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107: Modifications to Nonexempt Research

The intent of this Standard Operating Procedure (SOP) is to describe when it is necessary to submit a protocol modification at Illinois State University (ISU) and how the modification will be reviewed. Investigators are responsible for obtaining prior approval from the Institutional Review Board (IRB) for any modifications of previously approved research before implementing the proposed changes. This SOP is for use by anyone who conducts human subjects research (HSR) approved by the IRB.

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1. Modification of Approved Protocols

Federal regulations require that proposed changes to a protocol must be reviewed and approved by the IRB. prior to implementing the proposed changes. The only exceptions are for emergency actions to eliminate immediate harm to subjects (which must still be submitted within 1 business day), correction of typographical errors that do not impact understanding on the part of the subjects, or other administrative corrections such as updating contact information.

The PI must submit a modification submission in the electronic IRB submission system along with any revised supporting documents (such as changes to instruments or informed consent documents). Modifications to studies that have received an exempt determination have different requirements, which can be found in SOP 105: Exempt Research.

2. Review Process

Minor modifications to Expedited Review studies that do not change the overall nature of the approved research protocol may be reviewed and approved by the Human Subjects Research Specialist as delegated by the IRB Chair. Examples of minor modifications might include: expanding the subject pool size (due to a low initial participation rate), changing a data collection form to make it easier for subjects to read, changes in personnel other than the PI, or adding site permissions or an additional field site similar to those already being used. The HSRS may also choose to refer minor modifications of Expedited Review studies to the IRB Chair/Vice Chair for review on a case-by-case basis.

Significant changes to Expedited Review protocols including but not limited to, changes in the objective of the study as originally submitted and approved by the IRB, changes which increase risk to the subjects (such as those resulting in greater discomfort or in a greater degree of invasiveness), and a change in PI are reviewed and approved by the IRB Chair provided that the proposed changes do not increase the risks to participants. Changes in Expedited Review protocols that result in more than minimal risk will require Full Board Review and the protocol will thenceforth be designated as Full Board Review and require annual renewal.

For protocols originally designated as Full Board Review, modifications must be reviewed by the IRB Executive Committee at a convened meeting with the exception of changes in personnel other than the PI and submissions of site permission which may be approved by the HSRS. Modifications requiring review by the IRB Executive Committee are subject to the same submission deadlines as new protocols; modifications reviewed by the HSRS are not subject to the submission deadline.
As with an initial review, the requested modification may be approved, approval withheld pending minor revisions, denied, or tabled for further consideration. If approved, the revised protocol will carry the same approval period as the original approval. Modification approval does not change the expiration date of the study. If the modification request is denied, the originally approved research may still continue for the approval period.