# Manual 42
# sIRB Reconsent Guide

Version 1.0
July 7, 2022

# sIRB RECONSENT GUIDE

## 1. OVERVIEW AND FAQS

**What is a "single IRB (sIRB)"?**

The NIH made a rule that IRB oversight for all multi-site studies must come from a single IRB. This single IRB is then the "IRB of record" and responsible for all activities that take place in the study. This rule went into effect for all NIH Contracts issued on or after January 25, 2018.

**Why does ARIC have to switch to a single IRB now?**

ARIC is a multi-site study and Surveillance activities are funded by a NIH Contract. A requirement of the new ARIC Contract period, which began November 15, 2021, was that ARIC transition to a single IRB.

**Who is serving as ARIC's single IRB?**

Johns Hopkins School of Medicine IRB has agreed to serve as the ARIC single IRB.

**Are there any changes to the Surveillance activities that ARIC participants are being asked to take part in?**

No. The ARIC study has not changed. Participants will still be called twice a year for Surveillance (AFU and SAF), and when hospitalized medical records will be requested.

**Why do we need ARIC participants to be reconsented to continue Surveillance activities they have participated in for over 30 years?**

Johns Hopkins School of Medicine IRB considers this a new protocol. As such, they are requiring reconsent.

**Who provides consent, and what is a Legally Authorized Representative (LAR)?**

Consent must be obtained from either the participant, or if needed, the LAR.

If the participant is capable, they will provide consent for their continued participation.

If the participant is not capable of consenting for themselves, a LAR will need to provide consent. "LARs make decisions on behalf of a person not capable of making their own decisions." Details regarding who qualify as LARs are provided later in this guide.

**How do we know if someone requires a LAR?**

We will use existing ARIC methods to determine if a LAR is needed. A LAR is required in the following circumstances:

- The person is classified by ARIC as having dementia.

- If the interviewer has concerns about the participants' cognitive status during the reconsent process, the interviewer can request to administer the SIS. If the participant fails, a LAR would be needed.

ARIC staff can find information about whether a participant requires a LAR by going to one of the following reports:

- Annual and Semi-Annual Tracing Sheet
- Recruitment Report
- Snapshot Report

Within these reports, you will see a variable labeled "LAR Requirement". See Section 2 for more detailed information regarding the variables used for dementia classification and the derived variable of LAR Requirement.

**Who can reconsent ARIC participants?**

Clinic staff, recruiters, and follow-up interviewers are all able to reconsent participants, provided they have training in administering the Six Item Screener (SIS) in the event it is a needed tool.

**Do ARIC participants (or LARs) need to be reconsented for Surveillance activities every time we call them or only once?**

Reconsent only needs to happen once.

**Do ARIC participants (or LARs) need to sign and return a consent form?**

No. Consent will be verbal.

**What does the reconsenting process look like?**

Participants will be mailed a cover letter and a copy of the sIRB consent. A few weeks after the mailing, they will be called by Interviewers. Interviewers will briefly review the consent (scripts provided). If the participant agrees to continue in the study, this status will be updated in CDART in the ICTX form, and the Interviewer can continue with the scheduled AFU or SAF.

If a LAR is required, letters will go to both the participant and LAR. If the participant is using a LAR prior to reconsent, staff should reach out directly to the LAR to reconsent. If the participant has not previously used a LAR, then the participant will be asked to assent (give their approval to be in the study) and give permission to contact the LAR. In these instances, the participant will be briefly introduced to the reconsenting process in order to get assent*. The LAR will then be contacted to request consent for the participant to continue with the study. If the LAR agrees, the status will be updated in CDART in the ICTX form. If the LAR is also willing to serve as a proxy, the Interviewer can continue with the scheduled AFU or SAF.

Please see Sections 2 and 3 for more detailed information on the reconsenting process.

*There may be some instances when a participant does not provide assent. If the participant does not assent, that is a refusal and ICTX1 must be updated accordingly. ICTX2 and 3 should only be updated at visits, and ICTX4-11 should only be updated if the participant specifically requests a change. The LAR should not be contacted if the participant does not provide assent.

