Northwestern University IRB Guidance for Re-Consent / Notification of Study Participants

Purpose:

Throughout the course of a study, there may be new information that the Principal Investigator is responsible for communicating to participants, and this information might affect the participant's willingness to continue on the research study.

Federal regulations at 45 CFR 46.116 (c)(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."

Some examples of new information to be conveyed to participants include:

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; or
d. changes in study contact information.

Re-consent may be required when there are substantial changes to the research or to the participant's condition since providing informed consent. Some examples of situations that may warrant re-consent include:

- Changes in risk information
- Changes in study procedures / study visits (only participants affected by the changes in study procedures/visits need to be re-consented)
- New information that may affect the participant's willingness to continue on study, relevant to the current health or impacts the protection of their rights
- Research in which **pediatric participants** will reach adulthood while the study is still in progress, such as a longitudinal, prospective cohort study that follows children from birth through adulthood
- For research involving **adult participants with impaired decision making capacity**, 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 legally effective 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.

Process:

Develop the study team's re-consent / notification plan

Methods for Re-consent/Notification:

When there is new information that needs be provided to a research participant, the research team should take into consideration the participant population, the status of the participants, the information to be conveyed, and the length of the consent document. The study team should

document the re-consent / notification process within the participant record/study record using a documentation of consent checklist and/or a note to file.

Forms of re-consent and notification methods include:

- **Consent Form Addendum** – This method can be used when new information needs to be communicated to already enrolled participants. The consent addendum should consist of four main sections (new information, right to withdraw, contact information, and voluntary consent) with the new information as the focus of the document. If participants will be mailed a consent addendum and asked to sign and return a copy to the study team, two copies of the addendum should be sent to the participant, one for the participant to keep and one to be returned with the participant's signature. The participant should be given the opportunity to speak to a member of the study team should they have any questions about the new information.

- **Consent/HIPAA Authorization with a Revised Full Consent Form 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 during the re-consent discussion.

- **Participant Letter -** The letter should contain the following elements of consent (new information, right to withdraw, contact information, and voluntary consent). The nature of the new information dictates whether to use a letter or a consent addendum as described above. A participant letter may be appropriate to notify participants of a potential long-term or a late risk when all study/ follow-up visits have been completed.

- **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.

Obtaining IRB Review of Study Updates and Notification Plan:

When submitting a modification (MOD) and/or Reportable New Information (RNI) in eIRB+, please be sure to indicate if current / past participants will be notified of the changes and provide a notification plan. The plan should be documented under the modification rationale section of the MOD submission and within the RNI description field of an RNI submission. If the study team feels that participants do not need to be notified of a study update that would typically require re-consent/notification, please provide justification as to why it is not necessary.

The IRB will review the study team's notification plan and determine whether it is sufficient or if additional measures need to be put in place on a case-by-case basis. The IRB's determination for re-consent or concurrence with the PI's re-consent plan will be communicated in the IRB approval letter.

- Please note that if the RNI submission includes information that requires updates to the consent form, a modification (MOD) submission must also be submitted. Ideally, the RNI & MOD submission should be submitted together for IRB review. However, the IRB understands that the revised consent form / study documents may not be available at the time of reporting an event to the IRB.