Expedited Change of Protocol Guidance

Version Date: January 21, 2008; Revised December 1, 2012

Guidance for researchers regarding expedited review of minor changes of protocol

BACKGROUND AND REGULATORY BASIS

This document is to provide guidance to researchers and others regarding the procedures and guidelines followed as conducted 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 designated experienced reviewers designated by the chairperson from among members of the IRB member. 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

Criteria for Expedited Review of Changes of Protocol

The HS-IRBs have restricted the review of changes to include those that are minimal risk, or administrative in nature, AND:

• represent minor clarifications of study procedures approved previously approved by the full convened IRB,
• do not significantly change the study design, or AND
• do not alter the risk/benefit ratio of the study. To qualify for expedited

In addition, the HS-IRBs will typically review changes to non-exempt medical records studies under expedited procedures unless the change cannot adversely affect the risk/benefit ratio of PI is being changed, significant changes are being made to the aims or purpose, and/or changes are such that the study. Changes that will no longer qualify as a non-exempt medical records study.

Please see the Expedited Changes Examples table for specific examples of what changes may be reviewed under expedited procedures and when such changes may require full IRB review.

Criteria for Referring Expedited Changes for Full IRB Review
At its discretion, the HS-IRBs office may refer changes submitted as expedited for full IRB review. This may occur for reasons such as (but not limited to) the following:

- The change does not meet the criteria for expedited review provided above.
- The change requires assessment by one or more medical reviewers to determine the impact reviewers.
- The change is for a study that enrolls prisoners.
- The change requires input from other committees on the risk/benefit ratio of the study generally are reviewed by the full IRB campus (e.g., conflict of interest, RDRC) or consultants (e.g., legal services).

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 involve multiple revisions or changes that may individually qualify for expedited review, the reviewer(s) will either:

- forward the materials the researcher submitted but collectively represent a substantial change 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/ study.
- 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 C.F.R. 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 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 ratio 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

• Numerous changes have been made to a study within the previous 6 months, such that a reassessment of the full scope and purpose of the study may be warranted.