**What is the difference between a LAR and a proxy?**

LARs are legally allowed to make decisions on behalf of the participant. ARIC uses proxies to answer health questions about the participant. In many instances, a LAR and proxy may be the same person.

**Who can be a LAR?**

Policies regarding who can serve as a participant's LAR vary state-by-state, as well as policies regarding the order of priority. Generally, the following individuals may be a LAR:

- Health care agent
- Spouse
- Parent
- Adult child
- Adult sibling

**Do proxies now have to be consented?**

Yes. Under the single IRB, proxies also need to provide verbal consent to document their willingness to answer questions on behalf of the participant. The proxy consent is abbreviated, since we are not collecting health data on the proxies themselves.

**What if a participant (or LAR) does not reconsent?**

Unfortunately, if a participant (or LAR) does not reconsent, we will no longer be able to contact them for AFU/SAF calls, or to recruit them for clinic visits. As such, getting as many participants as possible to reconsent is essential to the future health and productivity of the ARIC study! Study staff will need to update this status in CDART in the ICTX form. Additional information is provided below about this process.

## 2. SOURCES OF INFORMATION

### 2.1 Dementia Variables and Reports

Given the complicated nature of dementia classification and the need to tailor reports to specific staff and site needs, ARIC has historically used multiple derived variables for dementia classification across different reports. These variables include, but are not limited to:

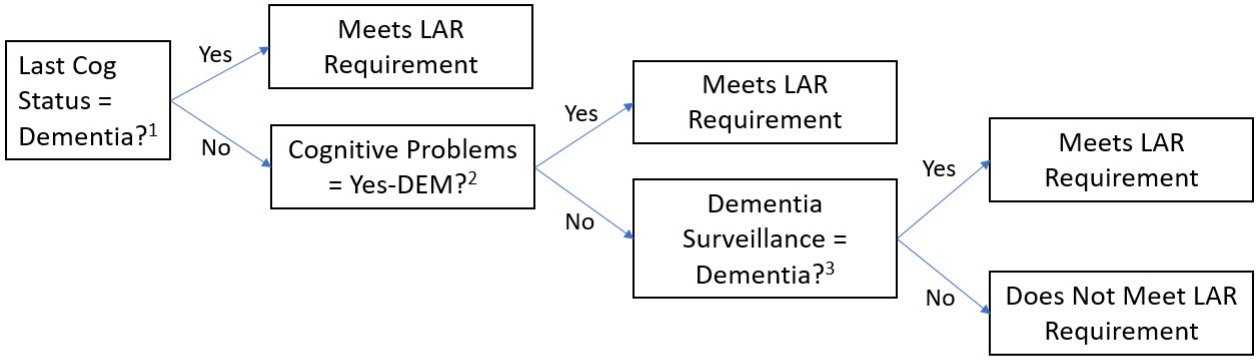
- Cognitive Problems (Yes-DEM, Yes, No)
- Last Dementia Surveillance Test and Results (None, SIS Normal, SIS Impaired, SIS Not Scored, ADS Normal, ADS Impaired, ADS Not Scored)
- Last Cognitive Status (Normal, MCI, Dementia, Unclassifiable)
- Neurocognitive Status (Typical, Atypical, Undetermined)

These dementia variables will continue to be utilized and displayed in reports. However, due to the need to provide reliable and consistent information for the sIRB reconsent process, the CC has

created a new derived variable called “LAR Requirement” (Meets LAR Requirement or Does Not Meet LAR Req). **This variable is derived one time and will not be changing based on future cognitive information.** This variable is based on data retrieved from 7/6/2022. The use of this new variable will ensure that AFU/SAF and Clinic Staff use the same information to determine whether a participant needs a LAR, and therefore if the LAR needs to be contacted to provide consent for the participant. Note, site staff still have the potential to determine the need for a LAR even if the LAR Requirement value of “Does Not Meet LAR Requirement”.

The following chart demonstrates how this new variable is defined.

