Grand Valley State University Institutional Review Board (IRB)	
Title: *Operational Support of the IRB*	
Section: 030.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 11/08/2011 Revised: 08/01/2012 Reviewed: 10/28/2014 Revised by HRRPPC: 3/23/2017 Revised by HRRPPC: 11/28/2017 Revised by IRBPPC: 04/18/2022	Approved by RIO/HRPA: 11/21/2011 Revision Approved: 08/01/2012 Revision approved by AIO/RIO: 03/24/2017 Revision approved by AIO/RIO: 04/16/2018 Revision approved by AIO/RIO: 03/13/2020 Revisions approved by AIO/RIO: 04/21/2022
Effective Date: 04/21/2022	
Related documents: *010: IRB Composition and Member Responsibilities* *020: Conducting Board Meetings* *050: Record Retention* *160: Institutional Review Board Policies and Procedures Committee (IRBPPC)* *210: Determination of Human Subjects Research* *220: Determining Engagement in Human Subjects Research* *901: IRB Protocol Review: Expedited Protocols* *911: Exemption Determinations and Research Ethics Standards* *1030: Research Noncompliance* *1040: Policy 1040: Post-Approval Compliance Review* *G-8: OHRP& FDA guidance on withdrawal of subjects from research: data retention*	

Policy

1. The Institutional Official (IO) is delegated the legal authority to represent GVSU and all components listed on the GVSU Federalwide Assurance (FWA) on matters related to human subjects research. The responsibilities of the IO related to IRB functions include, but are not limited to, the following:
    a. Ensuring the safety, rights, and welfare of human subjects participants are protected,
    b. Ensuring all components of the IRB are functioning effectively,
    c. Appointing members to the IRB and Institutional Review Board Policies and Procedures Committee (IRBPPC),
    d. Overseeing compliance with all applicable federal regulations and guidance, state law, and institutional policies,
    e. Overseeing processes to ensure investigators fulfill their responsibilities under applicable regulations and policies,
    f. Serving as the signatory authority for the FWA and IRB-related inter-institutional agreements, as appropriate,
    g. Conducting periodic reviews of IRB members (see Policy 010: IRB Composition and Member Responsibilities),
    h. Ensuring, in conjunction with the Vice Provost for Research Administration, that

GVSU provides the Office of Research Compliance and Integrity (ORCI) with appropriate support to perform its duties and sufficient resources are allocated to support the IRB,

i. Ensuring the independent authority of the IRB is maintained, and

j. Reviewing and approving IRB policies and procedures, as appropriate.

2. The IO may designate other individuals to act on the IO's behalf, with the exception of the following responsibilities:
    a. Signatory authority of the FWA,
    b. Completion of IO training,
    c. Ensuring the IRB functions independently and that members have access to the IO if they have concerns about the function of the IRB, and
    d. Ensuring adequate resources are provided to support the operation of the IRB and protection of human subjects research participants.

    Even upon delegation of duties, the IO retains overall responsibility of the IRB.

3. ORCI staff members provide administrative support to IRB members. The responsibilities of the ORCI staff related to IRB functions include, but are not limited to, the following:
    a. Overseeing the receipt and tracking of IRB submissions,
    b. As appropriate, completing determinations of engagement in human subjects research (See *Policy 220: Determining Engagement in Human Subjects Research*), requests for the determination of human subjects research (See *Policy 210: Determination of Human Subjects Research*), and exempt protocol submissions (See *Policy 911: Exemption Determinations and Research Ethics Standards*) on behalf of the IRB,
    c. As appropriate, assigning expedited submissions to IRB members for review (See *Policy 901: IRB Protocol Review: Expedited Protocols*),
    d. Preparing and distributing the agenda and other meeting documents for convened IRB meetings,
    e. Preparing minutes of convened IRB meetings (See *Policy 020: Conducting Board Meetings*),
    f. Serving as liaison between researchers and the IRB regarding submission requirements,
    g. Assisting researchers as needed with questions related to protocol development and submission,
    h. Developing and maintaining IRB submission forms,
    i. Drafting IRB policies and procedures for review by the IRBPPC (See *Policy 160: Institutional Review Board Policies and Procedures Committee [IRBPPC]*),
    j. Ensuring public access to current IRB requirements, policies, and procedures,
    k. Overseeing record retention and destruction, ensuring records are complete, stored securely, and easily accessible (See *Policy 050: Record Retention*),
    l. Registering, updating, and renewing GVSU's IRB registration and FWA,
    m. As appropriate, providing IRB member education,

n. Conducting periodic reviews of IRB members (See *Policy 010: IRB Board Composition and Member Responsibilities*),

o. As needed, assisting researchers and IRB members with questions regarding regulatory, legal, and ethical issues related to IRB protocols,

p. As needed, addressing questions and concerns from research participants regarding their rights as a study participant,

q. Conducting Post-Approval Compliance Reviews (PACRs) (See *Policy 1040: Post-Approval Compliance Review*), and

r. Assisting in noncompliance reviews as needed (See *Policy 1030: Research Noncompliance*).

4. The IO and ORCI staff members are required to possess familiarity with federal regulations and guidance pertaining to IRB operations and are expected to maintain expertise in the discipline through participation in ongoing training opportunities and professional networks.

Procedures

1. IO Training

   a. The IO is required to complete an IO training course prior to assuming this role, and every five years thereafter.

   b. Prior to assuming the IO role, and as appropriate thereafter, the ORCI will provide training to the IO regarding specific activities required of this role (e.g., maintaining the FWA, noncompliance procedures, policy review and approval procedures, etc.).

2. ORCI Training

   In addition to expected participation in ongoing training opportunities (such as conferences and webinars), ORCI staff members are required to complete human subjects research and responsible conduct of research courses every three years.

3. IRB Membership Rosters and Records

   Membership rosters and records will include members' names, affiliation, degree(s) earned, role on the IRB (scientist, nonscientist, affiliated/unaffiliated, regular/alternate member, etc.), representative capacity, and indication of experience to serve in their appointed IRB role.

4. IRB and FWA Registrations

   IRB and FWA registrations will be updated and renewed via the Department of Health and Human Services' (DHHS) electronic registration system, per the timelines and requirements set forth by DHHS.