

Grand Valley State University Human Research Review Committee	
G-13: <i>Multi-Institutional Collaborative Research Projects</i>	
Issued: October 29, 2013	Office of Research Compliance and Integrity

Multi-Institutional Collaborative Research Projects

The following guidance is provided to assist researchers and reviewers in determining the need for IRB review and approval of a collaborative research project between GV and non-GV researchers

The role of researchers in studies involving human subjects may be divided into three general categories:

1. Principal Investigator (PI) or co-PI
2. Key personnel (interact or intervene with study subjects or have access to participants' personally identifiable information)
3. Secondary personnel

The primary review of the protocol is the responsibility of the PI's home institution IRB. If neither PI or co-PI are GV researchers, the HRRC requires evidence of IRB approval from the PI's home institution and will seek to establish an *Inter-institutional Authorization Agreement* that specifies which IRB is responsible for which study components including review, approval & reporting requirements.

The HRRC's role may be **any** of the following:

1. No role; the IRB review is deferred to the PI's institutional IRB;
2. Comprehensive review; a duplicate review in addition to the PI's institutional IRB review. Any required modifications or clarifications must be coordinated between the two IRBs;
3. Review limited to the involvement of the GV researcher since that is the extent to which GV is engaged in the research;
4. A mutually agreed upon cooperative division of responsibilities as determined by the Chairs of the affected IRBs.

De-Identified personal information

The HRRC has determined in consultation with S. Smith from OHRP that analysis of de-identified study data where two conditions are met is not research on human subjects.

The two conditions are:

1. the person doing the analysis was not functioning as a PI, co-PI or key personnel, **and**

2. there is no link between the data and personal identifiers (including demographic clusters), **or**
(c) there is a written agreement that the existing link will never be shared until all participants are deceased.

This applies ***if and only if*** the GV researcher is using the data for a secondary purpose than that for which it was initially collected. If the research analysis is on information originally collected as part of an original research study and intent then the communication and information "firewalls" between the GV researcher and the participants' personally identifiable information must be determined by the HRRC or HRPP staff to be adequately secure.