**Figure 1: LAR Requirement Based on Cognition**




[1] Last Cog Status = RPT50a (Adjudicated Diagnosis from Last Exam)
[2]Cognitive Problems = RPT38a (Level 1 Dementia Diagnosis DEMDXL1)
[3]Dementia Surveillance = DEMDXL2

Staff can find the variable of LAR Requirement in the following reports:

- Annual and Semi-Annual Tracing Sheets
- Recruitment Report
- Snapshot Report.

### 2.2 Consent and Contact Information Tracking

The CC has made updates to the Informed Consent Tracking (ICTX) Form and the Contact Information Update (CIU) Form to reflect the needs of the sIRB reconsent process.

Proxy information is tracked in the CIU form, and changes have been made to allow for site staff to account for multiple proxies. LAR information is tracked in a separate LAR Contact Information (LAR) Form. On this form, staff can identify if the LAR is one of the listed contacts/proxies on the CIU form, or if the LAR is a different person. In cases where the LAR is not one of the previously identified contacts, staff should provide contact information for the LAR on the LAR form.

The ICTX form is **updated every time a participant or a LAR is consented**. The new response option of “LAR” has been added to item 0c and the new response option of “sIRB” has been added to item 0d. At a minimum, items 0a-0d should be updated every time consent is given or retracted. For example, if a participant has previously consented to all items on the ICTX form, and they again provide consent during the sIRB oral reconsent process, the staff member would simply update items 0a-0d, with the new date and time of consent signaling that reconsent has been

completed. The rest of the form should be completed according to the individual wishes of each participant and/or LAR.

If a participant refuses or declines to reconsent, ICTX1 must be updated accordingly. ICTX2 and 3 should only be asked and updated at clinic visits. The default for ICTX4-11 is to remain unchanged unless the participant or LAR specifically requests a change.

Note, a participant provides assent, which is defined as the expression of approval or agreement, when they are not capable of providing consent and a LAR is required. ARIC is not required to record and track participant assent in CDART for the sIRB reconsent process. Therefore, in instances where a LAR is required, the ICTX form would be updated based on LAR consent, and participant assent is assumed.

## 3. RECONSENT PROCESS GUIDE AND FLOWCHARTS

Staff should use the flowcharts and scripts outlined in this section to guide them throughout the reconsent process.

The first step in the process involves determining which ARIC participants to contact (Flowchart A). For participants that will be contacted for reconsent, staff first have the option to send the Reconsent Postcard, which should be sent to participants who may benefit from additional notice about the reconsent process. The Reconsent Postcard should be sent at least one to two weeks prior to sending the ARIC Reconsent Packet.

