



# INFORMED CONSENT TRACKING FORM

ID NUMBER:

FORM CODE:  I  C  T

DATE: 06/01/2011  
Version 1.0

## ADMINISTRATIVE INFORMATION

0a. Date:   /   /      
Month Day Year

0b. Staff ID:

0c. Who provided consent? (select one)

- a. Participant
- b. Proxy

0d. Time of consent:

- a. Visit 5
- b. Other (Pre- or Post-Visit 5)

**Instructions:** *This form should be completed during the participant's visit or during follow-up phone calls if consent has changed. **This form is intended to capture consent for both AFU and Visit 5. AFU staff will update item #1 in the rare case that a participant withdraws consent for Annual Follow-up.** The date is the date of consent or change in consent. If during the visit, after some data have been collected, it is determined that some else needs to provide consent (it becomes evident that a proxy is needed after already having consented the participant OR a proxy consents but it becomes evident that the participant is capable of answering the questions and performing the exam), then complete a second, new Informed Consent Tracking form in DMS, with a new occurrence. The last occurrence will be considered the current consent status.*

*The purpose of this consent tracking form is to capture (a) their consent status at the time of consenting for Visit 5 (occurrence = 1) and to (b) capture their consent status at the current time IF there are any changes to consent AFTER Visit 5.*

1. Allow ARIC staff to contact me twice per year to ask questions about my health and where I live (select one):

- <sub>2</sub> = Agree to twice per year
- <sub>1</sub> = Agree to once per year
- <sub>0</sub> = do NOT agree to AFU contact – withdraw AFU consent

2. Allow ARIC personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate:

- <sub>1</sub> = Agree
- <sub>0</sub> = do NOT agree

3. Allow **ARIC and investigators they work with** to study my samples (blood, cells and urine) in current and future research:

- <sub>1</sub> = Agree
- <sub>0</sub> = do NOT agree

4. Allow **scientists not associated with ARIC** to study my samples (blood, cells and urine) in current and future research:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

5. Allow **ARIC and investigators they work with** to use my blood and cells to obtain, store and study **genetic** material (DNA/RNA) for current and future research:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

6. Allow scientists and specialized laboratories not associated with ARIC to study my de-identified **genetic** data, information and samples:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

7. Allow **commercial or for-profit companies that are not part of ARIC** to use my **genetic and non-genetic** information and samples to develop new diagnostic tests and medical treatments that may benefit people:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

8. Allow ARIC staff to contact me about my interest in participating in future health-related studies:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

9. Allow ARIC personnel to contact my children or other family members in the future for health-related studies. They will be given the opportunity to agree or decline participation:

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

10. Allow ARIC personnel to access my medical records.

<sub>1</sub> = Agree

<sub>0</sub> = do NOT agree

10a. Consent to Release Protected Health Information

<sub>1</sub> = No

<sub>0</sub> = Yes

10b. Date of Consent:   /   /      
Month Day Year



## INSTRUCTIONS FOR THE INFORMED CONSENT TRACKING (ICT) FORM

### I. General Instructions

This form documents the participant's consent or their designated proxy's consent to the following:

- a) access to the participant's medical records,
- b) willingness to inform the participant's physician and ophthalmologist regarding examination results,
- c) use of the participant's DNA,
- d) use of the participant's other study data,
- e) annual and semi-annual follow-up contact.

The form is NOT administered to participants, but rather documents consent at the time of the Visit 5 examination or any change (revision) in existing consent before or after the Visit 5 examination. Any change in consent is documented as soon as a participant or proxy makes the request known; this is most likely to may occur during telephone contact phone calls (annual or semi-annual).

**There should never be more than two occurrences of the ICT form in the database for a given ID. The last occurrence documents current consent status.**

The first occurrence of the ICT is used to reflect consent prior to Visit 5 (e.g., if participant requests change in consent at the time of annual or semi-annual telephone contact) or at the time of the Visit 5 examination. If an ICT form exists to document consent prior Visit 5, but later consent is obtained for Visit 5, **update** the existing item 0d "Time of Consent" to 'Visit 5' and include information collected on the exam consent form.

The second occurrence is used if Visit 5 exam consent exists, but there is a change in consent after the exam. If this occurs, create a second occurrence of the ICT and select "Other" for item 0d "Time of Consent". Only change the item(s) for which consent has changed, leaving all other fields blank.

If the participant has provided consent to participate in the exam, but is deemed to require "proxy consent" to participate, or if a proxy consent was obtained when the participant is capable of providing his/her own consent, the first occurrence documents initial consent, and the second occurrence documents the second consent. Any further changes or updates to consent status are made to the second occurrence.

The following scenarios are possible:

1. Participant or proxy provides informed consent for the Visit 5 exam.  
**Action:** Create first occurrence of ICT form with item 0d 'Time of Consent' = 'Visit 5'. Key the ICT per the responses on the signed paper copy of the informed consent form.
2. Participant/proxy contacted for AFU and Visit 5 has not occurred (either because the participant has not yet been recruited or did not agree to participate).  
**Action:** Do NOTHING UNLESS the participant changes their existing consent with regards to a) access to medical records, b) reporting of results to physician or ophthalmologist, c) use of DNA or d) other study data, or e) if the participant does not agree to be contacted by telephone every 6 months.

