Grand Valley State University Institutional Review Board (IRB)	
Title: *Closure of Approved Research Protocols*	
Section: 1060.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Approved by IRBPPC: 05/03/2021	Approved by RIO/HRPA: 02/16/2011 Approved by AIO: 05/06/2021
Effective Date: 05/06/2021	
Related documents: *110: Ethical and Legal Standards and Practices for Human Subjects Research* *120: Compliance with Applicable Laws and Regulations* *210: Determination of Human Subjects Research* *310: Researcher Responsibilities, Qualifications and Training* *730: Collection, Management and Security of Research Information* *910: Continuing Review and Approval of Selected Non-Exempt Protocols* *1030: Research Noncompliance* *1040: Post-Approval Compliance Review* *1050: Suspension or Termination of Research Activities* *1070: Responding to Concerns and Complaints About Human Subjects Research Activities*	

Policy

1. Principal Investigators (PIs) have the responsibility of informing the IRB when a protocol is completed. This requirement applies to all levels of protocol review: full board, expedited, and exempt.

2. An IRB protocol is considered open and active until the PI notifies the IRB that the protocol activities are complete. A protocol can be closed by the PI if all of the following conditions are met:
    a. All participant enrollment is complete; and
    b. All data, including study follow-up data, pertaining to the participants have been collected; and
    c. No further participant interaction is planned for the research purposes; and
    d. No further analysis of identifiable private information is to be conducted.

    Note that if all data collected in a study has been completely de-identified, the protocol can be closed but analysis may continue, because the study no longer falls under covered human subjects research as defined in *IRB Policy 210: Determination of Human Subjects Research*. Consult the Guidance section below for further details regarding what activities are considered on-going research activities.

3. Following protocol closure, researchers must continue to honor any confidentiality protections of the data and any other commitments that were agreed to as part of the approved research, such as providing information about the study results to research participants or providing compensation for research participation. Researchers are further required to securely preserve and maintain all documents and other materials pertaining to the approval of the research study, including signed

consent forms, for all non-exempt research studies as required by the applicable federal regulations.

4. Protocols may be closed by the IRB without PI approval if any of the following conditions exist:
    a. It is determined that the PI is no longer affiliated with GVSU;
    b. The protocol expires because the PI has not provided a continuing review;
    c. The PI has not responded to the IRB's request for changes and/or clarifications within the timeframe determined by the IRB;
    d. The PI fails to respond to requests from the IRB, within a stated timeframe determined by the IRB, regarding the status of an open and active protocol (see *IRB Policy 1050: Suspension or Termination of Research Activities*); and/or
    e. In response to unanticipated problems involving risk to participants or others, serious and/or continuing noncompliance, or findings presented during an IRB review (see *IRB Policy 1050: Suspension or Termination of Research Activities*).

5. Multi-site studies, such as clinical investigations, may be closed when the sponsor has completed all data queries on the GVSU site's study records, has "locked" the site data, and remaining data analysis will not be completed by GVSU.

6. Once a study has been closed, it cannot be re-opened. A new protocol application will need to be submitted, and the IRB will complete a new initial review of the research under the current regulations and institutional policies.

7. No closure documentation is required for projects determined to be Non-Human Subjects Research or Non-Engaged Research.

Procedures

1. Researcher Responsibilities
    a. Notification of Protocol Closure to the IRB
        i. Exempt Protocols

        The PI may either contact the ORCI directly via email (rci@gvsu.edu) to request protocol closure or may submit an IRB Closure Form in the ORCI's electronic database management system.

        ii. Non-Exempt Protocols
            1. The PI must submit an IRB Closure Form in the ORCI's electronic database management system to initiate protocol closure. This applies to both non-expiring and expiring non-exempt protocols.
            2. Expiring Non-Exempt Protocols
                a. PIs do not have to wait for the end of the protocol approval period to request protocol closure.
                b. If the PI fails to apply for continuing review within 30 calendar days following the protocol expiration date (see *IRB Policy 910: Continuing Review and Approval of Selected Non-Exempt*

Protocols), the protocol will be administratively closed by the IRB. The PI is still required to submit an IRB Closure Form; failure to submit this form within 45 calendar days after the protocol expiration date will be considered noncompliance. See *IRB Policy 1030: Research Noncompliance*.

b. Researchers are not required to destroy research-related data unless so indicated in the IRB-approved protocol. Researchers may preserve study data and associated materials, including identifiable private information, if consistent with the IRB-approved research plan.

c. Upon termination of employment at GVSU, PIs are obligated to close their protocols or formally transfer them to another GVSU PI.

2. Protocol Closure Review
    a. IRB protocol closure requests are initially reviewed by the ORCI. If any concerns are identified during the ORCI review, the PI will be contacted as necessary to address the concerns.

    b. If the concerns are resolved satisfactorily, or if no concerns are identified during the ORCI review, the protocol is officially closed, and the PI is notified of the closure in writing.

    c. If concerns arise during the ORCI review that cannot be resolved, and/or noncompliance is identified, the IRB Chair will be notified, and the appropriate IRB policy or policies (i.e., *IRB Policy 1030: Research Noncompliance* and/or *IRB Policy 1050: Suspension or Termination of Research Activities*) will be followed.

    d. Protocol closures are reported to the IRB in the agenda of the next convened IRB meeting.

Guidance

1. Per Office of Human Research Protections (OHRP) Continuing Review Guidance (2010), Item K, a research project continues "to involve human subjects as long as the investigators conducting the research continue to obtain:
    - Data about the subjects of the research through intervention or interaction with them; or
    - Identifiable private information about the subjects of the research."

2. Furthermore, per OHRP Continuing Review Guidance (2010), Item K, the following activities constitute obtaining identifiable private information:
    - "Collecting or receiving identifiable private information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator);
    - Collecting identifiable private information by observing or recording private behavior without interacting or intervening with the human subjects; and
    - Using, studying, or analyzing identifiable private information (including identifiable biological specimens), even if the information was already in the possession of the investigator before the research begins. This includes using, studying, or analyzing any of the following:

- Identifiable private information obtained by interacting or intervening with the human subjects;
- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings provided to the investigators from any source;
- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings already in the possession of the investigator before the research begins;
- Identifiable private information obtained about an individual by interviewing other people (e.g., an individuals' healthcare provider or teacher);
- Identifiable biological specimens provided to the investigators from any source; or
- Identifiable biological specimens already in possession of the investigator before the research begins."

3. Researchers are encouraged to de-identify private information and destroy identifiers to the extent possible at the earliest point possible in the research.

4. GVSU IRB approval is not required for researchers new to GVSU who will be transferring an existing identifiable data set to GVSU, provided the researcher will only be storing the data (i.e., without conducting any additional research activities using the data). If the researcher plans to conduct additional research activities with the data, IRB approval may be required.

5. If a researcher wants to use identifiable data from a closed research study, whether by the original researcher or other researchers, this may be considered human subjects research requiring separate IRB approval. Researchers are encouraged to contact the ORCI/IRB for consultation.

6. Closing an expired study is not considered termination of approval of research per 45 CFR 46.113 and is not reportable to the Office of Human Research Protections.