

8.13 Providing Significant New Information/Findings (SNIF) to Participants

Regulations require that subjects be provided with significant new information/findings (SNIF) developed during the course of the research, which may affect a subject's willingness to continue participation [45 CFR 46.116(b)(5) and 21CFR50.25(b)(5)]. The IRB may require all previously enrolled subjects to be provided with new information concerning these findings.

The IRB must review and approve the new information to be provided to the research participant prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to subjects.

Examples of situations that may require the investigator to provide new information to the study participants consistent with [45 CFR 46.116\(b\)\(5\)](#) or [21CFR50.25\(b\)\(5\)](#) are as follows:

- Changes to the protocol that may affect a subject's willingness to participate in the research.
- New risks are identified or risks were previously described but now are found to occur with greater frequency or severity.

Methods for Providing Significant New Information/Findings to Participants

Although there is no regulatory requirement as to the specific method of providing this information to the subjects, the IRB must review the new findings and the proposed method chosen. It is important that such changes in approved research not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the human subjects [[21CFR56.108\(a\)\(4\)](#)].

If an apparent, immediate hazard to subjects is identified, notification to subjects must be initiated prior to IRB approval and a protocol deviation must be submitted to the IRB as soon as possible. Additionally, an amendment detailing changes to the informed consent and/or protocol should be submitted concurrently, when possible. Further, the Principal Investigator must document/notify as sponsor direct.

If significant new information/findings, do not warrant immediate subject notification, the investigator must inform subjects of the new information/finding using one of the following methods (which do require prior IRB review and approval):

- **Significant New Information/Findings (SNIF) Addendum for Currently Enrolled Participants:** Currently enrolled participants must be provided with a Significant New Information/Findings addendum to the original consent form as a separate document. The addendum provides the new information. When

appropriate, the addendum must clearly state that the information in the previously signed consent form is still current and valid, and that the new information in the addendum is supplementary. Subjects are required to sign a copy of the addendum, and a copy must be kept in the research records. -

Translation of addendum: The IRB will provide a Spanish translation of the Significant New Findings addendum. For study subjects whose language is neither English nor Spanish, a translator must be used. Use of the translator must be documented.

For the HSC addendum template, click: [HSC Significant New Findings](#)

For the UPC addendum template, click: [UPC Significant New Findings](#)

- **Revised Informed Consent Document for New Participants:** New participants must be provided with a revised informed consent document containing the new information. New participants are required to sign a copy of the approved revised informed consent, which carries, in general, the same signature requirement as the old consent, such as a witness and the signature of the person obtaining the informed consent. - **Translation of Revised Informed Consent:** The IRB will provide a Spanish translation of the IRB approved revised Informed Consent. For study subjects whose language is neither English nor Spanish, if the revised English informed consent is utilized, a short form consent must be used.
- **Fact Sheet/Memo/Other:** Participants can be notified of new information by memo, fact sheet or other documentation. In order to utilize this approach, the provision of the new information should itself be justified as a waiver of documentation of Informed Consent under [21CFR56.109 \(c,d\)](#), [45CFR46.116 \(d\)](#) or [45CFR46.117 \(c\)](#).

IRB Responsibilities:

The IRB takes into account whether changes to a study could potentially affect a subject's willingness to continue participation. If this is the case, the IRB must consider if there is a need to provide the SNIF addendum to existing participants and new participants with the revised Informed Consent. The IRB must review and approve any changes in the approved research [[45 CFR 46.103\(b\)\(4\)](#) and [21CFR56.108\(a\)\(4\)](#)], including alterations of the consent (as described in the elements listed at [45 CFR 46.116](#) or [21CFR50.25](#)) or in its timing.

From the USC Human Subjects Protection Program (HSPP) Policy and Procedures (August 2010).
<http://www.usc.edu/admin/provost/oprs/private/docs/oprs/pnp/PnPsFinalWeb.pdf>