

Grand Valley State University Human Research Review Committee Procedure	
Subject: <i>Responding to Reports of Possible Unapproved Research Activity Involving Human Subjects.</i>	
Section: 2.3	This procedure supersedes those previously drafted
Initially adopted as procedure on October 6, 2009	Approved by: Human Research Protections Administrator, October 14, 2009
Related Sections: 2.0; 2.1; 2.2	

GVSU holds a Federalwide assurance which obligates it to exercise due diligence in monitoring compliance with GVSU and HRRC human subjects research policies. When possible noncompliance is reported to the HRRC, initial inquiry is conducted and reporting of findings to the GVSU Human Research Protections Administrator/Research Integrity Officer (HRPA/RIO) is required. Report may include recommendations for further action.

Procedural steps

1. HRRC office receives a report or makes a discovery of possible unapproved research activity.
2. Determine if report involves covered research on live human subjects. If not covered research, terminate inquiry. If covered research proceed to step 3.
3. HRRC protocol database cross-referenced for record of questionable research activity. If record is found indicating research was properly approved, terminate inquiry, otherwise proceed to step 4.
4. Inquiry letter sent from HRRC to PI (and to faculty advisor if PI is a student). Letter requests responses to 10 standard questions (see attached template) with response requested in two weeks. If response to questions satisfies the HRRC Chair the inquiry is terminated and a letter sent to the PI indicating closure of inquiry without bias. If PI response is not received or is unsatisfactory to the HRRC Chair proceed to step 5.
5. Send a second letter to PI with cc to PI's unit head, requesting PI to meet with HRRC subcommittee, and proceed to step 6.
6. Subcommittee assigned by HRRC Chair meets with principals (e.g., PI, advisor (if any) unit head, if appropriate, etc). If meeting resolves the inquiry to the satisfaction of the HRRC Chair and subcommittee, inquiry is terminated. If meeting fails to reach resolution proceed to step 7.
7. HRRC Determination letter is sent to the PI with copies to HRPA and other administration officials as appropriate, specifying unresolved issues and requesting PI attendance at the next available HRRC regular full board meeting. If HRRC board meeting resolves the inquiry to the satisfaction of the HRRC a vote to that effect is recorded and the inquiry is terminated. If unresolved issues remain proceed to step 8.
8. HRRC Chair sends a letter to HRPA/RIO with copies to affected PI and unit head, summarizing the HRRC's initial inquiry steps, findings, any remaining unsettled matters of fact, and recommendations for further action, if any.

