O.M.B. 0925-0281
exp. 09/30/98

ARIC

A[therosclerosis] Risk in Communities

INFORMED CONSENT TRACKING FORM

ID NUMBER: | | | | | | | | CONTACT YEAR: | 1 | 0 | FORM CODE: | I | C | T | VERSION: A 07/18/96

LAST NAME: | | | | | | | | | | | | | INITIALS: | | |

INSTRUCTIONS: ID Number, Contact Year and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. On the paper form, if a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

INFORMED CONSENT TRACKING FORM (ICTA screen 1 of 4)

A. INFORMED CONSENT

1. Type of consent: .... Full F → Go to Item 4.a., Screen 2.
   Partial P

2.a. Restrictions on use/storage of DNA? ..... Yes Y
   Go to Item 3.a. ← No N

b. Type of restriction on use/storage of DNA:

   CVD research C
   ARIC only ..... A
   No use/storage of DNA ..... N
   Other ..... O

Specify details of DNA restrictions:

_____
_____
_____
_____

3.a. Other restrictions placed on procedures or use of study data? ..... Yes Y
   Go to Item 4.a., Screen 2. ← No N

b. Type of restrictions on procedures or use of study data:

   CVD research C
   ARIC only ..... A
   Other ..... O

Specify details of restrictions on procedures or use of study data:

_____
_____
_____
_____

INFORMED CONSENT TRACKING FORM (ICTA screen 2 of 4)

4.a. Restrictions on release of results to participant's physician? ..... Yes Y

Go to Item 5. ——— No N

b. Type of restriction placed on releasing ARIC results to the participant's physician:

Full restriction (release no results) .... F

Partial restriction ..... P

Specify details of restriction: _____

_____

_____

_____

5. Permission to access medical records? ... Yes Y

No N

Partial P

If partial, specify: _____

_____

_____

_____

B. ADMINISTRATIVE INFORMATION

6. Date of data collection: | | | / | | | / | | |

m m / d d / y y

7. Method of data collection: ..... Computer C

Paper Form P

8. Code number of person completing this form: ..... | | | |

INFORMED CONSENT TRACKING FORM (ICTA screen 3 of 4)

C. POST-VISIT CONSENT MODIFICATION

9.a. Consent changed? ..... Yes Y

Go to Item 12, Screen 4. ——— No N

b. Date of change? | | | / | | | / | | |

m m / d d / y y

10.a. Restrictions on use/storage of DNA? ..... Yes Y

Go to Item 11.a. ——— No N

b. Type of restriction on use/storage of DNA?

CVD research C

ARIC only ..... A

No use/storage of DNA ..... N

Other ..... O

Specify details of DNA restrictions:

_____

_____

_____

_____

11.a. Other restrictions placed on procedures or use of study data? ..... Yes Y

Go to Item 12, Screen 4. ——— No N

b. Type of restriction on procedures or use of study data:

CVD research C

ARIC only ..... A

Other ..... O

Specify details of restrictions on procedures or use of study data:

_____

_____

_____

_____

INFORMED CONSENT TRACKING FORM (ICTA screen 4 of 4)

12. Permission to access medical records? ..... Yes Y

No N

Partial P

If partial, specify: _____

_____

_____

_____

13.a. Withdrawal from study? ..... Yes Y

Go to Item 14. ——— No N

If "Yes", specify details of withdrawal request:

_____

_____

_____

_____

13.b. Date of withdrawal request: [ ][ ]/[ ][ ]/[ ][ ]

m m / d d / y y

14. Code number of person completing post-visit consent or withdrawal on this form: [ ][ ][ ]

INSTRUCTIONS FOR THE INFORMED CONSENT TRACKING FORM
ICTA, VERSION A, 07/18/96
PREPARED 08/21/96

I. GENERAL INSTRUCTIONS

This form is an internal form and is NOT administered to participants. The purpose of the form is to document and track in the ARIC central database the initial level of, and subsequent (if any) changes to, participants' restrictions on the use of their DNA or other study data by the ARIC investigators. Items 1-8 on the form are completed by an interviewer at the reception workstation, after participants have read and signed the informed consent form. Items 9 through 14 are completed when a participant notifies the study of a desire to either change his/her type of consent or access to medical records, or to withdraw from the study.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

