IRB AUTHORITY: OBSERVATION OF CONSENT AND CONDUCT OF THE RESEARCH

Description

The IRB has authority to observe or have a third party observe the consent process, and the conduct of the research. See SOP 104: IRB Authority and Signatory Authority.

Observation of Consent

During the initial review of a research proposal, the IRB reviews the proposed consent process. The investigator must provide information regarding the consent procedure so the IRB may determine that the regulatory requirements of consent are met. There may be situations when the observation of the consent process might provide additional protections such as but not limited to:

- Research involving adults with diminished decision-making capacity
- Research involving participants who may be vulnerable to coercion
- Complex projects

If deemed necessary during the subsequent review of the research (e.g. continuing review, review of an amendment to the research proposal, etc.), the IRB may determine observation of the consent process is required.

If the IRB requires the observation of the consent process, the IRB must also determine who will perform the observation of the consent process. The observation of consent may be performed by a member of the IRB, the IRB staff or the Research Participant Advocate (from the Office of the Associate Vice President for Research Integrity).

Documentation of the requirement to observe consent is made in the IRB Member Checklist and if applicable, in the minutes from the convened meeting.

Conduct of the Research

The IRB has the authority to conduct routine audits. The audit assesses the study conduct procedure, identifies errors and omissions, and is a means to provide the investigator with recommendations for corrections and improvements in order to protect the rights and welfare of research participants.

When and if the IRB is concerned about the conduct of a study, the IRB may consider whether, as part of providing adequate oversight of the study, an active audit is warranted. The need for a for-cause audit is determined by the IRB Director, IRB Chair, or by the convened IRB. See SOP 908: Routine and For-Cause Audits.

Points to Address

IRB Member Checklist – Initial Review	**Informed Consent Requirements Page**: The following question prompts the reviewer to indicate whether observation of the consent process is recommended. *"Based on the information provided, may the study be approved without observation of the consent process?"*
IRB Member Checklist – Continuing Review	**Renewal Checklist – Continuing Review Page:** The following question prompts the reviewer to indicate whether verification of information or observation of the consent process is recommended based on the information provided in the continuing review application. *"Based on the information provided, may the study proceed without an audit or observation of the consent process?"*

IRB Member Checklist - Amendment	**Amendment Checklist Page:** The following question prompts the reviewer to indicate whether verification of information or observation of the consent process is recommened based on the information "*Based on the information provided, may the study proceed without an audit or observation of the consent process?"*

References & Links

SOP 104: IRB Authority and Signatory Authority	*http://irb.utah.edu/guidelines/irb-sops.php*
SOP 908: Routine and For-Cause Audits	*http://irb.utah.edu/guidelines/irb-sops.php*
FDA Information Sheet: FAQ (Question 24)	*http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBProcedures*