Informed Consent Modifications or Withdrawal Form Instructions
ICM Version C, 8/17/2009
QxQ Date: 8/17/2009

I. GENERAL INSTRUCTIONS

The Informed Consent Modifications or Withdrawal Form (ICM) is completed at any contact occasion during which the participant notifies the study of a desire to either change his/her informed consent, withdraw from the study, add information regarding consent for study closure, reinstate a participant if they had previously withdrawn from the study as well as recording if a participant has been approached to extend follow-up beyond 5 years. 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 any changes made to the participant's consent during the course of the study.

II. SPECIFIC INSTRUCTIONS

1. Record the purpose of completing the form. If the purpose is to get consent for extended follow-up, enter "C" and continue to item 2. If the purpose is withdrawal, enter "W" and go to item 14. *Do not withdraw a participant if they have stopped taking their vitamins, have returned to dialysis, cannot be located or died*. If the purpose is reinstatement after previous withdrawal, enter "R" and go to item 15. If the purpose is some other consent change, enter "O" and go to item 6. If the purpose is to track consent for closure and extended contact, enter "L" and go to item 16.

2. Record "Y" if the participant has agreed to extend follow-up past 5 years and go to nest item. Otherwise record "N" and go item 4 .

3. Record the date the participant signed the consent to extend their follow-up, then go to item 6.

4. Record the reason the participant did not extend the follow-up past 5 years. If the reason is not listed, list the reason under "O" for other in a notelog.

5. Record whether the principal investigator discussed with the participant the importance of continuing follow-up and go to item 28

6. Record "Y" if there are restrictions on the use or storage of DNA, otherwise record "N" (no restrictions were requested) and go to item 8.

7. 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 in a notelog.

8. Record “Y” if there are any restrictions on stored (archived) blood, otherwise record “N” and go to item 10.

9. 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 in a notelog.

10. Record “Y” if there are any restrictions of stored (archived) urine, otherwise record “N” and go to item 12.

11. 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 in a notelog.

12. 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 in a notelog.

13. Record “Y” if the participant has granted full permission to contact any 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 in a notelog. Go to item 28.

14. Using the US order (month, day, year), enter the date on which the participant withdrew from the study. Go to item 28.

15. Using the US order (month, day, year), enter the date on which the participant was reinstated into the study. Go to item 28.

16. Record “Y” if the participant signed consent for closure and extended contact. Record “N’ if the participant did not sign consent for closure and extended contact and skip to item 26.

17. Using the US order (month, day, year), enter the date on which the participant signed consent for closure and extended contact.

18. Record “F” if the participant has signed for full consent, i.e. to receive study results, receive their treatment arm, contacting for future studies contact from the clinic, DCC or Operation Center and consenting to linkage with NDI, UNOS, USRDS or equivalents. Record “P” if the participant has not given full consent to all items above. Skip to item 28 if the participant gives full consent.

19. Record “Y” if there are restrictions on contacting the participant to receive study results. Record “N” if there are no restrictions on contacting the participant to receive study results and skip to item 21.

20. Record “N” if the participant does not want to be contacted to receive study results. Record “S” if the participant only wants to be contacted by the clinical site. Record “O” if other and specify details in a notelog.

21. Record “Y” if there are restrictions on contacting the participant to give them their treatment arm. Record “N” if there are no restrictions on contacting the participant to give them their treatment arm and skip to item 23.

22. Record “N” if the participant does not want to be contacted about their treatment arm. Record “S” if the participant only wants to be contacted by the clinical site. Record “O” for other and specify details in a notelog.

23. Record “Y” if there are restrictions on contacting the participant regarding future studies. Record “N” if there are no restrictions on contacting the participant regarding future studies and skip to item 25

24. Record “N” if the participant does not want to be contacted for future studies. Record “S” if the participant only wants to be contacted by the clinical site. Record “O” for other and specify details in a notelog.

25. Record “Y” if the participant has consented to allow linkage to NDI, UNOS, USRDS, or equivalents. Record “P” if the participant has consented to partial linkage to NDI, UNOS, USRDS, or equivalents. If partial, specify details in a notelog. Record “N” if the participant did not consent to linkage to NDI, UNOS, USRDS, or equivalent. Go to item 28.

26. Record “Y” if the participant received the consent via trackable mail. Send the letter via 1) United States Postal Service certified mail which allows a card to be returned verifying receipt by the participant or 2) via UPS Campus/ship, the system already in place for FAVORIT, and send UPS Ground. This requires using a plain brown~9 X 12 inch brown envelope, NOT the UPS mailer, and you'll be able to track the envelope to the participant. Record “R” if the participant received the consent via other mail (non-trackable). Record “N” if the participant did not receive the consent via mail (i.e., consented in clinic).

