



INSTRUCTIONS FOR THE VISIT INFORMED CONSENT TRACKING FORM

I. General Instructions

This form documents the participant's consent, the designated proxy's consent (prior to sIRB in June 2022), or the designated Legally Authorized Representative (LAR)'s consent (post-sIRB in June 2022) during follow-up, at visits, or during the sIRB re-consent process 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

One ICTX form exists for each participant ID. That singular record of the ICT in CDART reflects the participant's most recent consent status. The ICTX 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 should be updated each time consent is assessed and is used to track any changes or updates in consent.** At that time of assessment, staff should check to make sure that the responses to the items in the ICTX are consistent with the participant's latest intention. If the participant does not make any changes to consent, only the date and staff code need to be updated. If the participant agrees to all items in the consent, be sure to review all items carefully and change any "Do NOT agree" responses to "Agree."

ICTX1 is the most relevant for updating a participant's (or LAR's) consent. ICTX2 and 3 should only be asked when the participant is in the clinic for a visit. The default for ICTX4-11 is to remain unchanged, and these items should only be updated if the participant or LAR specifically requests a change.

Note, the option of LAR was added to 0c and the option of sIRB was added to 0d to meet the needs of the sIRB oral re-consent process. **Sites should not select the LAR or sIRB option until they have been approved by the sIRB and have received appropriate training.**

Please see the ARIC sIRB Re-consent Guide for more information about LARs, who requires a LAR, and the sIRB re-consent process.

II. Detailed Instructions for Each Item

Each time the consent is updated, all 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, sIRB re-consent) record the date of the change in consent. **For sIRB consent completion, the date field must be updated, even if consent status does not change.**

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

0c. Indicate whether the consent update was provided by the participant, their designated proxy, or their designated LAR (Legally Authorized Representative). **Note that the designated proxy cannot provide consent on behalf of the participant after the sIRB goes into effect.** The

consent status of a proxy, who agrees to participate in ARIC, is collected on the Proxy Consent Tracking form (PXY) and is **not** collected on the ICTX form.

In general, the LAR should always provide consent on behalf of the participant if the participant meets the criteria for requiring a LAR. However, there are some exceptions to this rule, for example when a mistake was made, or staff know the participant personally and know the diagnosis is incorrect. In these instances, staff should add a notelog to this question and document why the participant provided consent instead of the LAR.

- 0d. Indicate when the consent was updated: at the Visit, Other (such as Follow-up Interview Call), or sIRB. **The third option of sIRB should always be selected over Visit or Other, even if sIRB consent occurs at a Visit or during a Follow-up Interview.** This ensures the date of sIRB consent is properly tracked. In the rare instance of sIRB consent and Visit/Other consent occurring at two distinct time points **and** within 7 days (e.g., sIRB consent completed on Thursday and Visit consent completed on Friday of the same week), do not update 0d. Leave it marked as sIRB, and add a notelog indicating that Visit or Other consent was completed on MM/DD/YYYY.
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.
 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.
 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.
 8. No Longer Used
 9. No Longer Used
 10. **Access to medical records.** This item records whether the participant restricted access to his/her medical records.
 11. **Audio/video recording.** Record whether the participant agrees to both audio and video recording of some interviews for data analysis purposes.

