Grand Valley State University Institutional Review Board	
Title: *Post-Approval Compliance Review*	
Section: 1040.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 11/08/2011 Revised by HRRPPC: 05/08/2018	Approved by RIO/HRPA: 11/21/2011 Revisions approved by AIO/RIO: 05/09/2018
Effective Date: 01/21/2019	
Related documents: *030: ORCI document retention and maintenance* *120: Compliance with applicable laws and regulations* *710: Assessing risks to research participants* *1030: Research non-compliance* *1050: Suspension or termination of research activities* *1070: Responding to concerns and complaints about human subjects research activities* *OP-3: GVSU policy on research integrity*	

Policy

1. The purpose of post-approval compliance review is to ensure adequate protection of research participants. The principal use is in monitoring the implementation of approved protocols, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuous improvement of Institutional Review Board (IRB) processes. Post-approval compliance review applies to human subjects research protocols that have been determined to be exempt or have received expedited or full-board approval; this compliance review program is separate from the IRB continuing review process.

2. Compliance review of approved research protocols may be conducted either randomly or for cause at any time. Compliance review authority includes, but is not limited to, the following:

    a. Observation of the consent process
    b. Observation of research procedures including interactions and/or interventions with study participants
    c. Review of all documents and materials pertaining to the permission for or conduct of research activities

3. When research procedures or interactions with participants are observed as part of a compliance review, the authorized observer shall acquire prior consent of participants being observed. If the participant is a minor or an adult who did not directly provide informed consent to enroll in the research, permission to observe the process shall be acquired from the parent, guardian, or proxy of record who previously provided permission for the minor or adult to enroll in the research.

Procedures

1. Selection of protocols for compliance review
    a. For-cause compliance reviews: If a concern or complaint about the conduct of a research study is discovered or reported to the Office of Research Compliance and Integrity (ORCI) staff, any member of the IRB, or the university Research Integrity Officer (RIO), a for-cause compliance review may be initiated. The determination of the need for a for-cause compliance review shall be made by the IRB Chair in consultation with the RIO and the ORCI. A for-cause compliance review may occur at any time.

    b. Selected not-for-cause compliance reviews: Certain research protocols may be selected for a compliance review based on study factors. Such factors include, but are not limited to, protocols involving: greater than minimal risk; external sponsorship; and collection and/or use of Health Insurance Portability and Accountability Act (HIPAA)-, General Data Protection Regulation (GDPR)-, and/or Family Educational Rights and Privacy Act (FERPA)-protected data.

    c. Random compliance reviews: Research protocols, including protocols that are otherwise exempt from the federal regulations, may be randomly selected for a compliance review at any time.

    d. Less than 5 percent of all open research protocols, including protocols that are otherwise exempt from the federal regulations, shall be chosen for selected not-for-cause and random compliance reviews on an annual basis.

    e. Requests from Principal Investigators for voluntary post-approval compliance reviews will be considered.

2. Conducting a compliance review: The ORCI has the principal responsibility for conducting compliance reviews of research studies involving human participants. At the discretion of the ORCI, assistance conducting a review may be requested from the IRB Chair, RIO, IT staff, or other experts.

    - Note that external sponsors of human subject research may conduct research compliance audits, investigations, site visits, or evaluations as detailed in the sponsor contract. Such audits, investigations, site visits and evaluations may be random or for-cause and must be coordinated in advance through the GVSU Office of the Provost under the direction of the RIO. Audits initiated by research sponsors, internal or external to GVSU, normally do not include audit of IRB files, records, meetings, or interviews with IRB members, except as required by a federal agency or with prior written agreement by the IRB Chair. The procedures detailed in this policy are applicable only to internal audits of protocols; audits conducted by an external sponsor may be carried out via different procedures than those described in this policy.

3. Confidentiality: Knowledge of compliance review procedures and the content of any findings shall be kept appropriately confidential by all parties involved in the compliance review. A signed confidentiality agreement may be requested of participating parties.

4. Notification of Investigators: The Principal Investigator of a study selected for random or selected not-for-cause compliance reviews shall be notified at least ten (10) working days in advance of the compliance review visit and will be provided with a self-assessment checklist at the time of notification. The Principal Investigator of a study that has been selected for a for-cause compliance review will generally, but not always, be notified at least one (1) working day in advance of the compliance review visit; a self-assessment checklist may, but not always, be provided at the time of notification of a for-cause compliance review.

5. Compliance Review Visit and Final Report: ORCI, along with any identified experts if needed, will meet with the Principal Investigator and other team members as appropriate to conduct an in-person compliance review visit. Informal feedback will be given to the Principal Investigator during the visit; following the completion of the compliance review, ORCI will draft a final written report. This report will be sent to the Principal Investigator for review. The Principal Investigator will have five (5) working days to provide a written response to the final report, should they desire to do so. Pertinent documents related to the compliance review visit, including any subsequent written response from the Principal Investigator following the final report, will be stored in ORCI's electronic database management system.

6. Reporting to the RIO: If subsequent to the conduct of a compliance review, the ORCI has reasonable suspicion of serious or continuing non-compliance, or of research misconduct as defined by GVSU policy, the final written report shall be submitted to the RIO.

7. Reporting to the IRB and Institutional Review Board Policies and Procedures Committee (IRBPPC): A summary report of all compliance reviews and subsequent findings, including corrective action plans and preventive measures, but excluding personal identifiers, shall be made to the IRB and IRBPPC at least annually by the ORCI. This report will be shared with the Provost upon request.

Background

Federal regulations pertaining to the protection of human subjects in research at 45 CFR 46.109(g) and 21 CFR 56.109(f) state that an IRB has the authority to observe or have a third party observe the consent process and the research for any approved research study. Authorized parties include but are not limited to the following:

a. Staff members of the GVSU ORCI
b. IRB Chair
c. Representatives of a federal agency sponsoring the research (e.g., NSF, NIH, DOE, etc)

d. Representatives of a federal agency charged with overseeing protections of research study subjects (e.g., OHRP, FDA)
e. Representatives of research study sponsor
f. GVSU RIO
g. Other party designated by the RIO