

# Re-Consenting Human Subjects in Research

## Guidelines

If any significant changes are made in a research protocol, or new findings are developed during the course of the research, and such changes/new findings may relate to the subject's willingness to continue participation or may affect the long-term health of the subject, the IRB may determine that the investigator must provide already-enrolled participants in the research with this information. The investigator should use one of the following methods to accomplish this:

- **If previously-enrolled subjects are actively participating in the study**, then at their next scheduled meeting such subjects should be asked to sign either the revised consent form or an addendum to the original consent that presents the changes/new findings, as documentation of their willingness to continue in the research. The addendum will generally be identical to the approved changed consent form pages as presented to the IRB, with deletions shown by strikethrough and additions marked, e.g., by bolding, underlining, and/or highlighting. A clean copy of the entire revised form should also be provided to the subject. Whichever option is selected will be indicated on the amendment request form submitted for IRB approval.
- **If the study is closed to accrual, but subjects are being followed**, the subjects must sign either the revised consent form or an addendum to the original consent that presents the changes/new findings. A clean copy of the entire revised form should also be offered to the subject. Whichever option is selected will be indicated on the amendment request form submitted for IRB approval.
- **If the study is closed to accrual, and subjects are being followed only through phone contact**, the investigators may send the subjects an addendum to the original consent that presents the changes/new findings through the mail. Documentation of their receipt of this addendum may be noted in the written research record at the time of their next phone contact.
- **If the study is closed to follow-up and the significant changes/new findings may affect the long term health of the subject**, the investigator shall attempt to send all prior subjects an addendum at their last known address using certified mail if possible to document receipt. This addendum should contain a name and phone number for the subject to contact should they require additional information.