

Abbreviated Donor History Questionnaire Study, 2005

AABB

Donor History Task Force

Collection Site Instructions

Introduction

This document, Collection Site Instructions, is the companion to the Study Manual. It provides the detailed instructions for implementation of the study in Collection Sites at XXXXXX Blood Center.

Materials (to be provided by the Study Administrator)

Donor Registration Sheets

DHQ/aDHQ Assessment Sheets

Collection Site Summary Sheets

Consent Forms

Demographic Questionnaires

Abbreviated Donor History Questionnaires (aDHQ)

Data Collection -(Note: Operational modifications will be made based on logistics of each Blood Center).

To be done when the donor arrives at the collection site

1. Assess the donor’s eligibility to participate in the study by reviewing the donor record.
2. Keep a running tally of the number of donors that you have assessed for eligibility to participate in the study, and the number that were eligible and the number that were not eligible and how many eligible donors refused or did not complete the study protocol. Draft Collection Site Summary Sheets can be used for this purpose. In the event that an eligible donor refuses to participate, please ask gently as to the reason for refusal and include this information on the form. At the end of the day, all information will be recorded on the Collection Site Summary Sheet. All draft

Collection Site Summary Sheets should be attached to the final.

3. Explain the information included in the consent form and answer any questions the donor may have. Then ask the donor to read the consent form and sign it. If the donor asks you to compare the contents of the two questionnaires, please explain that discussing this might affect how the donor answers the questions, but offer to discuss it after the donor has finished making his or her blood donation. If a donor refuses to participate, give the donor his/her full-length DHQ and proceed as you normally would.
4. Record the donor's ID number on the Donor Registration Sheet and assign a Study ID number. All eligible donors should be assigned a Study ID Number even if they refuse to participate. A range of Study ID numbers will be assigned to each Center. A unique series of numbers should be provided to each collection site coordinator. For example, if your center's numbers were 1000 – 1999 and you are using 4 collection sites to collect the data, give each collection site its own range of numbers such as 1000 – 1250 for one collection site, 1251 – 1500 for the next collection site and so on. It is not important to use all of the numbers, but it is very important that each donor be assigned a unique Study ID number.
5. Write the Study ID number in the box on the Consent Form.
6. Write the Study ID number on the top right hand corner of the aDHQ and in the box on the Demographic Questionnaire.
7. Give the donor the aDHQ and ask him or her to fill it out. When they have returned the aDHQ, give the donor the full length DHQ and the Demographic Questionnaire, and ask him or her to complete the DHQ first, and then the Demographic Questionnaire. (Ask the donor not to write their name or donor ID number on the aDHQ or on the Demographic Questionnaire).
8. The donor will carry the DHQ to the health assessment room. The aDHQ, Consent Form and Demographic Questionnaire will be provided to the health historian by the staff.
9. When the day is finished, place the completed Donor Registration Form in the central study collection box. The draft Collection Site Summary Sheet(s) should be given to

the collection site coordinator.

During the Health Assessment

10. Each person who is carrying out health assessments in the collection site should have a DHQ/aDHQ Assessment Sheet to record the information from donors that they have assessed.
11. Both the aDHQ and the DHQ should be used to assess donor eligibility. The criteria for discordant results are described in the Study Manual.
12. Complete the DHQ/aDHQ Assessment Sheet using the Study ID number to identify the donor. For any donors that you identify as having discordant results, write the reason why you identified them as discordant. Please ensure that you document the donor's preferred contact telephone number for the follow-up interview. This may be written on the line below the line where the donor assessment information was entered on the DHQ/aDHQ Assessment Form. Please note that if the donor does not have a discordant result, the donor will not be asked to participate in an interview.
13. Paper-clip together the aDHQ, the Consent Form and the Demographic Questionnaire. Check to be sure that the Study ID Number is written on each sheet and place them in a central study collection box.
14. At the end of the day, each person who was carrying out health assessments that day should place their completed DHQ/aDHQ Assessment Sheet in the central study collection box.

Center Coordinator - at the end of the day

15. At the end of each day complete the Collection Site Summary Sheet and attach all draft Collection Site Summary Sheets.
16. The collection site coordinator (or their designee) should place all aDHQs, Consent Forms and Demographic Questionnaires (still paper-clipped together), the Donor Registration Sheet, the DHQ/aDHQ Assessment Sheets and the Collection Site Summary Sheet in an envelope and send it to you.
17. When you receive the envelope, check to see that the number of eligible donors that

- participated (on the Collection Site Summary Sheet) and the number of donors on the DHQ/aDHQ Assessment Forms is the same, and that you have that number of Demographic Questionnaires, Consent Forms and aDHQs.
18. Fax the Collection Site Summary Sheets from all sites that participated in the study that day to the Study Administrator.
 19. Then put the Collection Site Summary Sheet back in the appropriate envelope, and keep all of the envelopes together in a secure place. At the end of each week of the study, place all of the envelopes for the week in one envelope and send it to the Study Administrator.

If a follow-up cognitive interview is required

20. A follow-up interview is only required for donors that you have identified as having a discordant result.
21. If a trained interviewer is available at the collection site, ask all donors with discordant results to participate in the follow-up interview after they have finished their donation. If an interviewer is not available, forward a copy of the donor's aDHQ and DHQ to the interviewer on the same day along with the donor's name and preferred contact telephone number. The copy of the DHQ should have the Study ID number assigned to that donor written on the top right hand corner. Also send a fax or email to the Study Administrator indicating that you have provided the information to the interviewer and indicating the Study ID number of the donor.

Questions you may be asked at the collection site:

What is the purpose of this study?

We are trying to determine if a shorter history questionnaire for frequent donors will work as well as the longer questionnaire that we are now using. The goal of this study is to improve our donor screening procedures.

Why are you asking me to complete the Demographic Questionnaire?

It is important for us to know a little bit about the donors who are in the study. These questions help us to see if we have a good cross section of our donor base.

Why are you asking me to fill out this second questionnaire, when I already answered the same questions on the first questionnaire?

Because we are comparing the two questionnaires, we need to ask you to fill them both out today. Your help with this study is very much appreciated. In the future you will be asked to fill out one questionnaire when you come in to donate.