If the participant does request a change to his/her existing consent, create a first occurrence of ICT form with item 0d 'Time of consent' = 'Other' and update only the consent items that are changing. If the participant later provides consent for Visit 5, **update** the first occurrence, changing item 0d 'Time of consent' to 'Visit 5' and update the items per the paper consent form. Do not create a second occurrence in this case unless a change is requested after the Visit 5 examination.

3. Participant/proxy consented to Visit 5, but requests change in consent after Visit 5.  
**Action:** Create a second occurrence of the ICT, with item 0d 'Time of consent' = 'Other' and update the consent elements that are changing.
4. Participant consented to Visit 5, but "proxy consent" to participate is deemed necessary.  
**Action:** Create a first occurrence to document the participant's consent, and a second occurrence to document the proxy consent. Further changes/updates to consent status are made to the second occurrence.
5. Proxy consent obtained for Visit 5, but participant deemed capable of providing his/her own consent.  
**Action:** Create a first occurrence to document the proxy consent, and a second occurrence to document the participant's consent. Further changes/updates to consent status are made in the second occurrence.

## II. Detailed Instructions for Each Item

- 0a. Enter the date the consent information was collected. This is either the date the consent form for Visit 5 was completed, or the date the site is notified of a request for change to consent elements a) – e) above.
- 0b. Enter the staff ID for the person who administered the consent form at Visit 5, or the telephone follow-up interviewer ID who is notified of a change in consent, or the staff ID of the person acting on documenting a change in consent requested in writing.
- 0c. Indicate whether consent was provided by the participant or their designated proxy. If a change is being made to an existing ICT record, this is the person (Participant or Proxy) requesting the change is indicated.
- 0d. The choices for 'Time of consent' are either 'Visit 5' or 'Other', where 'Other' indicates any time in which consent may have been changed before or after Visit 5. If the record is for the consent form collected for the Visit 5 exam, select 'Visit 5'.

Items 1-9 correspond directly to the "ARIC Visit 5 Consent Form" that is common across all four field centers. The one exception is item 2a, which must be captured explicitly from the participant at the time of consent.

Any special instructions for keying the items into DMS are denoted below.

1. **Follow-up contact.** Consent for telephone contact twice a year is obtained explicitly documented on the Visit 5 Informed Consent form. A participant may also verbally refuse any further contact by ARIC follow-up staff outside the exam consent process.
2. **Release of findings.** If the participant does not want their exam findings released to anyone, including themselves, then a response of 'do not agree' will skip over #2a and go to item #3. [This question maps loosely to items #4a and #4b on the ICT version A. What about version B?]
3. **ARIC use – non-genetic data.** Use the response to #3 on Visit 5 consent form.

4. **Non-ARIC use – non-genetic data.** Use response to #4 on Visit 5 consent form.
5. **ARIC use – genetic data.** Use response to #5 on Visit 5 consent form. [This question maps loosely to items 2a, 2b, 10a, 10b on ICT version A; items 1a, 1b on ICT version B.]
6. **Non-ARIC use – genetic data.** Use response to #6 on Visit 5 consent form.
7. **Corporate use of genetic and non-genetic data.** Use response to #7 on Visit 5 consent form.
8. **Future health-related studies.** Use response to #8 on Visit 5 consent form.
9. **Children/family contact.** Use response to #9 on Visit 5 consent form.
10. This item records whether the participant restricted access to his/her medical records. This is not an item found in the tiered informed consent section that includes the 9 items listed above. Instead, item 10 of the ICT is based on the information included in the body of the informed consent form under the heading ***How will my medical records help ARIC?***

As stated in this section of the consent form, ARIC participants have granted ARIC personnel access to their medical records since the inception of ARIC. If the participant does not consent to give access to his/her medical records, the pertinent sentence or paragraph in the informed consent form signed by the participant is crossed out, and initialed by the participant. Item 10 of the ICT is answered **Agree** if this section of the informed consent was not amended in the process of obtaining informed consent. If any portion of the section titled 'How will my medical records help ARIC?' has been amended or restricted by the participant, Item 10 of the ICT is answered **Do Not Agree**, and a note log is added to this item to list the restriction in a few words. For example, note log entries could mention 'Does not agree to release hospital records', 'Do not contact physician's office', 'Do not contact next of kin in case of death', 'Does not allow use of SSN'.

If participant requests the Medicare number not be used by the study, the following steps need to be taken:

CSCC deletes Medicare number (or most of it) from V5INFO 157.

Field center deletes blanks out AQC1a (which asks whether ppt says the Medicare number we show is correct) and adds note log.

Field center adds note logs to ICT (Q.10, 10a) to indicate what participant requested, and when.