Grand Valley State University Institutional Review Board (IRB)	
Title: *Records Retention and Destruction*	
Section: 050.	
Approved by IRBPPC: 04/18/2022	Approved by AIO/RIO: 04/21/2022
Effective Date: 04/21/2022	
Related documents: *030: Operational Support of the IRB* *730: Collection, Management and Security of Research Information* *1060: Closure of Approved Research Protocols*	

Policy

1. Records associated with human subjects research include both research records and administrative records. The Principal Investigator (PI) has primary responsibility for retaining research records, including data and signed consent forms. The Office of Research Compliance and Integrity (ORCI) has primary responsibility for retaining administrative records on behalf of the IRB.

2. If applicable, records must be retained in accordance with any regulatory agency having oversight of the research, and with any requirements of the sponsor. In the approved protocol, the documented retention and destruction plan must reflect those applicable regulatory and sponsor retention requirements.

3. If regulatory and sponsor requirements are not applicable, records must be retained and destroyed in accordance with the approved protocol's documented retention and destruction plan. If the approved protocol does not specify a record retention and destruction plan, records must be kept for at least three years following closure of the IRB protocol (see *IRB Policy 1060: Closure of Approved Research Protocols*).

4. In cases where two different retention periods apply to the records (such as a sponsor requirement conflicting with a federal regulation), the longest retention time specified must be followed. Records may be retained longer than required or indefinitely, provided the approved protocol did not specify a specific destruction date for specific records or data.

5. All records must be accessible for inspection and copying by authorized representatives of the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), other federal or state government agencies, or others, as appropriate, at reasonable times and in a reasonable manner.

6. All records maintained by the PI must be stored consistent with the approved protocol and *IRB Policy 730: Collection, Management and Security of Research Information*. Administrative records maintained by the ORCI must be stored securely.

7. Records designated by GVSU Office of General Counsel, or any other authorizing body, as being on "legal hold" must not be destroyed or discarded while the hold is active.

Procedures

1. Research Records
    a. Research records may include, but are not limited to, the following:
        i. Forms and related documentation submitted to the IRB for review (i.e., initial submission forms, amendment requests, continuing reviews, etc.),

        ii. IRB approval/determination letters, notifications, and correspondence,

        iii. Copies of IRB-approved informed consent documents, parent permission forms, assent forms, recruitment materials, etc.,

        iv. Signed copies of informed consent documents, if applicable,

        v. Blank copies of data collection forms, questionnaires, and other study instruments,

        vi. Copies of research team training documents/certificates,

        vii. Raw data collected during the study,

        viii. Grant proposals, contracts, and progress reports, if applicable, and

        ix. FERPA and HIPAA authorization forms, or documentation of approved waivers, as applicable.

    b. To protect participant confidentiality, identifiers should be removed from research records as soon as possible, based on the needs of the research. The approved protocol's documented retention and destruction plan should specifically outline the process for destruction of such data to ensure this complies with regulatory guidelines and participant safety.

2. Administrative Records
    a. The ORCI will retain administrative records for at least seven (7) years following closure of an IRB protocol or denial of a study.

    b. Administrative records include, but are not limited to:

        i. Records directly pertaining to review and approval of protocols (including continuing review; informed consent and recruitment documents; IRB-approved waivers, alterations, or exceptions to informed consent or its documentation; correspondence of material relevance between the investigators and the IRB; etc.);

        ii. Reports of adverse events;

        iii. Research involvement or protocol review by entities not otherwise affiliated with GVSU;

        iv. Documents pertaining to qualifications of outside experts consulted for protocol reviews;

v. Complaints made by participants or other parties;

vi. Minutes of convened IRB meetings; and

vii. IRB membership rosters and training records.

c. A copy of all administrative records that are essential to IRB oversight are to be stored in a secure, password-protected electronic system; additional hardcopy versions of the record may exist, but they cannot be the only version of the record. Hardcopy administrative records are to be stored in a locked office.

3. Records Destruction
   a. Do not destroy or discard any records without ensuring the required retention period has been met. Data destruction of identifiable data for confidentiality purposes should follow the approved protocol's documented retention and destruction plan. Researchers are encouraged to contact the ORCI prior to destruction of any data, to ensure the minimum data retention period has been determined correctly and been met.

   b. Hardcopy items that include identifiable participant information, or confidential or proprietary information, should be shredded by a certified vendor. Electronic records identified for destruction should be destroyed in accordance with destruction procedures in place with GVSU Information Technology and/or the vendor of ORCI's electronic database management system, as applicable, at the time of destruction.

Guidance

The table below shows the most common regulatory agencies requirements for data retention.

Regulatory Agency	Minimum Retention Time
Office of Human Research Protections (OHRP)	3 years following completion of the research*
Food and Drug Administration (FDA), Drugs	2 years following marketing application approval for indication **OR** 2 years after discontinuation of investigation and notification to the FDA
Food and Drug Administration (FDA), Medical Devices	Period of time equivalent to the design and expected life of the device, but no less than 2 years from the manufacturer's date of release for commercial distribution
Food and Drug Administration (FDA), Biologics	Period of time beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report of unfavorable reactions, but no less than 5 years after the manufacturer's records have been complete or six months after the latest expiration date for the individual product, whichever is later
Health Insurance Portability and Accountability Act (HIPAA)	6 years after each subject signed a HIPAA authorization

*The completion date is interpreted as the date of IRB protocol closure.