INFORMED CONSENT TRACKING FORM - Visit 8

ID NUMBER: | | | | | | | |

FORM CODE: | I | C | T | 8 |

DATE: 2/20/2020
Version 2.0

ADMINISTRATIVE INFORMATION

0a. Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

0c. Who provided consent? (select one)

a. Participant

b. Proxy

0d. Time of consent or consent update:

a. Visit

b. Other

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 follow-up and visits.***

For changes in consent ***outside a visit****, staff should only update the items that have a change in the shared 'Follow-up and Visit' and/or the 'Follow-up only' sections, and leave all remaining items as is.*

For consent ***at a visit****, complete the shared 'Follow-up and Visit' section, and the site specific consent questions.*

FOLLOW-UP and VISIT: ALL SITES

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

☐2 = Agree to twice per year

☐1 = Agree to once per year

☐0 = 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:

☐1 = Agree

☐0 = do NOT agree

FOLLOW-UP ONLY: ALL SITES

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

   ☐$_1$ = Agree

   ☐$_0$ = do NOT agree

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

   ☐$_1$ = Agree

   ☐$_0$ = 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:

   ☐$_1$ = Agree

   ☐$_0$ = do NOT agree

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

   ☐$_1$ = Agree

   ☐$_0$ = 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:

   ☐$_1$ = Agree

   ☐$_0$ = do NOT agree

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

   ☐$_1$ = Agree

   ☐$_0$ = do NOT agree

9. No Longer Used

10. Allow ARIC personnel to access my medical records.

    ☐$_1$ = Agree

    ☐$_0$ = do NOT agree

FORSYTH COUNTY ONLY: VISIT CONSENT

11. Allow the ARIC staff to audio record some interviews for staff quality control. The investigator will not share these recordings with anyone outside of the immediate study team.

☐$_1$ = Agree

☐$_0$ = do NOT agree

12. Allow the ARIC staff to videotape the way I walk to aid with data analysis.

☐$_2$ = Agree and these videos can be used for future research studies → **SAVE & CLOSE**

☐$_1$ = Agree, but the videos must be destroyed after the study → **SAVE & CLOSE**

☐$_0$ = do NOT agree → **SAVE & CLOSE**

JACKSON ONLY: VISIT CONSENT

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

    ☐$_1$ = Agree

    ☐$_0$ = do NOT agree

14. 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.

    ☐$_1$ = Agree

    ☐$_0$ = do NOT agree

15. Allow the use of my medical records (hospital, emergency department, physician office/clinic records) to answer research questions important to the study. This permission has no expiration date.

    Consent to Release Protected Health Information

    ☐$_1$ = Agree → **SAVE & CLOSE**

    ☐$_0$ = do NOT agree → **SAVE & CLOSE**

MINNEAPOLIS ONLY: VISIT CONSENT

16. My deidentified information may be used by **commercial or for-profit companies that are not part of ARIC** to develop new diagnostic tests and medical treatments that may benefit people.

☐1 = Agree

☐0 = do NOT agree

17. The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.

☐1 = Agree

☐0 = do NOT agree

18. ARIC investigators may use my medical records (hospital, emergency department, physician office/clinic records or from the Minnesota Department of Health's Minnesota Cancer Surveillance System) to answer research questions important to the study. This permission has no expiration date.

☐1 = Agree

☐0 = do NOT agree

19. The investigator may contact me in the future to see whether I am interested in participating in other research studies by the ARIC Investigators.

☐1 = Agree → **SAVE & CLOSE**

☐0 = do NOT agree → **SAVE & CLOSE**

WASHINGTON COUNTY ONLY: VISIT CONSENT

20. I agree that my de-identified information may be used by **commercial or for-profit companies that are not part of ARIC** to develop new diagnostic tests and medical treatments that may benefit people.

☐$_1$ = Agree

☐$_0$ = do NOT agree

21. I agree to audio or video recording of my visit to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.

☐$_1$ = Agree

☐$_0$ = do NOT agree

22. I agree to allow the use of my medical records (hospital, emergency department, physician office/clinic records) to answer research questions important to the study. This permission has no expiration date.

☐$_1$ = Agree

☐$_0$ = do NOT agree

23. We may have ARIC personnel contact you or your family to determine if you are interested in participating in other studies done in collaboration with ARIC. You, of course, may choose at that time whether to take part in additional research. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research. Please indicate your decision below by checking the appropriate box. I agree to have ARIC personnel contact me or my family regarding future studies (select one).

☐$_2$ = Agree to contacting me AND family

☐$_1$ = Agree to contacting me

☐$_0$ = do NOT agree

INSTRUCTIONS FOR THE VISIT 8 INFORMED CONSENT TRACKING FORM

I. General Instructions

This form documents the participant's consent or their designated proxy's consent during follow-up or at visits, to the following:

- Contact by ARIC staff twice per year to ask questions about the participant's health and where they live
- Release of findings from the participant's exam and tests to the participant's physician, clinic, or another person designated by the participant
- Use of data by ARIC investigators and for-profit companies
- Access to medical records
- Allow audio and or video recording at clinic visits
- Interest in future studies for participant and or participant' family members

The ICT8 has been preloaded into CDART using the most recent data from version 1 of the ICT. This means sites have a baseline from which to work going forward.

