

**HUMAN RESEARCH AFFAIRS**  
**PARTICIPANT RE-CONSENT REQUIREMENTS**

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**New Information or Other Changes**

The informed consent process is an ongoing exchange of information throughout a participant’s involvement in research. During the course of conducting research, new information about the study or changes to the study may arise that affect the rights or welfare of participants. This may include newly identified risks or change in risk severity or frequency, new alternative treatments, decreased potential for benefit, and new study procedures. New information or changes and any accompanying revisions to the protocol, consent form/assent form/information sheet (“consent documents”), or other study documents must be submitted to the IRB for review and approval.

When new information is added to the consent documents that might affect the willingness of already enrolled and active participants to continue in the research, investigators must inform the IRB of the following:

- **Who will be re-consented:** Depending on the change, all participants or only those currently active may need to be re-consented.
  - In some cases, investigators may find that it may not be necessary to re-consent participants who have completed participation in the study to be informed of new information unless the new information relates to risks that may manifest after such participation.
  - It may also not be necessary to inform participants who are still actively participating of new information when the change will not likely affect their decision to continue in the study (e.g., an increase in the number of study participants).
- **When re-consent will occur:** This could be immediate once the change is approved by the IRB, or at the next scheduled study visit.
  - But in **ALL** cases re-consent must be obtained prior to initiating any newly added procedures or study activities.
- **How re-consent will be obtained:** Investigators can obtain re-consent using the updated consent documents, a letter, written notification to participants, or phone calls.

Investigators should follow the IRB approved plan for who is approved to obtain consent. To obtain consent from someone other than who has been approved to obtain consent, investigators must request approval from the IRB.

- Refer to the [Individuals Who Can Obtain Consent in Human Subject Research](#) guidance on Research Navigator.

In the event that the IRB disagrees with the investigator’s re-consent plan described in the Amendment form, the IRB will determine who needs to be re-consented, the timing and method of re-consent, and they will require modifications to the Amendment form to document this determination.

### **Documentation of Re-consent**

When a revised consent form is used to inform enrolled participants of new information and to document their willingness to continue in the study, the participant must sign and date the revised consent document if they are willing to continue participating in the research.

For studies approved to obtain consent from legally authorized representatives (LARs) or parents/guardians, the LARs or parents/guardians must provide re-consent. Re-consent should be documented in participant files and documentation should include what information was provided, by whom, and the date this occurred. The [Documentation of Consent Process Checklist template](#) is available on the Human Research Affairs Compliance and Education Office website.

### **Other Events**

When Other Event submissions are reviewed, investigators may be required to re-consent participants depending on the nature of the event. In some cases (e.g., consent not properly obtained or unanticipated problems), the IRB may ask the investigator to report the status of re-consenting participants.