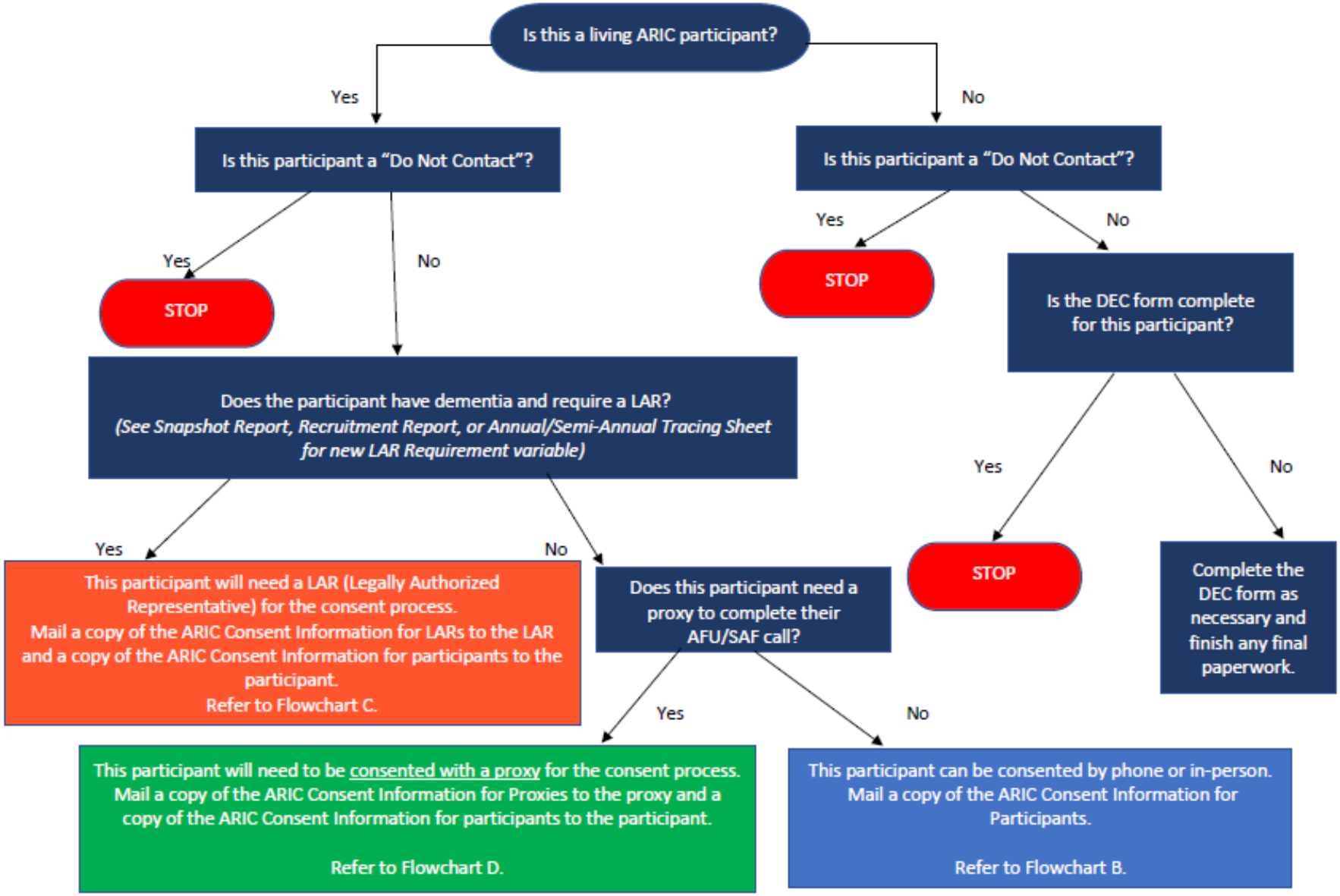
Sites should plan to send the ARIC Reconsent Packet to participants (Flowchart B) and LARs (Flowchart C) **no less than two weeks prior to attempting to gain oral reconsent**, which may occur either via phone or in-person at the clinic. When contacting the participant or LAR to gain reconsent, staff should ask if they received the reconsent packet in the mail. If they did not, staff may continue with the phone call or visit contact, but they should review key items from the Reconsent Packet with the participant.

For participants with a proxy, if the proxy is not the same person as the LAR, then the proxy must also be contacted to obtain their consent for continued participation in ARIC (Flowchart D). Note, proxies are not able to provide consent for the participant and are only providing consent for themselves to continue as a proxy in the ARIC study. For those participants with an identified proxy, staff should also plan to mail the ARIC Reconsent Packet to the proxy no less than two weeks prior to contact.

