

Guidance on Re-consent of Research Participants

When is re-consent necessary

Circumstances may arise when it is necessary to re-consent research participants who continue to undergo research related procedures. Although there may be various methods by which to provide this information to participants, the most common approach is to prepare a consent form addendum for participants to sign.

1. Federal regulations at 45 CFR 46.116 (b)(5) and 21 CFR 50.25 (b)(5) state that, when appropriate, the informed consent document include a statement that “significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.” This is particularly true when a substantive change has been made to the study protocol/consent such as:
 - a. new findings that change the risk/benefit profile including the identification of new risks, an increase in the magnitude of known or suspected risks, or a decrease in the expected benefit
 - b. study procedures have been added, modified, or removed
 - c. new alternative treatments become available

2. For research involving the participation of children, federal guidance states the following: “Unless the Institutional Review Board (IRB) determines that the requirements for obtaining informed consent can be waived, the investigators should seek and obtain the legally effective informed consent, as described in 45 CFR 46.116, for the now-adult participants for any ongoing interactions or interventions with the participants.” Therefore, when a minor participant reaches the age of 18 and is still undergoing research procedures, re-consent is necessary. The same is true if previously collected samples are still being utilized, or if medical records will continue to be accessed/reviewed. In some circumstances, the IRB may approve a waiver of consent for these purposes if an appropriate justification can be provided by the investigator.

3. For research involving adult participants with decisional impairment, IRB Policies and Procedures indicate that if the condition causing the participant’s decisional impairment is of an intermittent or temporary nature,

the informed consent process should include a mechanism for obtaining the participant's direct informed consent to participate in the research upon regaining decision making capacity. If a participant regains decision making capacity and declines to continue in the study, the decision must be respected.

4. The original consent was obtained improperly:
 - a. Consent was obtained by an unauthorized individual. For example, at the University of Pittsburgh, a study that involves a drug, device, or surgical procedure requires that the consent be signed by a physician who is listed as an investigator.
 - b. Consent was obtained utilizing the incorrect version of the document. This is only relevant if information in the consent document changed in the newer version. If the only difference between the consent documents is a change in the approval date, this can be handled by a note to file.
 - c. Consent was obtained but the investigator failed to include one of the research procedures or one of the common risks of the study intervention.
5. A change to consent form language is initiated by the IRB, sponsor, or other entity which alters the information originally provided.

Consent is an ongoing process and the investigator should engage the participant in a discussion throughout the study. However, it is not necessary to require active participants to sign a new consent document on an annual basis.

The IRB would not necessarily require re-consent under the following circumstances:

1. Changes to the study team unless this would be considered to be new information discussed under point #1 above. An example of when re-consent might be required in this situation would be a new conflict of interest declaration by a newly named Principal Investigator.
2. Typographical errors noted in the consent document unless the error significantly changes the intent of the sentence. An example of when re-

consent might be required in this situation would be a change from 5 tablespoons of blood to 50 tablespoons.

Methods for Re-consent/Notification

When circumstances arise which necessitate that new information be provided to a research participant, the research team should take into consideration the subject population, the status of the participants, the information to be conveyed, and the length of the consent document. Forms of notification methods include:

- Consent Form Addendum – The IRB recommends use of a consent form addendum when new information needs to be communicated to already enrolled participants. The advantage of using this method of re-consent is that the document consists of three main sections (new information, right to withdraw, and the investigator certification) with the new information being the focus of the document.
- Consent with a Revised Full Document – Some sponsors may require that the full consent document be revised and re-signed by enrolled participants. Although this may be easier for the investigator, it may be less informative for the participants. If this method is utilized, the new information should be highlighted in some fashion.
- Letter - The letter should contain the three elements of consent (new information, right to withdraw, and voluntary consent). The nature of the new information dictates whether participants need to sign and return a copy to the study team. In this case, two copies of the letter should be included; one for the participant to keep and one to be returned with signature.
- Telephone call - The information provided to the participant should be documented in the research record. The documentation should include what information was provided, by whom, and date of the interaction.

If you have any questions about the information in this guidance, please contact the IRB at askirb@pitt.edu. Thank you.