

Grand Valley State University Human Research Review Committee Procedure	
Subject: <i>Retaining research records.</i>	
Section: 12.0	This procedure supersedes those previously drafted
Initially adopted as procedure on June 18, 2007	Approved by: Dean of Graduate Studies and Grants Administration, 11-15-2007.
Related Sections:	

The federal regulations require institutions to retain records of HRRC activities and certain other records frequently held by investigators for at least three years after completion of the research (45 CFR 46.115(b)).

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

- (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- (2) 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.
- (3) Records of continuing review activities.
- (4) Copies of all correspondence between the IRB and the investigators.
- (5) A list of IRB members in the same detail as described in §46.103(b)(3).
- (6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
- (7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this procedure 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. All records shall be accessible for inspection and copying by authorized representatives of the department or

agency at reasonable times and in a reasonable manner.

Documentation of subjects' informed consent (either the signed informed consent form or the short form and the written research summary) are research-related records that typically are held by investigators and must be retained for at least three years after completion of the research, unless the HRRC waived the requirement for informed consent or the requirement for documentation of informed consent (45 CFR 46.117).

After three years the paper forms of the file may be destroyed, but electronic copies of the file records pertaining to HRRC review and approval of the research activities will be maintained indefinitely. The investigator's personal records of the protocol file should be a mirror image of the HRRC records with identical dates on all dated materials. Collection, safeguarding, and security for HRRC records pertain to the review and approvals of research protocols only and do not include study data except insofar as they pertain to subject protections and welfare. The informed consent template form, as well as any documents authorizing participation by or agreeing to assume supervisory responsibility for individuals not otherwise affiliated with GVSU, are part of the records that are required to be retained.

If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the HHS regulations at 45 CFR 46.115(b), they must retain the records in some form. Such records may be preserved in hardcopy, electronic, or other medium and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the GVSU procedures for retaining records. [GVSU procedure manual is under development and is anticipated to be available during AY 2007-08]. If investigators who have been designated to retain records on behalf of GVSU leave that institution, the investigators and GVSU should identify the successor responsible for maintaining those institutional records, either at GVSU or wherever the records are relocated, for the period of time required under HHS regulations at 45 CFR 46.115(b). Other regulations or procedures may apply to the retention of records, including study data.

In an effort to conserve space and exercise appropriate environmental stewardship at the university, it is the procedure of the HRRC at GVSU to routinely recycle or otherwise destroy in a secure manner the archival files and records of protocol materials that have been kept for seven (7) years following the completion of the research and closure of the protocol approval by the HRRC. Exception so this

procedure may be made by majority vote of the board in response to a petition from an interested party named in the research protocol, or a current board member.

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