1. **Type of consent.** FULL consent means the informed consent document was signed and all conditions on the signature page and all procedures in the narrative description were agreed to. If FULL consent is obtained, continue with Item 4.a. 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. **Restrictions on storage or use of DNA.** (Item 2.a.) NO means there are no restrictions on the use or storage of DNA and item 2.b is skipped. YES indicates that some type of DNA restriction was requested. (Item 2.b.) CVD RESEARCH means the participant has agreed to the storage and use of his/her DNA only in studies on cardiovascular diseases. ARIC ONLY is more limited and means the participant restricts the storage and use of his/her DNA to the ARIC Study. NO USE/STORAGE OF DNA is used to indicate absolute refusal of any DNA storage or DNA use. OTHER means that one of the above limitations on the use of DNA may have been requested AND/OR the participant has indicated ADDITIONAL/OTHER restrictions on the use of his/her DNA. List all of these restrictions under "specify", even if they include "CVD research" or "ARIC only".

3. **Other restrictions placed on procedures or use of study data.** (Item 3.a.) NO means that except for the use and storage of DNA or reporting of results to their physician, the participant has placed no other restrictions on his/her participation or the use of his/her study data. A NO response skips to Item 4.a. A YES response indicates that some other restriction has been requested. (Item 3.b.) CVD RESEARCH means the participant has agreed to the use of his/her study data only in studies on cardiovascular diseases. ARIC ONLY is more limited and means the participant restricts the use of his/her study data to only the ARIC Study. OTHER means that

one of the above limitations on the use of study data may have been requested AND/OR the participant has indicated ADDITIONAL/OTHER restrictions, either in the procedures or use of data. List all of these restrictions under "specify".

4. **Restrictions on release of results to participant's physician.** (Item 4.a.) NO indicates that no restrictions have been placed on the release of results to the participant's physician and item 4.b. is skipped. YES means that the participant has requested some type of restriction on reporting results to their physician. (Item 4.b.) FULL RESTRICTION means that no results are to be released to the participant's physician. PARTIAL RESTRICTION is used to indicate that some type of restriction less than full restriction has been placed on the release of results to the participant's physician. The details of the partial restriction need to be provided under "Specify".

5. **Permission to access medical records.** Select YES to indicate that ARIC has full permission to access the participant's medication records. NO indicates complete refusal to have ARIC staff access his/her medical records. PARTIAL means that some restriction less than full has been placed on ARIC staff accessing the participant's medication records. Details of the type of PARTIAL restriction are to be provided under "Specify".

6. **Date of data collection.** Using the standard date format, enter the date on which the informed consent document was administered and signed by the participant. This date is NOT changed when participants subsequently change their level of consent or withdraw from the study.

7. **Method of data collection.** Record "C" if the form is completed using direct data entry and "P" if the form is collected on paper for delayed data entry. If the form is completed partially on paper and partially on computer, select "P".

8. **Code number of person completing this form.** Enter the code number of the person completing the form.

Items 9-14 are only completed when participants subsequently contact the study and indicate one or more of the following:

a desire to change the original level of informed consent;

to revise the study's access to their medical records;

or to withdraw from the study.

It is possible that a change in the level of consent may not result in withdrawal from the study, or vice versa, withdrawal from the study may not *ipso facto* result in a revision of the restrictions placed on the use of study data in medical research. However, responses to all items in this section (Items 9-14) must be completed when participants recontact the study and request a revision of either status. Items 1-8 are not changed.

9. **Consent changed?** (Item 9.a.) Select YES or NO to indicate whether the participant requests any change in the previous type of informed consent. If no change is requested, select NO and go to Item 12. If a change is requested, enter the date on which the request was made in Item 9.b. using the standard date format and then SPECIFY the type of change(s) in Items 10 and 11.

10. **Restrictions on use/storage of DNA.** Follow the directions and definitions for Item 2.

11. **Other restrictions placed on procedures or use of study data.** Follow the directions and definitions in Item 3.

12. **Permission to access medical records.** Follow the directions and definitions in Item 5.

13. **Withdrawal from study.** (Item 13.a.) Select YES or NO to indicate whether the participant requests to be withdrawn from the ARIC Study. If NO, go to Item 14. If YES, provide details of the withdrawal under "specify". Document the date on which the request was made in Item 13.b.

14. **Code number of person completing the post-visit section of the form.** Enter the staff identification code of the person completing this portion of the form.