Re-Consenting Requirements

Research is an on-going process which involves the constant re-evaluation of current information and procedures. Therefore, investigators are ethically obligated to keep subjects apprised of all issues related to their participation in the study. New information should be presented to research subjects in a written form and the subjects should be asked to sign a copy of the form or to sign a revised consent form or addendum.

**If a study has active subjects**: It is important to ensure that study subjects are made aware of new contact information, if this information has changed as a result of the change in PI. All active subjects must be notified about the change in PI either using the [Change in PI Letter](https://irb.metrohealth.org/eIRB/sd/Doc/0/A88AS8FAQ08USUKH0K1A4LIG00/Change%20in%20PI%20Letter%20v.%2003-25-24.docx)or by reconsenting using the IRB approved consent that includes the new PI contact information.   Proposed language for communicating the change with subjects must be submitted in the modification request form.

Federal regulations do not require re-consenting of subjects who have completed their active participation in the study, or of subjects who are still actively participating, when the proposed change will not affect their participation. However, when changes do occur in the conditions or the procedures of a study that would affect an individual subject, the investigator should once again seek informed consent from the subjects. Those subjects who are presently enrolled and actively participating in the study should be informed of the change and re-consented if it might relate to the subjects' willingness to continue their participation in the study. Adverse events may occur during a research activity that would directly affect whether prospective or enrolled subjects would wish to continue in a particular research activity. The IRB also does not require a subject re-consent at the time of the study continuation approval, unless there have been modifications to the consent form that would affect an individual subject.

Investigators should note that the IRB requires IRB review and approval prior to an investigator providing subjects with any new research information.

Information also may arise regarding the study which should be shared with previously enrolled subjects after the completion of a study, or a specific treatment or procedure. For example, dysfunctional families may participate in qualitative research examining parenting techniques. Following data analysis, the investigator finds that a specific technique is superior to the other study arms of the project. As agents of a health care and educational institution, investigators are ethically obligated to provide this valuable new information to research subjects.

It is difficult to be confident that subjects truly understand the nature of their participation in research when they are confronted with volumes of complex scientific details in a brief and isolated session. Creating an on-going consent process will facilitate an exchange of information between subjects and investigators in a scientific environment of increasing complexity. By providing subjects with the opportunity to give effective and on-going informed consent in a process that incorporates the free exchange of information between both the researcher and the subject, investigators will continue to set standards for the conduct of ethical research.

**Re-Consenting Subjects Who Are Cognitively Impaired**

Consenting is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study shall apply to subjects whose consent has been provided by a LAR. In addition:

* A subject who regains the cognitive ability to consent as determined by the PI, must be re-consented using standard consenting procedures.
* In the event a subject has been initially consented by a LAR, and a LAR of higher priority subsequently notifies the investigator of that relationship to the subject, the investigator must defer to the higher priority LAR's decision regarding whether the subject will continue to participate or withdraw from the study.
* Investigators shall describe to potential LARs the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures, changes to the study, etc., to ensure that the LAR will be willing to undertake these on-going responsibilities.
* If the LAR dies, the subject must be re-consented subsequently upon any event that would otherwise trigger re-consenting the subject.