Grand Valley State University Institutional Review Board (IRB)	
Title: *Unapproved research*	
Section: 341.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 11/08/2011 Revised: 2/14/2012 Reviewed: 10/28/2014	Approved by RIO/HRPA: 11/21/2011 Revision approved: 2/16/2012 Revision approved by AIO/RIO: 3/13/2020
Related documents: *030: ORCI document retention and maintenance* *110: Ethical and legal standards & practices for HS research* *120: Compliance with applicable laws and regulations* *210: Determination of HS research* *310: Researcher responsibilities, qualifications and training* *330: Authorization to conduct HS research* *OP-1: GV charge to the HRRC* *OP-3: GV policy on Research Integrity*	

Policy

1. It is the responsibility of researchers to:

    a. know the GVSU policy on Research Integrity
    b. know what constitutes human subjects research;
    c. know under what circumstances approval from the IRB and/or another IRB is required;
    d. know their responsibilities as investigators; and
    e. acquire all necessary approvals of research activities *before* commencing such activities.

2. Conducting unapproved research is a form of research non-compliance and is subject to corrective and/or punitive action by the IRB, the University Research Integrity Officer (RIO), and/or other internal or external authorities. Such actions may include, but are not limited to suspension or termination of a research study or of an investigator's privilege to submit as principal investigator future proposals for conducting human subjects research at GVSU. Pending an inquiry, suspected unapproved research activities may be immediately suspended by the IRB Chair, the RIO, or the researcher's authorizing official.

Procedures

When unapproved research is suspected and/or reported, the Office of Research Compliance and Integrity (ORCI) will conduct an initial inquiry under the direction of the office. As appropriate, the inquiry findings may be referred to the IRB Chair, the RIO or an IRB subcommittee for further investigation. The inquiry and reporting shall be completed within sixty days of the initial report or record of discovery. If the conclusion of the inquiry results in a report of a positive finding of unapproved research, the IRB Chair in consultation with the RIO shall determine notification to the researcher and others as appropriate.

Procedural Steps:

1. When suspected unapproved research is reported to the ORCI, relevant ORCI records shall be searched for any information pertaining to the research activity in question. If a record is found indicating the research activities in question were properly reviewed and approved, the inquiry shall be terminated.
2. If no record of IRB approval of the research activities is located, the office will make a determination as to whether the activities involve research on human subjects as defined by DHHS, FDA and PHS regulations. If the activities in question do not constitute human subjects research according to the federal regulations, the inquiry shall be terminated.
3. If research activities in question are found to constitute unapproved human subjects research, the office will refer the matter to the chair of the IRB and the RIO. The referral shall include a written summary of findings of fact.
    a. After a review of the office written summary, the IRB chair and the RIO shall determine what subsequent referrals, consultations and actions are appropriate.
    b. A summary report to the IRB of the findings and actions taken by the RIO and IRB chair shall be made at the next convened board meeting. The privacy of all parties affected will be maintained, as appropriate and feasible.
    c. Documents relating to the ORCI inquiry, including but not limited to the findings, determinations, recommendations, and the reports of administrative actions by the RIO will be retained per ORCI Policy 030. *ORCI document retention and maintenance*.

Background

1. For purposes of this policy, *unapproved research* is defined as the commencing of any research activity involving living human participants that requires approval from the Institutional Review Board (IRB), but has not received such approval. This includes research:
    a. for which no protocol has been submitted to the IRB;
    b. for which a protocol was submitted, but not approved;
    c. that was initially approved, but for which continuing review has lapsed;
    d. that differs from what was approved by the IRB; or
    e. that required, but did not receive approval from another IRB or was outside of what was approved by another IRB, even if the protocol was approved by the GVSU IRB.