Grand Valley State University Institutional Review Board (IRB)	
Title: *Modifications to Approved Protocols*	
Section: 1010.	This policy and procedure supersedes those previously drafted.
Approved by HRRC: 3/13/2011 Revised by HRRPPC: 11/28/2017 Revisions Approved by HRRPPC: 10/23/2018 Revised by IRBPPC: 01/26/2021 Revised by IRBPPC: 03/30/2021	Approved by RIO/HRPA: 03/15/2012 Revisions approved by AIO/RIO: 04/16/2018 Revisions approved by AIO/RIO: 12/19/2018 Revisions approved by AIO/RIO: 03/01/2021 Revisions approved by AIO/RIO: 05/06/2021
Effective Date: 05/06/2021	
Related documents: *900: IRB Protocol Review* *911: Exemption Determinations and Research Ethics Standards* *1020: Reportable Events: Protocol Deviations, Unanticipated Problems and Adverse Events* *1030: Research Noncompliance* *1040: Post-Approval Compliance Review* *1050: Suspension or Termination of Research Activities* *1060: Closure of Approved Research Studies* *1070: Responding to Concerns and Complaints About Human Subjects Research Activities*	

Policy

1. Proposed Modifications (Non-exempt studies). Researcher initiated modifications to non-exempt research studies may not be initiated without prior written IRB approval except as provided for under the Emergency Modification Rule. This includes any modifications including those required by other entities (e.g., additional IRBs with oversight responsibility).

2. Proposed Modifications (Exempt studies).
    a. With the exception of personnel additions, if a proposed modification to an exempt research protocol does not alter the level of review required (i.e., does not require upgrading to expedited or full board review), in part or in total with previously made changes, and does not increase the risk-to-benefit ratio, the researcher may implement the change without prior approval from the IRB. Reporting to the IRB is not required. This authorization applies *only* to exempt studies.

    b. Proposed personnel additions to exempt studies may not be initiated without prior written IRB approval. Authorized Office of Research Compliance and Integrity (ORCI) staff members may approve personnel changes to exempt studies on behalf of the IRB without additional review by the IRB.

3. Required Modifications. The IRB may require modifications to any protocol at any time in order to minimize risks to study participants or to enable researchers to comply with changes to federal, state, or local laws/mandates, or institutional policies.

4. Emergency Modification Rule. If a researcher determines that a study modification is necessary in order to minimize emergent and immediate risks of harm to enrolled or future study participants, the modification(s) may be implemented without prior IRB approval. In compliance with *IRB Policy #1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events,* within seven (7) calendar days following implementation of the modification the IRB chair must be notified in writing of the nature of the risks, the steps taken to minimize the risks, and any additional proposed modifications to minimize future risks (45 CFR 46.108(a)(3)(iii)). Final acceptance of the proposed modification is subject to IRB approval under normal review procedures.

Procedures

1. All changes requiring review by the ORCI/IRB must be submitted using the appropriate form in the ORCI's electronic database management system.

2. Exempt Studies

    a. If the proposed modification increases the risk-to-benefit ratio, but does not alter the IRB review level required, the researcher must submit a modification request and receive IRB approval prior to implementing the modification.

    b. If the proposed modification alters the IRB review level required, the researcher must submit a new protocol application request and obtain approval from the IRB prior to implementing the change.

    c. If the researchers are unsure if proposed changes to the study increase the risk-to-benefit ratio and/or alter the IRB review level, they should contact the ORCI/IRB for consultation.

3. Non-Exempt Studies

    a. Personnel change requests, with the exception of a request to change the principal investigator, may be reviewed and approved by the IRB Chair without additional review by the IRB.

    b. For greater than minimal risk research, minor changes to approved research can be reviewed under expedited procedures. Minor changes are defined as changes that do not significantly increase risk and do not materially affect the risk/benefit ratio. Examples of minor changes include adding or revising recruitment methods, adding a minimal risk procedure, or changes in wording in the consent form or other study documents.

    c. When submitting the modification in the electronic IRB submission platform, ensure all documents being added or changed as a result of the modification are attached for IRB review. Examples of revised documents include:

        i. New or updated recruitment materials

ii. Revised informed consent forms
iii. New or revised surveys, questionnaires, or assessment tools

d. All proposed modifications, with the exception of Procedure 3a above, will be reviewed as outlined in *IRB Policy 900: IRB Protocol Review*. The following criteria are applied when determining if a proposed modification can be approved:

i. The IRB verifies that the criteria for IRB approval in *IRB Policy 900* are still met with the inclusion of the proposed modifications.
ii. The IRB assesses whether the amendment increases risks to subjects and, if so, that sufficient safeguards are in place to minimize risks.
iii. The IRB ensures that the informed consent document reflects changes to any required elements of consent or to anything that could affect participants' willingness to participate, and subsequently determines if re-consenting or informing previously enrolled participants is required.