Grand Valley State University Institutional Review Board (IRB)	
Title: *Contingency Plans for IRB Operations and Human Subjects Research*	
Section: 060.	
Approved by IRBPPC: 01/31/2023	Approved by AIO/RIO: 02/06/2023
Effective Date: 02/06/2023	
Related documents: *010: IRB Composition and Member Responsibilities* *020: Conducting IRB Meetings* *030: Operational Support of the IRB* *050: Records Retention* *730: Collection, Management and Security of Research Information* *1010: Modifications to Approved Protocols* *1050: Suspension or Termination of Research Activities*	

Policy

1. Emergency situations could arise that impact the internal functioning of the IRB (e.g., a data breach of IRB records) and/or that are external to the study but potentially impact the welfare of the research participants (e.g., an infectious disease outbreak affecting the ability to conduct an intervention with participants). Such emergencies may require the development of a contingency plan in order to safeguard the rights and welfare of research participants, and to minimize disruptions and ensure the continuity of IRB operations to the fullest extent possible.

2. In the event of an emergency:
    a. Office of Research Compliance and Integrity (ORCI) staff members, the Institutional Official (IO), and the IRB Chairperson are collectively responsible for identifying threats to the functioning of the IRB and the continued conduct of research, and for determining the appropriate response to each situation. If necessary, the IO and/or IRB can suspend the research (See *Policy 1050: Suspension or Termination of Research Activities*).

    b. Principal Investigators (PIs) are responsible for assessing their protocol(s) to determine if the rights and welfare of the participants will be impacted by continuing to conduct the protocol during the disruption.

3. The nature of the emergency will dictate the scope, duration, and severity of the disruption, and therefore the most appropriate contingency plan to implement. As such, contingency plans will vary depending upon the emergency, but should address the following components:
    a. Disruptions to IRB operations and the ability to conduct research, including impacts on participants and participant safety,

    b. Recovery efforts,

    c. Availability of records, and

    d. Availability of personnel.

Procedures

1. Disruptions to IRB Operations and the Ability to Conduct Research
    a. Potential disruptions to IRB operations will be monitored on an on-going basis by ORCI staff members, the IRB Chairperson, and the IO. Disruptions include, but are not limited to, loss of facility access, loss of service of personnel due to reduced workforce, and loss of service due to equipment or systems failure.

    b. Upon identifying a potential disruption, ORCI staff members, the IO, and the IRB Chairperson will assess the likely scope, duration, and severity of the interruption, and determine if a contingency plan is needed. This assessment will include analyzing available data to determine the potential impact on research studies, such as:
        i. Regulatory body oversight (FDA-regulated, etc.),
        ii. Level of review (exempt, expedited, full board),
        iii. Risk level (minimal risk or greater than minimal risk),
        iv. Possibility of direct benefit to participants
        v. Occurrence of in-person interactions,
        vi. Location of research site(s), and
        vii. If the project is researching the emergency occurring.

        Contingency plans will be developed with the goal to return to normal operations within the shortest possible timeframe.

    c. ORCI staff members, the IO, and the IRB Chairperson will collectively determine additional actions, if any, that are needed to respond to the emergency. Such actions could include, but are not limited to:

        i. Advising researchers to continue following their previously approved protocols,

        ii. Instructing researchers that studies may only proceed with alternative procedures that address the emergency situation (noting that such alternative procedures may require additional IRB review and approval),

        iii. Instructing researchers to pause some or all protocol activities, and/or

        iv. Suspending or terminating studies per *IRB Policy 1050: Suspension or Termination of Research Activities*

    d. Researchers will be notified by ORCI staff members and/or the IRB Chairperson what additional action(s), if any, is required. Information will primarily be relayed through direct email to Principal Investigators (PIs), but may also be communicated via other means, such as direct phone calls and/or the ORCI website.

    e. PI Assessment of Impact to Participants
        i. If the PI determines their approved protocol cannot be conducted safely during the emergency (i.e., the rights and welfare of the participants will be negatively impacted), the researchers must immediately pause the study. The PI should then assess if additional modifications to the protocol would allow for safe continuation of the study.

