

New Information, Re-Consent



Summary

The intent of this document is to identify mechanisms for providing new information to participants in a manner that is both consistent with the principle of respect for persons and compliant with the requirements of the 2018 Common Rule.

Definitions

Re-Consent- Participants will go through a complete consent process that supersedes the original consent using a document that contains all required elements of consent and is documented in accordance with the federal regulations.

New Information- There is information that should be provided to participants who then have an opportunity to consider the information and reaffirm their willingness to continue participating in the research.

Consent Addendum- Additional consent documentation provided to the participant specific to the new information being provided. Usually requires consent discussion and signature.

New Information Sheet- Similar to an addendum, but less formal. May be emailed, mailed to subjects or given in conjunction with discussion about new information.

Guidance

1. Neither the Common Rule regulations nor the FDA regulations use the term “re-consent” or otherwise describe a process for approving the mechanism for providing new information to participants who are already enrolled in a research study. There is, however, a regulatory provision that when appropriate, significant new findings developed during the research “that may relate to the subject's willingness to continue participation will be provided to the subject”. (§46.116(c)(5)) However, providing new findings is not the same as asking an individual to explicitly review their consent to participate in research and confirm their willingness to continue participation.
2. Instances where changes to the study may affect a research participant’s willingness to continue and therefore should be disclosed to participants are, but not limited to, the following:
 - Identification of new research-related risks
 - Increase in the frequency or magnitude of previously described risks (e.g., serious cardiac event, severe allergic reaction)

- Unanticipated problem that exposes subjects to new risks, such as a data breach.
 - Decrease in expected benefits to participation (e.g., limited efficacy of experimental therapy)
 - Change to the research that results in increased burden / discomfort
 - Availability of new alternative therapies (e.g., FDA approval of a new drug or device for the condition under study)
 - Impact of participation on alternative therapies (e.g., investigational agent reduces effectiveness of alternatives or precludes future treatment with standard of care therapy)
 - Change in drug dosage/device application or in exposure to the drug/device
 - Change in duration of participation in the trial or other changes likely to increase the burdens or discomforts of participation
 - Significant changes in the research study design (i.e., elimination of a study arm)
 - Change in use of specimens obtained in the research (e.g., addition of genetic testing)
 - Changes to medical treatment choices if research subject is injured due to the study
 - Change in the financial burden of participation
 - Changes in the investigator's financial conflict of interest
3. Possible approaches to providing new information include:
- “Re-Consent”- repeat the informed consent process with the revised informed consent document(s) and document consent
 - Use of an “Addendum”- present the new information using an addendum to the original informed consent document and either obtain documentation directly or describe the communication process in the participant’s research records.
 - Orally communicate the new information and document the communication process in each participant’s research records. Can provide New Information Sheet to participants as well.
4. With each of these options, the timing may vary depending on the perceived urgency of the new information. All revised consent documents, addendums, information sheets, changes to the protocol, including who will be given the information, and how, should be approved by the IRB via a Modification.
5. The PI, Sponsor, or IRB may all determine if they feel re-consent is necessary. When submitting modifications related to re-consent or new information, the study team must also include the process of relaying the information and documentation of the process in the modification.



References

Adapted from materials developed by the Collaborative Institutional Training Initiative (CITI Program)

Adapted from materials developed by SACHRPP, "Considerations for re-consent 12.9.2019"

Questions

Contact the IRB at irb@choa.org

