

INFORMED CONSENT (General UDC)

Data Collection On Complications of Hemophilia and Serum Testing and Storage

DESCRIPTION AND EXPLANATION OF PROCEDURE

The hemophilia treatment center where you or your child receives care is working with the Centers for Disease Control and Prevention (CDC) to monitor the health status of people with hemophilia and other bleeding disorders. This research project is expected to last for multiple years.

For participants less than 2 years old

Participation in this study consists of answering questions at the time of your child's visit to the HTC. You will also be asked to sign a form to release medical records of your child's birth as well as your medical records from 6 months prior to conception to a month after delivery. The purpose is to determine if events during pregnancy, the type of delivery and/or being a carrier mother poses a risk for bleeding in the baby. Your HTC will obtain data for the CDC from the medical histories, medical treatments of you and your child, as well as maternal reproductive history. *No measurements of joint motion and no blood testing will be done on your child as part of this study.*

For participants 2 years and older

Participation in this study includes collecting some information about health status from the medical record and, during the annual comprehensive exam, measuring how well your/your child's joints work and asking some questions about how the complications of hemophilia and other bleeding disorders affect activities of living, such as working or going to school. In addition, participants ≥ 14 years old will be asked 15 questions about their general health and well-being. The information from this project will be used to help your/your child's center plan your/your child's medical care and help the CDC develop and evaluate programs to reduce or prevent the complications of hemophilia.

The CDC is also providing free annual testing to determine exposure to blood-borne viruses. You or your child are/is asked to provide a blood specimen (10cc [about 2 teaspoonsful]). The blood will be tested to see whether you or your child have/has been exposed to hepatitis A, B, or C or human immunodeficiency viruses (the virus that causes AIDS). The results of these tests will be provided to your/your child's doctor. Before and after this testing your/your child's doctor will provide you with information about the meaning of these tests and how to reduce your/your child's risk of exposure to these viruses. The drawing of this blood can be done at the same time that blood is drawn for other tests that your/your child's doctor may wish to perform. Should your/your child's blood test be positive for hepatitis or human immunodeficiency virus, the CDC may contact your/your child's doctor to obtain more information from you/your child to determine how you/your child may have acquired the infection.

Because it is possible that at some time in the future we might discover other viruses or other diseases or conditions of particular importance to persons with hemophilia, CDC would like to perform the testing required for this project and save the remaining portion of your/your child's blood specimen for possible future testing. If the results of tests performed at a later date are important to your/your child's health or care, CDC will forward these results to your/your child's physician. Your/your child's doctor will provide these results to you, explain what they mean, and answer any questions you may have. The specimen will not be used for human genetic testing. As part of follow-up investigations, CDC may contact your/your child's doctor to seek your permission to obtain additional blood or other specimens.

CONFIDENTIALITY

You/your child will be assigned a study number that will identify your/your child's serum sample and questionnaire. Your/your child's name will not be sent to the CDC. Your/your child's test results and the information collected will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it is okay. But under the law, we must report suspected cases of child

abuse or if you tell us you are planning to cause serious harm to yourself or others.

RISKS AND DISCOMFORTS

There may be some discomfort to you/your child associated with the withdrawal of blood samples. Occasionally there may be soreness or bruising at the site and rarely an infection can occur. Although no injuries are expected, if you/your child were injured, neither CDC nor the medical center conducting the blood draw would provide payment for hospital or medical expenses, or financial compensation. However, the researchers involved in this study would arrange for appropriate management and treatment of any physical injury resulting from participation in this project.

It will take approximately 10 minutes to answer the questions about health-related matters. Depending upon test results, you may be asked some sensitive questions. You don't have to answer any questions if you don't want to and your choice to answer any questions or not will not influence your care.

BENEFITS

The potential benefit to you or your child is the knowledge of whether you or your child has been exposed to hepatitis or human immunodeficiency viruses. If you or your child tests positive for exposure to one or more of these viruses, you will be counseled by your doctor about the significance of this finding. The detection of infection by blood test is important because persons with these viruses may have few, if any, symptoms. Early detection of viral infection can help your/your child's doctor better plan your/your child's future care. Finding the source of the infection can help to prevent the virus from further spread to others. Patients who have a negative blood test for viruses will benefit by being reassured that they are not infected. All tests for viruses will be provided to you free of charge. You will be responsible for charges for usual medical care.

By permitting CDC to save what is left of your/your child's blood sample, you will be making an important contribution toward national efforts to monitor infection in the hemophilia community and to enhance the safety of blood products in the future. Your/your child's blood sample (along with those of others) will form a national serum bank that will allow the CDC to evaluate potential threats to blood product safety in the future as new diseases of clinical importance are discovered and tests become available. For example, the existence of such a resource in the early 1980s may have led to the earlier recognition of the transmissibility of HIV through blood products and may have resulted in decreased exposure in the hemophilia community.

If you do not wish to participate in the project you/your child will not have your/his data collected and you/your child will not be offered free annual testing for hepatitis viruses and HIV. However, these tests could be done by your doctor if you wish although you will be responsible for any charges for such testing.

CONSENT

I have been informed of the above-described procedure with its possible risks and benefits and all of my questions have been answered. I give permission for my/my child's participation in this project. I know that my/my child's doctor (*insert name and phone number*) will be available to answer any questions I may have. I can also contact Dr. Meredith Oakley or Dr. Rodney Presley in the Division of Blood Disorders of CDC at (404) 498-6750 for further information about this project. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form and it will not affect my/my child's care. If I have any questions about my/my child's rights as a subject in a research study, I may contact (*insert name and phone number*). Also, if I have questions about my/my child's rights as a participant in this research study or if I feel that I/my child have/has been harmed by taking part in this study, I may contact the CDC Human Research Protection Office at 1-800/584-8814. I will be asked to leave a brief message including my name, phone number, and that I am calling in reference to CDC protocol # 1671. Someone will return my call as soon as possible. I have been offered a copy of this form.

Participant's Name (please print)

Date _____

Signature of participant or parent/guardian

CDC Identification Number

Street Address

City, State and Zip Code

Phone Number

Witness to Signature

Should you wish to have your serum specimen returned to your doctor in the future, please obtain the code

number used on these specimens from your physician and then contact the Division of Blood Disorders of CDC by calling (404)498-6750.

ASSENT FORM FOR CHILDREN

Statement to be read to children in the presence of a witness:

Your doctor would like to collect some information about your health from your medical record and, during your physical exam, measure how well your joints work. Your doctor or nurse would also like to ask some questions about how hemophilia affects your every day activities, such as working or going to school. Your doctor or nurse would also like to take about 2 teaspoonsful of blood from a vein in your arm. Taking the blood might cause some soreness or a bruise on your arm. The blood will be used to test whether or not you have had contact with viruses. A virus is a germ like the kind that causes a cold. It is important to find out if you have had contact with a virus so that your doctor can take care of you in the best way possible. Any of the blood sample that is left over after the tests will be saved in case new tests need to be done in the future that will help your doctor take care of you. Your mother/father has said that it would be all right for you to take part in this project. If you do not want to be part of our study, you will continue to get the same care that you have been getting. Do you have any questions?

Can we take your blood now?

Date: _____

Child's name: _____

Signature: _____

Witness: _____

CDC Identification Number _____

Further questions about this project should be addressed to the Division of Blood Disorders at the CDC by calling (404)498-6750.