1. If modifications would allow for safe continuance, the PI must follow *IRB Policy 1010: Modifications to Approved Protocols* to determine what, if any, additional reviews and approvals are required by the IRB before the changes can be implemented.

2. If modifications would not allow for safe continuance of the study, the study must remain paused until such time that it is safe to resume the study, or the PI may choose to close the study (see *IRB Policy 1060: Closure of Approved Protocols*). The PI is encouraged to contact the ORCI/IRB to discuss their protocol if they cannot continue their study safely during to the emergency but wish to resume the study at a later time.

ii. If the PI determines the research can continue to be safely conducted as outlined in the approved protocol during the emergency (i.e., the rights and welfare of the participants will not be negatively impacted), the researchers may continue the research unless directed otherwise by the ORCI/IRB or other institutional official.

f. Researchers should be cognizant of when IRB approval for their research expires. During disruptions, research that is determined to be in the best interest of already-enrolled participants may continue after expiration of IRB approval. The researcher must notify the IRB of this occurrence at the earliest possible time.

2. Recovery Efforts
   a. Recovery efforts will be led by ORCI staff members, the IO, and the IRB Chairperson; other relevant institutional offices or departments will be contacted for assistance on an as-needed basis.

   b. The type of recovery efforts utilized will depend upon the type of disruption that has occurred and the resources currently available to respond to the disruption. For example, recovering from a data breach might consist of attempts to recover lost data and taking steps to improve data security, whereas recovering from a natural disaster might involve re-establishing a physical location or moving operations to a new location.

   c. If the required resources to respond to the disruption are not available, an assessment will be conducted by the ORCI, in conjunction with the IO, to determine if, when, and by what means, such resources may be obtained.

3. Availability of Records
   In the event of an identified emergency/disruption:
   a. ORCI staff members, the IO, and the IRB Chairperson are responsible for assessing if any administrative records (see *IRB Policy 050: Records Retention*) will be unavailable during the emergency, and if so, determining what actions (if any) will need to be taken to ensure participant rights and protections are not compromised.

   b. PIs are responsible for assessing if any study-specific research records (see *IRB Policy*

730: Collection, Management and Security of Research Information) will be unavailable during the emergency. If the unavailability of research records affects the participants' rights or welfare, the PI must contact the IRB/ORCI for further instructions.

4. Availability of Personnel
    a. Personnel disruptions occur when there is a lack of some or all ORCI/IRB staff. This could result from resignations, illness, epidemics/pandemics, natural disasters, or other factors.

    b. If a physical location disruption occurs, the ORCI/IRB will conduct operations remotely from an alternative location. ORCI staff members are able to access documents and conduct work remotely, and IRB meetings may be conducted via electronic means (see *IRB Policy 020: Conducting IRB Meetings*).

    c. The ORCI Director and Vice Provost for Research Administration (VPRA) are responsible for identifying and responding to personnel disruptions involving ORCI staff members. The IRB Chairperson and the IO are responsible for identifying and responding to personnel disruptions involving IRB members.

    d. The following steps will be taken by the responsible individual (ORCI Director/VPRA or IRB Chairperson/IO) when a personnel disruption is identified:
        i. Determine what services are needed to maintain operations, including review and processing of new IRB submissions and oversight of active research studies.

        ii. Assess if existing internal resources are available to provide these services. If so, implement the use of these resources.

        iii. If external resources will be required:

            1. Determine the level of funding available for obtaining external services,

            2. Identify and enter into a service agreement with another organization (such as a commercial IRB or the IRB of another academic institution) that can provide IRB oversight and review on behalf of GVSU,

            3. As appropriate, notify researchers of any necessary actions they need to complete as a result of using an external IRB, and

            4. As appropriate, notify regulatory agencies and sponsors about the change in IRB oversight.

        iv. Monitor the response to the disruption to assess the impact of the contingency plan and implement changes to the plan as necessary.

        v. Determine when the disruption has been resolved, and terminate responses and service agreements, as appropriate.