27. Record “A” if after repeated attempts, you were unable to contact the participant to determine a reason for not signing the consent. Record “D” if you did not attempt to contact participant to determine a reason for not signing the consent. If you were able to contact the participant, record “M” if the participant did not sign the consent because of medical reasons or being incapacitated, record “N” if the participant did not sign the consent because they were not interested, record “U” if the participant did not give a reason for not signing the consent and record “O” if there was another reason for not signing the consent. If other “O”, specify a reason in a notelog.

28. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

29. Using the US order (month, day, year), enter the date the form was completed.

30. Enter the 3 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.

Informed Consent Modifications or Withdrawal Form Instructions
ICM Version B, 2/14/2007
QxQ Date: 2/15/2007

I. GENERAL INSTRUCTIONS

The Informed Consent Modifications or Withdrawal Form (ICM) is completed at any contact occasion during which the participant notifies the study of a desire to either change his/her informed consent or to withdraw from the study. It is also used to reinstate a participant if they had previously withdrawn from the study as well as recording if a participant has been approached to extend follow-up beyond 5 years. 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 any changes made to the participant's consent during the course of the study or to document withdrawal from the study.

II. SPECIFIC INSTRUCTIONS

1. Record the purpose of completing the form. If the purpose is to get consent for extended follow-up, enter "C" and continue to item 2. If the purpose is withdrawal, enter "W" and go to item 14. *Do not withdraw a participant if they have stopped taking their vitamins, have returned to dialysis, cannot be located or died*. If the purpose is reinstatement after previous withdrawal, enter "R" and go to item 15. If the purpose is some other consent change, enter "O" and go to item 6.

2. Record "Y" if the participant has agreed to extend follow-up past 5 years and go to nest item. Otherwise record "N" and go item 4 .

3. Record the date the participant signed the consent to extend their follow-up, then go to item 6.

4. Record the reason the participant did not extend the follow-up past 5 years. If the reason is not listed, list the reason under "O" for other in a notelog.

5. Record whether the principal investigator discussed with the participant the importance of continuing follow-up and go to item 16.

6. Record "Y" if there are restrictions on the use or storage of DNA, otherwise record "N" (no restrictions were requested) and go to item 8.

7. 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 in a notelog.

8. Record "Y" if there are any restrictions on stored (archived) blood, otherwise record "N" and go to item 10.

9. 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 in a notelog.

10. Record "Y" if there are any restrictions of stored (archived) urine, otherwise record "N" and go to item 12.

11. 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 in a notelog.

12. 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 in a notelog.

13. Record "Y" if the participant has granted full permission to contact any 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 in a notelog. Go to item 16.

14. Using the US order (month, day, year), enter the date on which the participant withdrew from the study. Go to item 16.

15. Using the US order (month, day, year), enter the date on which the participant was reinstated into the study.

16. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

17. Using the US order (month, day, year), enter the date the form was completed.

18. Enter the 3 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.

Informed Consent Modifications or Withdrawal Form Instructions
ICM Version A, 05/24/2002
QxQ Date: 06/10/2002

I. GENERAL INSTRUCTIONS

The Informed Consent Modifications or Withdrawal Form (ICM) is completed at any contact occasion during which the participant notifies the study of a desire to either change his/her informed consent or to withdraw from the study. 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 any changes made to the participant's consent during the course of the study or to document withdrawal from the study.

II. SPECIFIC INSTRUCTIONS

1. Record "Y" if the participant has changed their consent since the date on which the informed consent document was administered and signed by the participant, or since it was last modified. Otherwise record "N" and go to item 11.

2. Using US date format (month,day,year), enter the date on which the participant changed the informed consent document.

3. Record "Y" if there are restrictions on the use or storage of DNA, otherwise record "N" (no restrictions were requested) and go to item 5.

4. 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.

5. Record "Y" if there are any restrictions on stored (archived) blood, otherwise record "N" and go to item 7.

6. 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.

7. Record “Y” if there are any restrictions of stored (archived) urine, otherwise record “N” and go to item 9.

8. 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.

9. 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.

10. Record “Y” if the participant has granted full permission to contact any 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.

11. Record “Y” if the participant has withdrawn from the FAVORIT study, and record the details of the withdrawal. Record “N” if the patient has not withdrawn from the study and go to item 13.

12. Using the US order (month,day,year), enter the date on which the participant withdrew from the study.

13. Enter the 3 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.