To Re-Consent or Not To Re-Consent, That is the Question...

- Informed consent is an ongoing educational process that takes place between the investigator and prospective subject throughout the duration of the study. One may consider that a “re-consent” process is prudent as a means to ensure subjects continue to have an understanding of what participation in the study will entail (e.g., a substantial period of time elapsing between the time consent was obtained and the study begins). However, there are circumstances under which re-consent may be required.

- Regulations require that participants be informed when there is new information that might affect his/her willingness to continue participation [§45 CFR 46.116(b)(5); 21 CFR 50.25(b)(5)]. Many times, re-consent with a current or revised consent form is used to communicate new information to study participants, or to ensure that consent remains legally valid (e.g., a child participant reaches adulthood (18 years old)).

- There are various reasons re-consenting may be required. Examples of cases are:
  - a change in procedure;
  - discovery of new safety information (e.g., changes the risk/benefit ratio);
  - a new alternative treatment becomes available;
  - a child participant reaches adulthood (18 years old);
  - original consent process was not properly executed;
  - fluctuation in the participant’s consent capacity;
  - other changes as required by a sponsoring agency.

- Both the Modification Request Form [WORD] and the Continuation Review Form [PDF] have questions prompting the PI to make the initial judgment on whether the requested change or any new information/findings may affect the willingness of subjects to continue to participate, and if so, how re-consenting will be accomplished.

- The IRB makes the determination “if” and “how” re-consent should occur, and who needs to be re-consented (e.g., all subjects enrolled vs. subjects actively participating). Note, depending on the nature of the new information, the IRB may agree it does not impact currently active participants, and only newly enrolled subjects need to be informed.

- To initiate procedures for re-consenting outside the Continuation Review process, complete and submit a modification request [WORD] to the IRB providing the new information, a proposal for how re-consent will be carried out, and applicable materials to conduct the re-consent process (e.g., a modified consent form; a letter to send to the subject; an addendum consent form). IRB approval should be obtained prior to initiating the re-consent process.

- If the study is approved at Continuation Review (which for active full and expedited review studies occurs at least annually based on the degree of risk), the IRB stamps the informed consent document for the given approval period. Once the continuation review is approved and the consent is stamped by the IRB, the updated stamped consent form should be used for enrollment of future study participants; re-consent of currently active subjects is not required unless there is an IRB or sponsor directive dictating otherwise.

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