD

Flesch-Kincaid: 3.9

BACKGROUND

Your doctor thinks that your sore throat is caused by diphtheria. The medicine you are being offered may make you feel better. But, this medicine is made from horse blood and can make you feel sick after you take it. Scientists want to make a better medicine so in the future there will be no need to get it from horse blood. We want to test your blood before and after you get your treatment. This will help find the best dose for the new medicine. We want your permission to get a little blood from you for research. It is ok if you don't want to give any. You will still get your medicine if you say no.

WHAT IS THE PURPOSE OF THE BLOOD DRAWS?

Your doctor thinks you have a bad sore throat (diphtheria) and you are getting a special medicine. We want to test your blood before and after you get the medicine. We will find out how much medicine is in your blood and how long it stays in your body. Your doctor will send the blood to the Centers for Disease Control and Prevention with the first letters of your name, age, if you are boy or girl, how much you weigh, how much medicine you got, and when you got the medicine.

ARE THERE ANY BENEFITS FROM THE BLOOD DRAWS?

If you give a little blood, you will not get any reward. Your blood will be used to help find out how much of the new medicine people must take.

ARE THERE ANY RISKS WITH BLOOD DRAWS?

Drawing blood may hurt a little. Your skin may get a little red, or bruise, or get swollen and hurt a little.

IS THIS PROTOCOL VOLUNTARY?

It is your choice if you want to give blood or not. You can say no anytime. If you say no, it is still fine.

WHAT ARE THE COSTS?

Your parents will not have to pay anything. Everything for taking blood will be given to your doctor.

WHAT OTHER CHOICES DO YOU HAVE BESIDES THIS PROTOCOL?

If you do not want to give a little blood that is fine. You will still get the medicine to treat your sickness.

ASSENT STATEMENT

I have read the above information; or I had it read to me. I had all my questions answered. I agree to blood collection from me before and after getting treatment.

Signature of patient:

Date:

Type/Print name of patient: