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Re-Consenting Research Participants

A Spectrum Health IRB Guidance Document

Purpose

This document provides guidance on when the IRB may require re-consent of a participant.

Regulatory Guidance

45 CFR 46.116
21 CFR 50.25

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.***"

According to the FDA's Institutional Review Boards Frequently Asked Questions – Information Sheet (1998) "Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects (21 CFR 56.108(a)(4)). Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). FDA does not require re-consenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects."

Discussion

After a study is approved, the IRB may determine that research participants must receive additional information about changes or findings that may affect the participants and/or their willingness to continue participation in the research. The IRB will take into account an investigator or sponsor determination to inform or re-consent subjects; however, the IRB will make the final determination about how to notify subjects based upon each individual situation. The below questions are considered to protect the participants' safety and rights.

Which participants need to be notified or re-consented? Does it affect only the participants actively undergoing research intervention, all participants, or a subset of participants? Will the change affect participants differently? If it does, then it should be clearly defined how each subset is affected differently

by the change (i.e., males, females, specific age groups, participants in active treatment, specific study arm, participants off study, etc.).

What is the change and what requires communication?
The IRB will evaluate changes and whether the change may affect a participant's decision to remain in the study. Communication to participants may be required for the following changes:

- Additional risks or changes to risk severity or frequency
- A change in the level of discomfort or other inconvenience
- A procedural change including change in remuneration or reimbursement
- Availability of a new treatment option
- Regulatory, ethical, or policy change
- New research findings
- A change involving a different level of commitment from the participant

When, where and how should a participant be notified or re-consented? The IRB takes into account the above considerations when determining if participants should be notified immediately, before the next study visit, before a specific study procedure, at their next study visit or within a specific time period. It's also important to determine how the notification should be implemented. Depending on the complexity, subject limitations (age, disabilities, language, level of understanding, vulnerable population) and need for interactive explanation, it may need to be communicated in person. However, in some circumstances a letter with a phone follow-up is appropriate. The IRB also takes into consideration the method of notification based on a study participant's status. The IRB will permit the use of a consent addendum or a summary sheet along with the revised informed consent form in certain situations. Consent addendums or summary sheets are typically 1-3 pages and list the new information or findings that may affect the subject's willingness to continue participation. Consent addendums may also be utilized to consent a subject enrolled as a minor who reaches the age of majority during the lifetime of a study. Consent addendums, regardless of the length or source, must be IRB approved prior to use with any subject and will be stamped with an approval date.

When would re-consenting of the participant likely not be required? Re-consenting is not required when only editorial (i.e., fixing typographical errors) or administrative changes (i.e., re-wording a paragraph) are made to the consent form that does not affect the overall content or add new information that may affect a participant's willingness to continue. While there may be situations where the sponsor requires re-consent for editorial or administrative changes, this should not be viewed as an IRB requirement unless the IRB specifically so determines. In addition, see the below examples of other situations when re-consenting may or may not be required.

Study Participant still active in study

Participant Affected by Changes	**Participant Not Affected by Changes**
Examples: • New risk or increase risk of drug • New risk or increased risk of procedure subject will undergo • Changes to compensation Method of Notification: • Re-consent • If next study visit is greater than 30-60 days, notify via phone/letter as well, re-consent at next in-person visit	Examples: • New procedure that the subject will not undergo (such as at baseline) • Arm/treatment not affected by change or risk (on a different treatment) • Subgroup not affected (women only - pregnancy testing) Method of Notification: • Typically, no notification needed

Study Participant has completed procedures and all study visits

Participant Affected by Changes	Participant Not Affected by Changes
Examples: • Newly identified long term or late-occurring risk Method of Notification: • Letter to notify of potential long term or late-occurring risk.	Examples: • Changes to procedure or protocol • Newly identified immediate, short-lasting risk Method of Notification: • Typically, no notification needed.

Conclusions

Investigator Responsibilities

- Inform the IRB, through a modification, of any new information or changes in study design that might have an impact on any subject's willingness to continue in the study. The modification should include a recommendation for the method of notification.
- Re-consent or notify the subjects, as required by the IRB.
- Re-consent subjects prior to their involvement in the procedural change.
- For increased study risks, re-consent the subjects as soon as possible.
- Submit informational letters for IRB approval.

IRB Responsibilities

- The IRB is responsible for determining when re-consent or other notification of subjects is required.
- The IRB may determine that re-consent or other notification is required for some or all of the subjects of the research project.
- The IRB will also determine whether a new signed consent document is required, verbal re-consent, addendum or a letter to subjects if appropriate.