Grand Valley State University Institutional Review Board (IRB)	
Title: *ORCI document retention and maintenance*	
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	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
Effective Date: 01/21/2019	
Related documents: *020: Conducting board meeting: voting* *G-8: OHRP& FDA guidance on withdrawal of subjects from research: data retention*	

Policy

1. The Office of Research Compliance and Integrity (ORCI) will retain certain records for at least seven (7) years following completion of a research project or denial of a study. These include:

    a. Records directly pertaining to review and approval of protocols (including continuing review).

    b. Researcher's progress reports.

    c. Reports of adverse events.

2. All other ORCI documents, such as documents pertaining to qualifications of outside experts consulted for protocol reviews, shall be retained for a minimum of three (3) years following the closure of the protocol. All records must be accessible for inspection and copying by authorized representatives of the federal or state government or GVSU administration at reasonable times and in a reasonable manner.

Procedures

1. Following the required minimum data retention period defined above, existing records may be destroyed.

2. Records to be retained for the requisite time period defined above include, but are not limited to:

    a. Protocols submitted for review, including informed consent templates and documents used for advertising and recruitment.

    b. Documentation of any IRB approved waivers, alteration, or exceptions to informed consent or its documentation.

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

d. Minutes of Board meetings.

e. Complaints made by participants or other parties.

Background

1. §46.115 IRB records:

    a. An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

        i. Copies of all research proposals reviewed, scientific evaluations that accompany the proposals, approved sample consent documents, progress reports submitted by the principal investigators, and reports of injuries to subjects.

        ii. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

        iii. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).

        iv. Copies of all *correspondence* between the IRB and the principal investigators.

        v. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

        vi. A list of IRB members in the same detail as described in §46.108(a)(2).

        Written procedures for the IRB in the same detail as described in §46.108(a)(3) and(4).

        vii. Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

        viii. The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

        ix. Documentation specifying the responsibilities that an institution or organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

- *Note:* the correspondence intended in section (iv) refers to information that is of material relevance to IRB or authorizing official approval processes or decisions. It does not refer to extraneous

correspondence.

b. The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency [sponsoring the research] at reasonable times and in a reasonable manner.

2. For FDA regulated research, see: 56 CFR 115. Records to be retained include all of the information included in sections (a)(i-vii) above. See Appendix.