Title: Changes to An Approved Protocol
SOP # 11
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Subject: Changes to an Approved Study (Modifications/Amendments)

Policy:
All changes to previously approved research require IRB review and approval prior to initiation of the change, except when necessary to eliminate apparent immediate hazards to the human subject.

Procedures:
Investigators are required to submit proposed changes to IRB-approved research prior to initiation of the changes. This requirement is stated in the IRB approval letter issued for all new and continuing approved studies. The only exception to this requirement is when a change is necessary to eliminate apparent immediate hazards to the subject. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.
The IRB Chairperson/designee is responsible for reviewing and determining whether the proposed change is minor or major in nature. This determination will dictate the level of review required, whether full committee or expedited review. IRB administrative staff may assist the IRB Chair/designee and review the materials to determine the level of review required.

Levels of Review and Type of Modification:
Modifications to protocols that were initially reviewed by Expedited procedures or Full Committee may be reviewed by Expedited review if the modification fulfills the criteria below:

Protocols Initially Approved by Expedited Review Process that *May* be Reviewed as Expedited	**Protocols Initially Approved by Full Committee Review that *May* be Reviewed as Expedited**
• The modification continues to pose no more than minimal risk to subjects. • The modifications involve procedures that meet Expedited categories 1 through 7.	• Modifications do not pose an increased risk to subjects; AND • Modifications constitute a minor change to previously approved research (see examples below). • Any added procedures must fall within Categories 1-7 of research that may be reviewed using the expedited procedure.

Examples of ***minor*** and ***major*** changes to previously approved research:

Minor Changes	Major Changes
• Administrative changes • Minor consent form changes • Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods. • Minor changes to study documents such as surveys, questionnaires or brochures • New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved • Changes in payment to subjects of the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study • Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study • Editorial changes that clarify but do not alter the existing meaning of a document • Addition of or changes in study personnel • Addition of a new study site (in many but not all cases) • Translations of materials already reviewed and approved by the IRB	• Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects • Changes in inclusion/exclusion criteria that impact the risk level of the study • Significant changes in the study design, such as the addition of a new subject population or the elimination of a study arm • New risk information that is substantial or adversely affects the risk level of the study • Significant changes to the study documents to be distributed to or seen by subjects • New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB • New or revised financial conflict of interest management plans

Submission of Proposed Changes to the IRB:
Proposed changes to a study are submitted to the IRB using the Modification submission form found in Cayuse IRB. The submission summary must include a description of and justification for the proposed change(s) and information about any change in the level of risk to the study participants. The Modification submission form should make all related changes within the submission sections as appropriate and provide any study documents that require changes.

Review Procedures:
Expedited Review and Approval - The IRB Chair/designee reviews the Modification submission. When the changes have been approved, the approval will be documented in Cayuse IRB. An email approval notification will be sent to the researchers. The submission and approval will remain in the electronic Cayuse IRB record of the study. Researchers must ensure that a copy of the Modification and approval or access to the file in Cayuse IRB be available for inspection.

Under expedited review, a change cannot be disapproved; however, the IRB Chair/designee can recommend that the change be reviewed by the full IRB.

Federal regulations require that all IRB members be informed of all changes to ongoing research approved through the expedited review procedure. The IRB administration satisfies this requirement by inclusion of this information on all IRB agendas.

Full Committee Review and Approval – The IRB will review the Modification at an IRB meeting. When the changes have been approved, the approval will be documented in Cayuse IRB. An email approval notification will be sent to the researchers. The submission and approval will remain in the electronic Cayuse IRB record of the study. Researchers must ensure that a copy of the Modification and approval or access to the file in Cayuse IRB be available for inspection.

References:
45 CFR 46.110(b)(2)(c)

Institutional Review Board Management and Function by Elizabeth A. Bankert and Robert J. Amdur, Chapter 7, Revisions to an Approved Study

UCLA OHRPP Guidance and Procedure: IRB Review Type – Amendments to Previously Approved Research