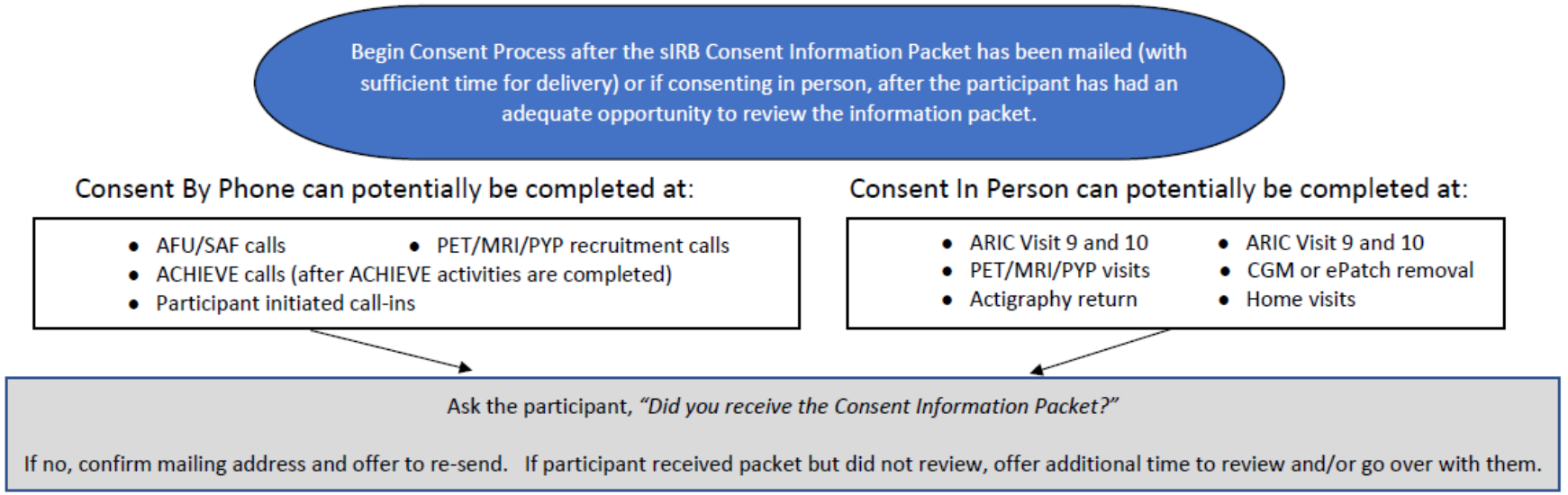
### 3.1 Flowcharts

The following flowcharts outline the steps needed for the reconsent process for the participant, LAR, and proxy.

## A. Sending ARIC sIRB Consent Information



## B. sIRB Consenting ARIC Participants That Do Not Require a Proxy or LAR (Not impaired)




Begin the Consent Process with this script:

*"Thank you for being part of the ARIC research study. As outlined in the packet information, although the ARIC Study has not changed, we have a new administrative committee that has asked us to re-share information with you about your participation in the study. We would like to know if you have any questions about the information packet you received and if you agree to continue.*

*"I would like to review a few key points about the ARIC Study. Feel free to ask any questions that you may have."*

- *"As the information mentions, we would like to continue to contact you at least twice a year by phone."*
- *"Additionally, we would like to continue to access your medical records if you are hospitalized."*
- *"As you may know, the ARIC study keeps the information that we collect about you confidential, insomuch as possible. We will continue to do that in the future."*

*"We would like to know if you have any questions about the information packet that you received and if you agree to continue in the ARIC study?"*

Select from the categories to designate their level of participation but do not read the categories verbatim - allow the participant to express their preference. You can use the field "Other variation" to specify preferences that are not listed.

**The participant agrees to the following contact:**

☐ Full contact without restrictions.

☐ Phone calls and medical records access only.

☐ Limited phone calls or visits ( ____ per _____).

☐ Medical record access only, no other contact.

☐ Limit current contact, but a future phone call is allowable (wait until_____).

☐ No further contact.

☐ No further contact, destroy my stored specimens.

☐ Other variation. Specify:_____.

**Complete the following to record the participant consent:**

☐ Ripple database (sIRB form)

☐ CDART (ICTX form)

Date: _____ ARIC Staff ID:_____

## C. sIRB Consenting ARIC LARs

Confirm that a LAR has been identified for the participant by checking the CIU and LAR Contact Information Form

Begin Consent Process after the sIRB Consent Information Packet has been mailed (with sufficient time for delivery) or if consenting in person, after the LAR has had an adequate opportunity to review the information packet.

Ask the LAR, *"Did you receive the Consent Information Packet?"*

If no, confirm mailing address and offer to re-send. If LAR received packet but did not review, offer additional time to review and/or go over with them.

