

AABB
Name of Blood Center

Abbreviated Donor History Questionnaire Study
Consent Form

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. *If you choose to take part, you will need to sign this form.*

Purpose of the Research

In 2000, AABB began developing the blood donor history questionnaire that you are using here today. AABB has also developed a shorter questionnaire called the abbreviated donor history questionnaire to be used by frequent donors like you. The Food and Drug Administration (FDA) has not yet accepted this shorter questionnaire and they are asking AABB to gather some information on how well it works in capturing the health information needed to protect the safety of blood donors and the blood recipients. The results of the study will be used to help FDA decide whether the abbreviated questionnaire should be accepted for donor screening .

Procedures

First, we would like you to fill out the abbreviated questionnaire. Once you are finished you will be asked to fill out the standard full-length questionnaire and a donor information sheet to help us understand how well the two questionnaires perform in collecting the information we need. Your responses to both questionnaires will be used to determine whether you are eligible to donate today.

In some cases an interviewer will ask you questions at the donation site or contact you by phone within 3 days to ask you to explain how you interpreted some of the questions, what you were thinking about while you were answering, and whether any questions were confusing. The interviewer will also ask you about your opinions of the questions. You may stop this follow-up interview at any time. You may also choose not to answer any question for any reason. You can just move on to the next question. The interview will be audiotaped for analysis at a later time, but only your study number will be used to identify you. No other identifying information will be used on the tape.

Possible discomforts and risks associated with the procedure(s):

There are no known risks associated with this study beyond what would normally be encountered in donating blood. All information you provide us is kept strictly confidential. Anything that identifies you personally will be seen or heard only by Blood Center employees. Any information you give us that we share with outside study personnel will be identified by a study number only. No personal identifiers will be released. Information will be stored in a locked room that only study personnel can enter. What you tell us will help us know more about

people's understanding of the questions on the abbreviated donor history form. We will not use this information for anything else. Your name and other personal facts will not be used when we discuss this study with outsiders or publish its results. We may include quotes from this study, but no names would be used.

Possible Benefits

This study may provide the data needed to have the FDA approve the abbreviated donor health questionnaire. As a frequent donor you would have a shorter, but equally effective questionnaire to complete when you come to donate blood.

I understand that I shall receive a copy of this consent. I am free to decide whether or not to participate in this study and am free to withdraw. Refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I have had the opportunity to ask questions concerning the procedures to be used. I understand that if I have any further questions concerning this project, I can contact Name at xxx-xxx-xxxx.

If I have concerns about my rights regarding the consent process or research participant rights I may contact, Name/Title at xxx-xxx-xxxx.

Please Read and Sign Below

I freely choose to take part in this research study. I will fill out the abbreviated donor questionnaire, the full-length questionnaire and donor demographic form. If contacted, I will answer questions related to my reasons for completing the two donor questionnaires as I did. I understand that if I decide to not complete the study process I still must complete the full-length donor history questionnaire in order to donate blood today.

Donor Participant (print name): _____

Donor Participant (signature): _____

Person administering consent (print name): _____

Person administering consent (signature): _____

Study ID number