

Human Research Protection Program Policies & Procedures



Re-Consent and Notification - Due to New Information or Changes

Version 1.0
Date Effective 5/5/2011

Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-494-5081

Background

Respect for persons requires that research participants, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. One way this opportunity is provided is by using adequate standards for informed consent. The Belmont Report defines the consent process as consisting of three elements: information, comprehension, and voluntariness.

Furthermore, federal regulations dictate that no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The regulations also require that when appropriate, as an element of the consent process, subjects be informed that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation.

Respect for persons must be practiced throughout the research study, not just at the beginning when initial consent is obtained. Therefore, when new information or changes in the research arise that may affect a subject's willingness to continue participation, communicating those changes and potentially obtaining additional consent may be necessary.

I. Scope

This policy describes when new information or changes arising during the course of a research study warrants re-consent and/or notification and provides guidance on the methods through which it may be obtained. Re-consent of subjects reaching the age of majority and subjects regaining decisional capacity are addressed in separate policies.

II. Responsible Parties

- A. IRB
- B. Investigators

III. Policy

- A. The IRB may permit or require re-consent or notification of subjects when significant new information or changes arise during the course of the research that may relate to the subject's willingness to continue participation. Examples of such information include:
 1. Findings of increased risk to subjects;
 2. Addition of new procedures requiring more intervention/interaction with subjects;
 3. New uses of subject data or specimens that do not otherwise qualify for a waiver of consent;
 4. Evidence that the study treatment may not be as effective as originally anticipated or that another treatment may be available;
 5. Significant changes in study schedule; and/or

6. Significant changes in investigator conflicts of interest
- B.** In some cases where new information arises during or after the research has begun, full re-consent may not be necessary or appropriate. Written or verbal notification to subjects or no action at all may be acceptable. In determining the methods to be used to provide subjects with new information, the IRB may consider a variety of factors, including:
1. The significance of the information and the likelihood that it might affect subjects' willingness to continue participation
 2. The subjects' progress in the research (e.g. active study treatment vs. long-term follow-up)
 3. Whether there is a possibility of intervention (now or in the future) based on the new information
 4. Whether re-consent would require unnecessary inconvenience for subjects and/or excessive administrative burden for study staff
 5. Whether re-consent might create additional anxiety for subjects
- C.** Investigators are authorized to act in the best interest of subjects with regard to relaying new information to subjects prior to IRB approval.
1. If an investigator finds it appropriate due to the critical nature of the new information, subjects may be contacted and informed at the next reasonable opportunity, and given an opportunity to withdraw from the study.
 2. If feasible, the IRB must be notified prior to such action.

IV. Procedure

A. IRB Review of New Information

1. Investigators becoming aware of new information related to study participation should evaluate the information and make an initial determination as to the need for re-consent or notification and the format that the communication should take.
 - a. The investigator should submit a modification via the eIRB that includes all changes to study documents and procedures based on the new information.
 - b. A plan for re-consent or subject notification, or justification for taking no action, should be included with the modification.
 - c. If any subjects have already been informed of any of the new information, the investigator should provide a summary of the communications.
2. The IRB will consider the investigator's proposed plan when considering whether to approve the modification. The IRB may require changes to the plan based on consideration of the factors listed above and any other relevant considerations. Specific IRB requirements regarding the re-consent or notification process will be stated in the review communication.
3. Sponsors may require re-consent even when the IRB may not otherwise require it. If the sponsor requires re-consent, investigators should notify the IRB at the time the modification is submitted. The IRB may permit re-consent even if the IRB finds it unnecessary.
4. In rare occasions, the time for IRB review may unacceptably delay communication of new information to subjects. If the PI feels that it is in the best interest of research subjects to notify them immediately of the new information, then the IRB should be notified via "contact IRB" function in the eIRB.

B. Example Methods for Re-consent and/or Notification

1. Re-consent using an updated version of the original consent form. This is the most complete method of re-consent and is best reserved for extensive changes to the study design, procedures, or risks. A cover letter and/or a system for showing subjects what has changed (e.g. highlighting new information) may help improve subject comprehension.

2. Re-consent using an addendum to the original consent form. This may be useful when new information is limited to a relatively narrow topic, such as new or modified risks. It gets quickly to the point and avoids burdening the subject with the entire consent form when most of it is unchanged. For studies that are actively enrolling, the original consent form will still need to be updated.
3. Re-consent using a letter with signature. When subjects are not scheduled for an in-person visit and the nature of the information does not necessitate a personal conversation (because it's a clear or simple change or little action is required), researchers may send subjects a letter and ask them to return a signed acknowledgement. The letter should include a contact phone number that subjects may call if they have questions.
4. Oral Re-consent. Generally, subjects may be verbally informed of new information and asked if they wish to continue participating in the study in situations where the requirement to document informed consent has been waived. Oral re-consent may also precede written re-consent when necessary to relay time-sensitive critical information to subjects.
5. Notification via letter or conversation. Information unlikely to change a subject's willingness to participate in the study may not warrant re-consent. Oral or written notification, depending on the circumstances (such as whether the subject is scheduled for a visit in the near future), may be sufficient.

V. Authority

45 CFR 46.116 and 21 CFR 50.20 provide the general requirements for informed consent.

45 CFR 46.116(b)(5) and 21 CFR 50.25(b)(5) specifically require that, where appropriate, subjects be told of new findings that may affect their decision to continue participation in the research.

[The Belmont Report](#) sets forth three basic ethical principles that guide human subjects research: respect for persons, beneficence, and justice. Informed consent is essential in maintaining respect for persons.

VI. Definitions

Re-Consent – Obtaining informed consent during the course of the research study, after the subject has given initial consent to participate. All required elements of informed consent must be present with regard to the new information, unless waived by the IRB. Subjects must be asked whether they want to continue participating in the study.

Notification – Providing subjects with new information about the study, but not seeking specific consent to continue participation. Subjects retain the right to withdraw at any time.

Legally Authorized Representative (LAR) – An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.