The form is divided into sections, depending on clinic site and when the consent is administered. The first section is completed by all sites at follow-up and visit. The second section is completed at follow-up only. The final section (which is specific to each site) is completed at the visit. Specifically:

- For changes in consent **outside a visit** (such as a follow-up interview), staff should only update the 'Administrative Information' section and items that have changed under the 'Follow-up and Visit' and/or the 'Follow-up only' sections, and leave all remaining items as is.
- For consent **at a visit**, update the 'Administrative Information' section, the shared 'Follow-up and Visit' section, and the site specific consent questions. If a participant is being seen at an alternate field center, the participant's "home" center must notify the Coordinating Center help desk so that the appropriate items can be enabled in the participant's ICT8 form at the alternate center at the time of their exam.

In either scenario above, update the ICT8 form in CDART. There is no need to create another occurrence of the form.

II. Detailed Instructions for Each Item

Administrative Information: All Sites

Each time the consent is updated, all administrative questions must be appropriately updated.

0a. For a study visit, enter the date the consent form for the visit was completed and signed. For an update to consent at another time (i.e. follow-up interview) record the date of the change in consent.

0b. Enter the staff ID for the person who administered the consent form.

0c. Indicate whether consent was provided by the participant or their designated proxy.

0d. Indicate when the consent was updated, either at the Visit or Other (such as Follow-up Interview)

Follow-up and Visit: All Sites (see highlighted exceptions below)

1. **Follow-up contact**. Record whether the participant agrees to be contacted TWICE per year for follow-up interviews. For a no response, see if the participant would agree to be contacted ONCE per year for a follow-up interview.

NOTE: For Washington County, item 1 is not part of their Visit 8 consent.

2. **Release of findings**. Record whether agrees to site staff releasing exam findings to their physician or their provider of medical care or a person they designate (***other than themselves***). If they do agree, then the physician/provider of medical care name and address information is collected in the Contact Information Update (CIU) in section F – PHYSICIAN INFORMATION, items 27-29. Question 27 also asks if the participant would like the summary of results to be sent to their physician/provider of care.

NOTE: For Minneapolis, item 2 of their visit informed consent excludes the word "non-genetic". For Washington County and Forsyth, item 2 of their visit informed consent reads "allow ARIC personnel to release my non-genetic findings from exams and tests to the physician, clinic or person that I designate."

Follow-up Only: All Sites

3. **ARIC use – non-genetic data.** Record whether the participant allows ARIC investigators to use their non-genetic samples for research.
4. **Non-ARIC use – non-genetic data.** Record whether the participant allows non-ARIC investigators to use their non-genetic samples for research.
5. **ARIC use – genetic data.** Record whether the participant allows ARIC investigators to use their genetic samples for research.
6. **Non-ARIC use – genetic data.** Record whether the participant allows non-ARIC investigators to use their non-genetic samples for research.
7. **Corporate use of genetic and non-genetic data.** Record whether the participant allows for-profit companies to use their genetic and non-genetic samples for research.

NOTE: Forsyth and Jackson should respond to this question. Minneapolis and Washington county should skip this question and respond to the question in their site specific visit questions (items 16 and 20 respectively).

8. **Future health-related studies.** Record whether the participant allows staff to contact them for future studies.

NOTE: Forsyth only should respond to this question. Jackson, Minneapolis and Washington county should skip this question and respond to this question in their site specific visit questions (items 13, 19, and 23 respectively).

9. No Longer Used

10. **Access to medical records**. This item records whether the participant restricted access to his/her medical records.

NOTE: Forsyth only should respond to this question. Jackson, Minneapolis and Washington county should skip this question and respond to this question in their site specific visit questions (items 15, 18, and 22 respectively).

FORSYTH COUNTY ONLY

11. **Audio recording.** Record whether the participant agrees to audio recording of some interviews for quality control purposes.

12. **Videotape record.** Record whether the participant agrees to video recording of the walking tests for data analysis purposes.

JACKSON ONLY

13. **Future health-related studies.** Record whether the participant agrees to be contacted regarding participation in future health-related studies.

14. **Contact family members.** Record whether the participant agrees to allow ARIC staff to contact children or family members reading health-related studies.

15. **Access to medical records**. Record whether the participant restricted access to his/her medical records. For additional information, refer to your center's consent form documents.

MINNEAPOLIS ONLY

16. **Corporate use of genetic and non-genetic data.** Record whether the participant agrees to the use of their data by commercial or for-profit companies not part of ARIC.

17. **Audio and video recording.** Record whether the participant agrees to audio and video recording for data analysis purposes.

18. **Access to medical records**. Record whether the participant restricted access to his/her medical records. For additional information, refer to your center's consent form documents.

19. **Future health-related studies.** Record whether the participant agrees to be contacted regarding participation in future health-related studies.

WASHINGTON COUNTY ONLY

20. **Corporate use of genetic and non-genetic data.** Record whether the participant agrees to the use of their data by commercial or for-profit companies not part of ARIC.

21. **Audio and video recording.** Record whether the participant agrees to audio and video recording for data analysis purposes.

22. **Access to medical records**. Record whether the participant restricted access to his/her medical records. For additional information, refer to your center's consent form documents.

23. **Contact regarding participation in future ARIC-related studies.** Record whether the participant consents to allow the study to contact both participant and their family or only the participant. Select "no" if the participant does not agree to be contacted and does not agree to allow the study to contact their family.