Begin the Consent Process with this script:

*"As you know, Mr./Mrs. _____ has been a member of the ARIC Study for over 30 years and we appreciate his/her willingness to be a part of this research about older adults and their health. Mr./Mrs. _____ has provided your name and contact information and gave permission for you (as the legally authorized representative) to answer questions about him/her for the ARIC Study in case he/she could not. We are contacting you because the ARIC Study has a new administrative committee. Although the ARIC study has not changed, the committee has asked that we re-share information with you about Mr./Mrs. _____'s participation in the study.*

*"I would like to review a few key points about the ARIC Study. Feel free to ask any questions that you may have."*

- *"As the information mentions, we would like to continue to contact you at least twice a year by phone to ask questions about Mr./Mrs. _____."*
- *"Additionally, we would like to continue to access Mr./Mrs. _____'s medical records if he/she is hospitalized."*
- *"As you may know, the ARIC study keeps the information that we collect about participants confidential, insomuch as possible. We will continue to do that in the future."*

*"We would like to know if you have any questions about the information packet that you received and if you agree to continue as a LAR for Mr./Mrs. _____?"* (Questions about ARIC and discoveries covered on "sIRB Scripts" addendum)

Select from the categories to designate their level of participation but do not read the categories verbatim - allow the participant to express their preference. You can use the field "Other variation" to specify preferences that are not listed.

**The LAR agrees to the following contact:**

☐ Full contact without restrictions

☐ Limited phone calls ( ____ per _____)

☐ Limit current contact, but a future phone call is allowable (wait until_____)

☐ No further contact ***If LAR is not willing to participate and there is no alternate LAR, stop interview, thank LAR for their previous participation, and offer that if they change their mind they can recontact ARIC at any time.) See "Scripts" addendum for assistance.

☐ Other variation Specify:_____

**Complete the following to record the LAR consent:**

☐ Ripple database (sIRB form)

☐ CDART (ICTX form)

Date: _____ ARIC Staff ID:_____

**Now, working with the LAR, obtain assent from the participant.**

Begin the Assent Process with this script:

*"Thank you for being part of the ARIC research study. As outlined in the packet information, although the ARIC Study has not changed, we have a new administrative committee that has asked that we re-share information with you about your participation in the study. We would like to know if you have any questions about the information packet you received and if you agree to continue."*

*"I would like to review a few key points about the ARIC Study. Feel free to ask any questions that you may have."*

- *"As the information mentions, we would like to continue to contact your LAR at least twice a year by phone."*
- *"Additionally, we would like to continue to access your medical records if you are hospitalized."*
- *"As you may know, the ARIC study keeps the information that we collect about you confidential, insomuch as possible. We will continue to do that in the future."*

Ask participant, *"We've been talking with you and _____(LAR) about your participation in the ARIC Study. Do you agree to continue participating?"*

Working with the LAR, select from the categories to designate the participant's level of participation but do not read the categories verbatim - allow the participant to express their preference. Use the field "Other variation" to specify preferences that are not listed.

**The participant (and LAR) agree to the following contact:**

☐ Full contact without restrictions.

☐ No further contact.

