

Health Sciences Institutional Review Boards

GUIDANCE FOR RESEARCHERS REGARDING EXPEDITED IRB REVIEW OF MINOR CHANGES OF PROTOCOL

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BACKGROUND AND REGULATORY BASIS

The purpose of this document is to provide guidance to researchers and others regarding the procedures and guidelines followed by the Health Sciences Institutional Review Boards (HS IRBs) related to the expedited review of minor changes of protocols. The Common Rule (45 CFR 46.110) and FDA regulations (21 CFR 56.110) allow for the review under expedited procedures of “certain kinds of research involving no more than minimal risk” and “minor changes in previously approved research during the period (of one year or less) for which approval is authorized” by the IRB Chair or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB **except that they may not disapprove the research**. Any expedited approvals must be reported to the full IRB.

UW-MADISON HEALTH SCIENCES IRBS GUIDELINES

The HS-IRBs have restricted the review of expedited changes to include those that are minimal risk, administrative in nature, represent minor clarifications of study procedures approved previously by the full IRB, do not significantly change the study design, or do not alter the risk/benefit ratio of the study. To qualify for expedited review, the change cannot adversely affect the risk/benefit ratio of the study. Changes that require assessment by a medical reviewer to determine the impact on the risk/benefit ratio of the study generally are reviewed by the full IRB.

If a researcher submits a *Request for Review of a Minor Change (Expedited Change) Form* or *Personnel Change form* and the IRB reviewer(s) determine(s) the change does not qualify for expedited review, the reviewer(s) will either:

- a) forward the materials the researcher submitted to the full IRB for review if the reviewer feels that sufficient information is present for the IRB to make a decision related to the proposed change
- b) return the change and accompanying materials to the researcher with a request for the researcher to resubmit the request using the Change of Protocol Form and describe the reason(s) the change does not qualify for expedited review.

Examples of changes that generally CAN be reviewed under expedited procedures:

- administrative changes
- minor consent form or HIPAA authorization form changes
- changes to recruitment materials or submission of new recruitment materials that are easily compared to the approved consent form
- increase in local enrollment, as long as study-wide enrollment does not increase from what was approved previously
- minor changes to study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures)
- new study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures) that are similar in substance to those already approved by the convened IRB
- changes in payment to subjects or the amount subjects are paid or compensated that are not so great as to affect the risk/benefit ratio of the study

- **Note: If the study involves children, the issue of remuneration may require full IRB review if the full IRB has not agreed to compensation previously**
- increase in number of study visits to increase subject safety
- 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 (protocol or consent form)
- minor study design changes that are minimal risk and which do not significantly alter the risk-benefit ratio of the study
- requests for the inclusion of activities that fall under the categories of allowable expedited review set forth in 45 CFR 46.110
- addition of study personnel locally or changes in cooperative group personnel that result in a revised protocol
- addition of a new study site
- certified translations of materials already reviewed and approved by one of the HS-IRBs

Examples of changes that generally CANNOT be reviewed under expedited procedures:

- changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects
- changes in inclusion/exclusion criteria that require assessment by a medical reviewer as to the impact on the risk/benefit ratio of the study
- addition of or changes to medical procedures (e.g., dosage changes, alterations in the route of administration of a study drug , extension of the treatment period), except those specified by the Office of Human Research Protections (see <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>) as presenting minimal risk and which can be reviewed under expedited procedures
- significant changes in study design (e.g., addition of subjects, eliminating a study arm, addition or elimination of a phase)
- new risk information that is substantial or adversely affects the risk/benefit ration of the study
- study-wide increase in number of subjects to be enrolled
- extending the duration of a clinical trial (unless for a brief period)
- significant changes to study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures)
- new study documents to be distributed to or seen by subjects (e.g., surveys, questionnaires, brochures) that include information or questions that is substantively different from materials already approved by the convened IRB
- deletion of study procedures, visits, or procedures that may impact subject or study safety adversely
- changes in radiation or biosafety