Grand Valley State University Institutional Review Board (IRB)	
Title: *Researcher Conflict of Interest*	
Section: 320.	This policy and procedure supersedes those previously
Approved by HRRC: 04/12/2011 Revised: 09/10/2013 Reviewed: 10/28/2014 Revised by HRRPPC: 1/26/2017 Reviewed by IRBPPC: 4/23/2019 Reviewed by IRBPPC: 11/04/2024	Approved by RIO/HRPA: 05/12/2011 Revision approved: 09/10/2013 Revision approved by AIO/RIO: 3/6/2017 Revision approved by AIO/RIO: 5/23/2019 Revision approved by AIO/RIO: 3/13/2020 Approved by IO: 12/13/2024
Effective Date: 12/13/2024	
Related documents: *110: Ethical and Legal Standards and Practices for Human Subjects Research* *310: Researcher Responsibilities, Qualifications and Training* *820: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation* *830: Voluntary Termination, Participation and Withdrawal from Research* *C-01: Procedures for Reporting Conflicts of Interest and Commitment in Research and Sponsored Activities*	

Policy

1. Human subject research protocols shall be reviewed for potential real or perceived conflicts of interest involving possible financial gain or other personal advantage to persons associated with the research. Researchers are required to disclose potential conflicts of interest when submitting a protocol for approval and during the research process, should a conflict later arise. Willful failure to disclose a significant conflict of interest is considered serious and continuing noncompliance.

2. Conflicts of interest may arise in several forms, but most commonly involve explicit or anticipated financial benefit to the researcher. The benefit may be direct payment or it may be indirect, such as through ownership interest in a firm that may benefit from a particular outcome of the research. A conflict of interest also may exist for a researcher's immediate family member(s) or life partners who could potentially benefit in such ways from the research results.

3. Researchers must disclose any and all of the following conflicts related to the project under review that exist for themselves (and their spouse and dependent children, if applicable):
    a. All financial interests of $5,000 or more (in the previous 12 months or anticipated in the next year) in the research project sponsor, including compensation/payment for service, equity interest (if sponsor is a publicly traded entity), intellectual property interests, and/or sponsored/reimbursed travel
    b. All equity interests of any amount (even $0) in the research project sponsor if sponsor is a non-publicly traded entity
    c. All personal or fiduciary relationships to the project personnel, including study

participants

d. All personal or fiduciary relationships to entities that stand to benefit from the research results

All disclosures must be made as part of the initial protocol submission, or if arising after protocol approval, within 30 days of the conflict arising.

4. Disclosure may not be sufficient to discharge the conflict. In some cases, the IRB will direct the researcher to the Office of Research Compliance and Integrity, who in conjunction with the Research Integrity Officer, will be responsible for reviewing the disclosures and instituting an adequate plan for the management of any potential conflict of interest.

Procedures

1. Initial steps required to mitigate actual or perceived conflicts of interest identified or suspected upon initial review of a research protocol will depend on the nature and seriousness of the perceived conflict. Actions to minimize or discharge conflicts of interest may include, but are not limited to, any of the following:

    a. Modification of the protocol procedures or of the roles of specific research team members;

    b. Independent safety monitoring and/or review of study data and methods of data analysis;

    c. Divestiture of significant financial interest;

    d. Reassignment, suspension, or termination of specific roles among research team members; and/or

    e. Withdrawal from all or part of the research project of one or more researcher team members.

2. The IRB will review the conflict of interest mitigation plan, if available, as part of their review of the research protocol. They may accept the mitigation plan as written or require additional mitigation measures that must be incorporated into the research protocol in order for it to be approved. Additional mitigation measures enforced by the IRB will also be documented as an addendum to the existing conflict of interest mitigation plan.