

Grand Valley State University Institutional Review Board	
Title: <i>Review Standards for Research Not Covered by Federalwide Assurance</i>	
Section: 121.	This policy and procedure supersedes those previously drafted
HRRC approved: 09/09/2014 Reviewed: 10/28/2014 Administrative update: 03/25/2020 Revised by IRBPPC: 09/09/2024	IO approved: 9/22/2014 Revisions approved by IO: 10/25/2024
Effective Date: 10/25/2024	
Related Sections: <i>110: Ethical and Legal Standards and Practices for Human Subjects Research</i> <i>120: Compliance with Applicable Laws and Regulations</i>	

Policy

Grand Valley State University has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research only. This does not create a two-tiered application of ethical principles or protections; rather, it allows for an appropriate level of flexibility without compromising protections. This policy applies to research considered by the IRB to be of no greater than minimal risk.

Policy Scope

1. This policy describes how GVSU IRB reviews and documents determinations for research not covered by the FWA 00002829. This policy ensures the highest standards for protection of research participants, while still allowing for the greatest amount of flexibility for research involving no greater than minimal risk. A goal of the policy and practice is to reduce administrative burden for researchers, IRB members, and staff.
2. This policy applies to the ORCI staff and GVSU researchers and partner institutions.
3. This policy does not apply to projects that receive federal support from agencies such as National Institutes of Health (NIH), National Science Foundation (NSF), Centers for Disease Control (CDC), Food and Drug Administration (FDA), or United States Department of Agriculture (USDA), as those projects are subject to the GVSU FWA. Projects that anticipate receiving federal funds, where a grant proposal is pending or planned, are not subject to this policy but are reviewed using the appropriate “Federally Funded Research” policy or agency specific policy.
4. Eligibility of research projects under this policy is determined by the IRB.
5. GVSU applies commensurate protections for research projects that fall out of the scope of the FWA. The criteria for approval articulated in the regulations at 45 CFR 46.111 must be met to receive IRB approval.
6. This policy applies to all research projects that are not externally funded or instances where the sponsor does not require adherence to federal regulations.
7. This policy does not apply to projects involving an NIH-issued Certificate of Confidentiality.
8. This policy does not apply to research involving data in repositories intended to be used to support applications to the FDA.

Background

The following are only examples of review standards and do not constitute the entirety of the scope of the policy in each subsection.

1. **Reporting Requirements:** Research projects that fall out of the scope of the FWA are not subject to the same reporting requirements as federally funded projects for reporting of serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others. The IRB/ORCI does not report those matters to the federal agencies but follows internal reporting requirements as directed by the RIO.
2. **Children:** Research projects involving children are subject to the regulations and tiered review standards at 45 CFR 46 Sub Part D. Requirements for assent and parental permission are consistent with the federally funded research standards, though the IRB may, at its discretion, determine that consent from one parent is sufficient. Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.
3. **Prisoners:** Research projects involving prisoners are subject to the same requirements for review as those at 45 CFR 46 Sub Part C, with the exception of the requirement for review by the Secretary cited at 45 CFR 46.306. Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review by the prisoner representative. The IRB/ORCI will not consider persons in transitional custody whose liberty is restricted such as half-way houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.
4. **Pregnant Women, Human Fetuses and Neonates:** Research projects involving Pregnant Women, Human Fetuses and Neonates are subject to the requirements at 45 CFR 46 Sub Part B with the exception of the requirement at 45 CFR 46.204(d) which requires the research develop “important biomedical knowledge”, which precludes most social and behavioral sciences research with pregnant women, a condition which the IRB finds violates the rights and dignity of women. Research projects that are funded by sources other than federal agencies, that involve greater than minimal risk, involve physical intervention, and include pregnant women, human fetuses, or neonates will be subject to the requirements of Sub Part B irrespective of the funding source. In no instance may research be approved that does not comply with Michigan State Law pertaining to these populations.
5. **Multicenter Research:** Multicenter or multisite research projects involving other “engaged” institutions that are funded outside the federal funding stream are not subject to the same formal inter-institutional agreements or assurance requirements as are federally funded projects. Other forms of communication documenting collaborations are sufficient at the discretion of the IRB Chair with concurrence from the RIO.
6. **Expansion of Expedited Review:** Research projects involving no greater than minimal risk that are not covered by the FWA may be reviewed through the established expedited review process by the IRB Chair or designees at the discretion of the Chair. Research projects or changes in approved research funded from sources other than the federal agencies that do not appear on the list “Categories of Research That May be Reviewed by the Institutional Review Board Through an

Expedited Review Procedure”, November 9, 1998, may be reviewed, at the discretion of the Chair, through an expedited process. The list is considered to be guidance, not an exclusive or limiting list of procedures.

7. **Processes Followed:** All forms and checklists and documentation requirements outlined in other policies within the IRB/ORCI apply to this segment of research. Continuing review requirements follow those outlined in *IRB Policy 910: Continuing Review and Approval of Selected Non-Exempt Protocols*.