NEW INFORMATION: Would you ever need to notify or reconsent a research participant?

Informed consent is a process that involves dynamic and continuing exchange of information throughout a study.

Federal human subject research regulations do not reference the term reconsent. However, the regulations do state that, when appropriate, participants will be provided with significant new findings that develop during the research which may relate to their willingness to continue participation (45 CFR 56.116(c)(5)).

When new information related to the study becomes available, study modifications proposed, or new risks/alternatives identified, investigators notify the IRB. The IRB maintains documentation of significant new findings provided to participants (45 CFR 56.115(a)(7)). The investigator, sponsor, and IRB determine whether reconsent is warranted, or other means of notification is most appropriate. In addition, reconsent may be necessary when a substantial period of time has elapsed since initial consent, or when there is potential for participants to have fluctuations in decision making capacity.

Notification
Provides new information without consent to continue.

Reconsent
Provides new information & documents consent to continue participation.

Communication Methods and Process to Inform Participants

The investigator proposes, and the IRB determines the method or combination of methods for providing new information to future, current, and/or past participants (i.e., notification, reconsent, both).

The following is a list of potential communication methods:

- reconsent with revised consent document;
- reconsent with a consent addendum;
- consent cover letter outlining changes;
- notification letter or email;
- phone consent with a waiver of documentation; and
- phone call with a notification script.

Regardless of the method chosen, participants should be provided with the opportunity to discuss the information with the researchers and the researchers should ensure participants' understanding of the information and appreciation for implications.

Consider the following criteria when submitting justification to the IRB about who, what, and how you propose to communicate new information.

Considerations and Criteria for Determining Communication Method/Process	
• Nature of the information (e.g., protocol change, schedule or procedure change, new risk, new advantageous alternative, minor administrative edits)	• Would it impact a participant's ability or willingness to continue participation? • Does it impact participation (e.g., added study requirements)? • Administrative changes that do not impact rights, welfare, safety or participation do not warrant reconsent.
• Complexity of the information	• Does it need a verbal explanation or would written notification be self-explanatory? • Study personnel communicating new information should be qualified and authorized to obtain informed consent.
• Stage of the research (e.g., recruitment, treatment, follow-up)	• Does it affect current, past, future or a sub-set of participants? For example, a change in enrollment criteria for a multi-site study is irrelevant for sites closed to recruitment.
• Participant population (e.g., all or select sub-set)	• Does it affect all or only select individuals? New risk may apply to a treatment group; however, if the study is blinded, will need to notify all.
• Degree of documentation (e.g., note to file, phone script, written notification, signed consent addendum, or revised consent)	• External sponsors may choose reconsent over notification based on this criterion. However, overuse of reconsent may diminish the participant's perspective of the importance of the consent process.
• Urgency of information (e.g., safety information, schedule change)	• Do participants need to be promptly or immediately informed (e.g., discontinue treatment for safety concerns; breach of confidentiality involving social security numbers)? • When is the next scheduled visit or opportunity for interaction and reconsent?

IRB Application Questions to Assess New Information

- When requests to revise consent documents are submitted, the UK IRB Modification Request Form includes questions to assess whether the change increases risk to study participants, is due to an Unanticipated Problem or Adverse Event (UP/AE), Protocol Violation, or could involve information that might relate to a participant's willingness to continue to take part in the research.

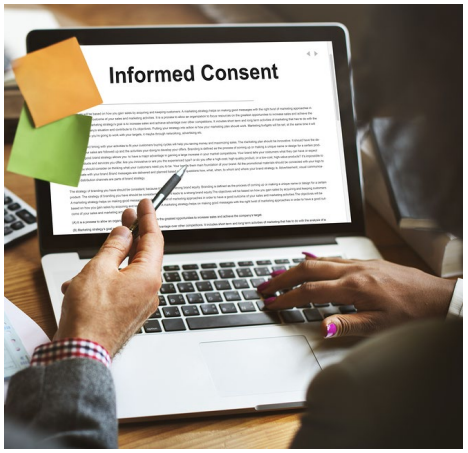
  If so, the researcher is asked to state how the information will be communicated to participants (i.e., reconsent, letter, etc.).

- The UP/AE Forms include questions to assess need for consent revision and whether participants should be informed.

Potential Reasons for Reconsent or Notification

Notification or reconsent may be required for various reasons including, but not limited to, cases where:

- the study protocol/procedure has been modified;
- new safety information exists;
- new alternative treatment becomes available;
- a pediatric participant reaches adulthood (18 years old);
- original consent or process was not properly executed (e.g., participants were consented by individuals not listed on the study personnel list or not HSP trained or using invalid form);
- consent form template language is updated;
- potential for consent capacity to fluctuate;
- a substantial period has elapsed; or
- any other changes as required by the IRB or sponsoring agency.



Reconsent Form and Process

The IRB reviews the revised consent form and materials, as well as the proposed methods and process to reconsent participants. Typically, all **active participants** must be reconsented with the revised form unless the investigator and IRB agree the change does not impact current active participants. To facilitate the reconsent process, provide participants with a cover page outlining the changes and potential impact on participants. Use the IRB-approved revised form for enrollment of future participants.

If no Changes in Consent Form at time of Continuation Review (CR) or Annual Administrative Review (AAR)

At the time of continuation review (CR) or annual administrative review (AAR), if approved, the informed consent is stamped with the new approval date. Use the new approved stamped consent form for enrollment of future study participants. If **no** changes were made to the consent form during CR or AAR, the investigator should not need to reconsent **active participants**.

Some of the material in this guidance was adapted from Cornell Medical College Office of Clinical Trial Administration; University of Kansas Human Research Protection Program, Mayo Clinic Human Research Protection Program, and 2019 AAHRPP Conference Session F3: Revisiting Reconsent: Is it an Urban Legend or a Regulatory Requirement.