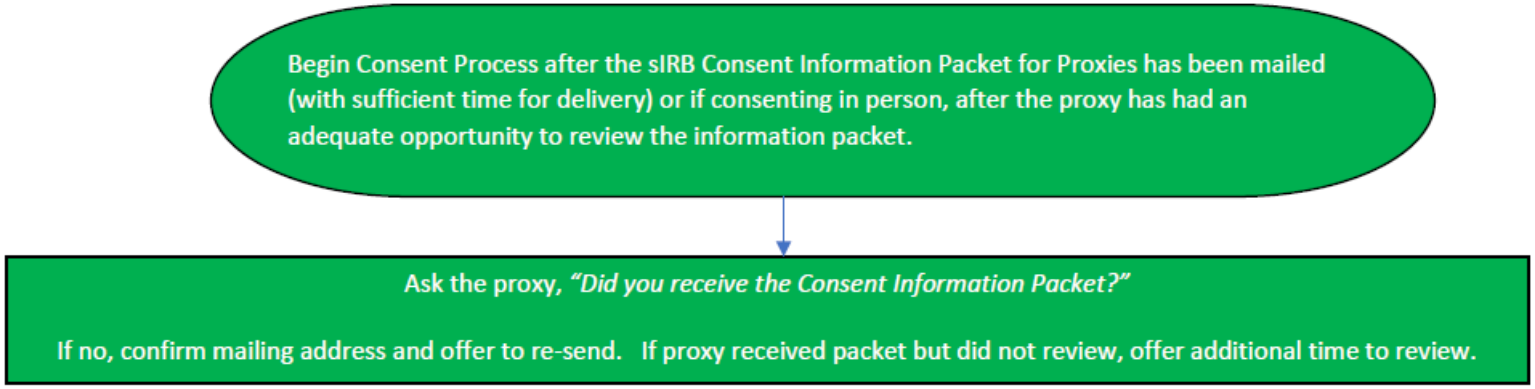
☐ Other variation. Specify:_____

**Complete all of the following to record the participant assent:**

☐ Ripple database (sIRB form)

Date: _____ ARIC Staff ID:_____

## D. sIRB Consenting ARIC Proxies




Begin the Proxy Consent Process with this script:

*"As you know, Mr./Mrs. _____ has been a member of the ARIC Study for over 30 years and we appreciate his/her willingness to be a part of this research about older adults and their health. Mr./Mrs. _____ has provided your name and contact information and gave permission for you (as their proxy) to answer questions about him/her for the ARIC Study in case he/she could not. We are contacting you because the ARIC Study has a new administrative committee. Although the ARIC study has not changed, the committee has asked that we re-share information with you about Mr./Mrs. _____'s participation in the study.*

*We would like to know if you have any questions about the information packet that you received and if you agree to continue as a proxy for Mr./Mrs. _____? "*

Select from the categories to designate their level of participation but do not read the categories verbatim – allow the proxy to express their preference. Use the field "Other variation" to specify preferences that are not listed.

**The proxy agrees to the following contact:**

- ☐ Full contact without restrictions.
- ☐ Limited phone calls ( ____ per _____).
- ☐ Limit current contact, but a future phone call is allowable (wait until_____).
- ☐ No further contact.
- ☐ Other variation Specify:_____.

**Complete the following to record the proxy consent:**

- ☐ Ripple database (sIRB form)

Date: _____ ARIC Staff ID:_____

**Now, working with the proxy if needed, obtain consent from the participant.**

Begin the Consent Process with this script:

*"Thank you for being part of the ARIC research study. As outlined in the packet information, although the ARIC Study has not changed, we have a new administrative committee that has asked us to re-share information with you about your participation in the study. We would like to know if you have any questions about the information packet you received and if you agree to continue.*

*"I would like to review a few key points about the ARIC Study. Feel free to ask any questions that you may have."*

- *"As the information mentions, we would like to continue to contact you at least twice a year by phone."*
- *"Additionally, we would like to continue to access your medical records if you are hospitalized."*
- *"As you may know, the ARIC study keeps the information that we collect about you confidential, insomuch as possible. We will continue to do that in the future."*

Ask participant if they consent to continue. Select from the categories to designate their level of participation but do not read the categories verbatim - allow the participant to express their preference. Use the field "Other variation" to specify preferences that are not listed.

**The participant agrees to the following contact:**

- ☐ Full contact without restrictions.
- ☐ Phone calls and medical records access only.
- ☐ Limited phone calls or visits ( ____ per _____).
- ☐ Medical record access only, no other contact.
- ☐ Limit current contact, but a future phone call is allowable (wait until_____).
- ☐ No further contact.
- ☐ No further contact, destroy my stored specimens.
- ☐ Other variation Specify:_____.

**Complete the following to record the participant consent:**

- ☐ Ripple database (sIRB form)
- ☐ CDART (ICTX form)

Date: _____ ARIC Staff ID:_____