

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 Revisions approved by HRRPPC: 03/28/2018	Approved by RIO/HRPA: 02/10/2014 Revisions approved by AIO/RIO: 4/16/2018
Effective Date: 05/01/2018	
Related Sections: 121: <i>Review standards for research not covered by FWA</i> 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:

- 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.