Grand Valley State University Human Research Review Committee	
Title: *Continuing review and approval of selected non-exempt protocols*	
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: 04/24/2018	Approved by RIO/HRPA: 02/10/2014 Revisions approved by AIO/RIO: 05/23/2018
Effective Date: 01/21/2019	
Related Sections: 121: Review standards for research not covered by FWA 911: Exemption determinations and research ethics standards	

Policy

Under the current federal regulations for human research, some 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.

Protocols approved prior to January 21, 2019 (before the revised Common Rule was implemented) will be subjected to continuing reviews—as stated in the 45 CFR 46 regulations prior to January 21, 2019—until a determination has been made that a continuing review is no longer necessary. Protocols approved after January 20, 2019, will be subjected to the new changes to the 45 CFR 46 regulations.

Procedures

1. Protocols approved after January 20, 2019

*Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research eligible for expedited review in accordance with §46.110;
- Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

  (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

  (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. (46.109 (f)(1).

2. Protocols approved prior to January 21, 2019

The existing approval period for studies approved under the expedited review process prior to January 21, 2019, will be retained. When a study is submitted for continuing review or for a change in approved research, the chair or designated reviewer(s) may determine that the revised Common Rule regulations

apply and that continuing review is no longer required. This determination can only be made if the research complies with all applicable elements of the revised Common Rule. If any part of the research is not in compliance with the revised Common Rule, the research must remain under the previous version of the Common Rule (i.e., the version of the Common Rule that was in effect when the protocol was originally approved) or it must be amended to bring it into compliance with the revised Common Rule. (E.g. if participants are still being enrolled in the research, the consent document must be updated to include any additional elements required in the revised Common Rule.)

It is not required that all existing research comply with the revised Common Rule. If the researcher chooses to remain under the previous version of the Common Rule, this will be permitted. In these cases, the HRRC may approve a non-exempt study for a two-year approval period following the previously established guidelines below.

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

Note: HRRC applications granted a two-year approval period will need to be revised if the study receives federal funding. Contact the ORCI office for instructions if federal funding is anticipated.