

Grand Valley State University Human Research Review Committee	
Title: <i>Continuing review and approval of selected non-exempt protocols</i>	
Section: 910.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 10/29/2013 Revisions approved: 01/14/2014	Approved by RIO/HRPA: 02/10/2014
Related Sections: 911 <i>Exemption determinations and research ethics standards</i>	

Policy

Under the current federal regulations for human research, non-exempt studies must undergo continuing review of the research at least annually, depending on the degree of risk to the subjects. Many research studies under the oversight of the HRRC pose no more than minimal risk to the subjects. Thus, it is unlikely that HRRC determinations about potential benefits, informed consent, or risks to subjects would be affected by new information gathered directly from the research interim results or from other sources if the approval period were lengthened beyond one year.

To exercise existing flexibility in the application of federal regulations to non-federally funded studies, the HRRC will undertake a demonstration project (i.e., pilot) to assess the feasibility of issuing *two year* approval periods for certain types of studies. The longer approval period will eliminate the need for principal investigators to submit scheduled continuing reviews on an annual basis. This demonstration project is limited to five years, ending on December 31, 2018. It will be eligible for renewal or permanent adoption at that time. This demonstration will begin on January 1, 2014.

Procedures

To qualify for two-year approval studies ***must***:

- Pose *no more than minimal risk* to subjects (initial review may be expedited or full board)
- Receive the recommendation for a two year approval from all HRRC reviewers

and

Must not include any of the following:

- Student PI led research
- Federal funding or federal training grants
- FDA regulated components
- Sponsor or other contractual restrictions
- Prisoners as subjects

HRRC applications granted a two-year approval may not be used to support proposals or future awards involving federal funding. Contact the ORCI office for instructions if federal funding is anticipated.

Background

Grand Valley State University (IORG0002093) maintains a federalwide assurance (FWA00002829) with the Department of Health and Human Services (HHS) in which it pledges to comply with federal regulations for all federally supported research. This includes using the ethical principles of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research) for guidance. The GVSU authored FWA limits compliance assurance to federally funded studies and does not include the additional provisions of the subparts B, C and D. This limited commitment allows the HRRC (IRB00002615) some flexibility in its application of federal regulations to

studies that are not federally funded. While continuing to apply the highest ethical standards for the protection of human subjects, this initiative will decrease the administrative burden on investigators.

What does this mean?

New or renewing applications meeting the criteria cited above will be reviewed by the HRRC to determine that subject protections comply with federal regulations. If appropriate protections are in place, and there are no additional extenuating circumstances, the HRRC can issue a two year approval. All other regulatory requirements, including amendments, adverse event and other required reporting, remain unchanged.