

<b>Grand Valley State University Human Research Review Committee Procedure</b>	
Subject: <i>HRRC-required changes to protocols following initial review.</i>	
Section: 8.0	This procedure supersedes those previously drafted
Initially adopted as procedure on June 18, 2007	<b>Approved by:</b> Dean of Graduate Studies and Grants Administration, 11-15-2007.
Related Sections:	

If upon initial or continuing review the HRRC determines that a protocol application requires changes to be compliant with federal regulations, current ethical standards, or the safety of research subjects, it shall inform the investigator of the required changes and require resubmission or amendment of the protocol, at the discretion of the reviewers. Resubmission of revised or amended protocol applications normally should be made by the investigators within 60 days of receiving the HRRC response letter. After 60 days the protocol application will be closed by the HRRC unless the investigator requests in writing for an extension to respond, which normally should be granted. Revisions normally should be reviewed by the same HRRC members who conducted the initial review whenever possible.

Changes submitted by investigators to protocols that have been reviewed and approval tabled by the HRRC for deficiencies in the submitted application materials will be considered for approval in the same manner in which the initial review was conducted. Specifically, changes to full board reviewed protocols will normally be considered for approval at the next regularly scheduled full board meeting. Changes to expedited reviewed protocols will normally be considered for approval by the same reviewers who conducted the initial expedited review.

Exceptions:

**Full board reviewed protocols.** At the discretion of the full board, where no more than minimal risk to enrolled subjects is anticipated, the board may authorize a named subcommittee of board members, or the Chair of the HRRC, to review and approve the required revisions and clarifications under expedited review and approval procedures. This authorization must be a separate vote in accord with normal HRRC voting procedures. The vote to authorize the

subcommittee or Chair must be taken at the time of decision to table approval, and recorded in the meeting minutes.

**Expedited reviewed protocols.** At the discretion of the initial reviewers, the Chair of the HRRC may be authorized to review and approve the required revisions and clarifications under expedited review and approval procedures. This authorization must be explicitly written in the reviewers' initial remarks indicating recommendation to table the protocol pending satisfactory revisions.