

<b>Grand Valley State University Human Research Review Committee Procedure</b>	
Subject: <i>Unanticipated Problems</i>	
Section: 13.0	This procedure supersedes those previously drafted
Initially adopted as procedure on June 18, 2007	<b><i>Approved by:</i></b> Dean of Graduate Studies and Grants Administration, 11-15-2007.
Related Sections:	

Investigators are required to report to the HRRC in writing all unanticipated problems that potentially may involve risks to subjects. Any unanticipated problem that also constitutes an adverse event should be reported for review. The HRRC chair in consultation with at least one Vice-Chair shall determine:

- a. whether the reported unanticipated problem or adverse event constitutes a risk or harm to enrolled subjects or others,
- b. whether the investigator has adequately addressed the problem, and
- c. whether corrective or protective actions are required.

The necessity of additional reports to offices or officials at GVSU, OHRP, sponsors, or others will be determined by the HRRC chair, and such reporting shall be made by the investigator, HRRC chair, or both, as appropriate.