Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail niddk-cr@imsweb.com. Include the Web site and filename in your message.

Informed Consent Tracking Form Instructions
ICT Version A, 05/24/2002
QxQ Date: 06/10/2002

I. GENERAL INSTRUCTIONS

The Informed Consent Tracking Form (ICT) is completed during the screening visit after the participant has signed the Informed Consent document. Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

This form is an internal form and is not administered to the participant. The purpose of the form is to document and track in the FAVORIT database the initial level of participant consent for the use of participant DNA and other study data by the FAVORIT investigators.

II. SPECIFIC INSTRUCTIONS

1. Record "F" if the participant gives full consent then go to item 10. Record "P" if they give only partial consent and go to the next item. Full consent means an informed consent document permitting complete use of DNA, stored (archived) blood, and urine specimens, access to medical records, use of informants, and use of participant identifiers to link with external databases was signed. Partial consent means the document was signed, but restrictions were placed on one or more conditions on the signature page or in the description of the study.

2. Record "Y" if there are restrictions on the use/storage of DNA, otherwise record "N" (no restrictions were requested) and go to item 4.

3. Record "C" if the DNA can be used only for cardiovascular disease or renal research. Record "F" if the DNA can be used only for the FAVORIT study. This is more limited and means the participant restricts the storage and use of DNA to the FAVORIT study. Record "N" if the DNA absolutely cannot be used or stored. Record "O" if the DNA has any other restrictions, and list these restrictions.

4. Record "Y" if there are any restrictions on stored (archived) blood, otherwise record "N" and go to item 6.

5. Record "C" if the blood can be used only for cardiovascular disease or renal research. Record "F" if the blood can be used only for the FAVORIT study. This is more limited and means the participant restricts the storage and use of blood to the FAVORIT study. Record "N" if the blood absolutely cannot be used or stored. Record "O" if the blood has any other restrictions, and list these restrictions.

6. Record “Y” if there are any restrictions of stored (archived) urine, otherwise record “N” and go to item 8.

7. Record “C” if the urine can be used only for cardiovascular disease or renal research. Record “F” if the urine can be used only for the FAVORIT study. This is more limited and means the participant restricts the storage and use of urine to the FAVORIT study. Record “N” if the urine absolutely cannot be used or stored. Record “O” if the urine has any other restrictions, and list these restrictions.

8. Record “Y” if the participant has given permission to fully access medical records. Record “N” if the participant has not given permission to access medical records. Record “P” if the participant has given permission to partially access medical records (i.e., some restriction has been placed on the FAVORIT staff accessing the participant’s medical records), and describe the restriction.

9. Record “Y” if the participant has granted permission to fully contact an informant on their behalf. Record “N” if the participant has not granted permission to contact an informant on their behalf. Record “P” if the participant has granted limited permission to contact an informant on their behalf, and describe the restriction.

10. Using standard US date format (month,day,year), enter the date on which the informed consent document was administered and signed by the participant.

11. Enter the initials of the staff person who obtained consent using the 3 letter initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.