

<b>Grand Valley State University Human Research Review Committee Procedure</b>	
Subject: <i>Investigator-initiated changes to an approved protocol.</i>	
Section: 8.1	This procedure supersedes those previously drafted
Initially adopted June 18, 2007 Revised November 9, 2010	<b>Approved by:</b> RIO/HRPA 11-09-2010.
Related Sections: 8.0	

### **Exempt Studies**

If a proposed modification to an HRRC approved exempt research protocol does not alter the level of review required (i.e., does not require upgrading to expedited or full board review), the investigator may implement the change and report it to the HRRC in the annual protocol update submitted. A separate Change in Protocol application is not required. This applies only to exempt studies.

### **Non-Exempt Studies**

If an investigator proposes to modify a non-exempt research protocol that previously was approved by the HRRC, the investigator must submit a Change in Protocol form and receive HRRC approval of the proposed modification before implementing it. The only exception to this is if the modification is designed to eliminate an apparent immediate hazard to study participants (45 CFR 46.103(b)(4)). If the modification is done to eliminate an immediate hazard to participants and without prior HRRC approval, the investigator must report the change(s) promptly to the HRRC. The federal regulations allow for expedited review and approval of requests for minor changes in previously approved studies (45 CFR 46.110(b)(2)).

1. If the proposed modification is to waive informed consent, approval requires review by two board members and the chair or a vice-chair (3 votes total). Approval requires a majority vote of the three reviewers. Reasons for any no votes must be documented in the protocol file.
2. **Minor** changes to a non-exempt protocol may be approved administratively.
3. **Major** changes to a non-exempt protocol must be approved by the original reviewer(s) plus the chair or a vice-chair. Approval requires a majority vote of the three reviewers. Reasons for any no votes must be documented in the protocol file. Major changes include changes to one or more of the following:

- key personnel\*
- research procedures;
- informed consent/assent process or documentation;
- study target population;
- substantive venue changes for interacting with subjects;
- advertising/recruitment procedures

\*Key personnel are defined as any persons directly involved in interactions or interventions with study participants or with direct access to participants' personally identifiable information.