

Grand Valley State University Institutional Review Board (IRB)	
<i>G-11: Guidance on Conducting Retrospective Chart Reviews</i>	
Issued: May 27, 2026	Office of Research Compliance and Integrity

Retrospective chart reviews are research projects where study data are collected only by accessing electronic health records (EHRs) of patients who meet a project’s inclusion criteria. Retrospective chart reviews are commonly used to compare potential treatment or patient outcomes between methods. These projects are usually initially reviewed by the Institutional Review Board (IRB) of the clinical site (CS) or hospital system that treated the patients, sometimes as part of a larger research study. The CS or hospital system’s IRB also often issues waivers of consent and HIPAA authorization as part of their review process. For additional information on HIPAA compliance in research, please refer to [*IRB Guidance G-2: HIPAA Compliance, Coded Private Information, and De-Identified Data*](#).

1. GVSU IRB Review of Retrospective Chart Review Projects

Because GVSU students and faculty members will potentially access identifiable patient information to conduct these research projects, review by the GVSU IRB is **required** before a retrospective chart review may begin. The level of IRB review the project receives is determined by multiple factors, including:

- The level of IRB review conducted by the CS’s IRB,
- Whether GVSU personnel will access identifiable patient information, and
- Whether GVSU personnel can reidentify patients from the collected data.

Depending on these factors, the GVSU IRB will either:

- Accept the research determination of the CS’s IRB (including Not Research determinations, Not Human Subjects Research determinations, and Exempt determinations),
- Execute an Institutional Authorization Agreement (IAA) with the CS’s IRB, also known as a “reliance agreement” for protocols approved by the CS’s IRB under Expedited or Full-Board review, or
- Conduct an independent IRB review of the protocol.

Further description of these three review options is provided below. See Table 1. at the end of this guidance document for more information on determining the appropriate level of GVSU IRB review for a retrospective chart review project.

A. Acceptance of CS’s IRB determination

If the CS’s IRB issued a research determination for the project, including an exempt determination, the GVSU IRB can accept that determination in lieu of conducting its own determination or exempt review. The researchers will still need to submit a protocol form through the ORCI’s electronic system, OneAegis. Copies of certain documents from the original submission to the CS’ IRB will need to be included, as outlined below and in Table 1.

B. Institutional Authorization Agreement (IAA)

An IAA or “reliance agreement” is a formal document executed between assured institutions collaborating in human subjects research defining which institution will conduct the IRB review and approval of the research. GVSU IRB policy requires an IAA be executed between collaborating institutions for projects receiving expedited or full-board IRB review; an IAA is not required for projects receiving exempt IRB review. Please see *IRB Policy 1120: Collaborating Research with Investigators Covered by an External FWA* for additional information.

When appropriate, the GVSU IRB will first seek to rely on the review of the CS’s IRB. The GVSU ORCI will work with the CS IRB to complete an IAA if needed. The IAA process can take several weeks to complete, depending on the responsiveness of the CS IRB.

C. Conducting Independent IRB Review

Independent GVSU IRB review of the study protocol will occur if:

- Independent IRB review is requested by the investigators,
- The CS’s IRB declines to serve as the reviewing IRB,
- The CS’s IRB is unresponsive after three contact attempts, or
- The CS did not review the research. (Note: Review by the CS IRB may be required after the GVSU IRB review.)

2. Accessing Identifiable Data and the Honest Broker

Multiple methods can be used to create a dataset from patient electronic health records. The method used can impact the level of IRB review. Two common methods are described here.

Method 1: GVSU researchers access or record **identifiable** patient data to create a deidentified data set, and/or can **reidentify** individual patients, either through the combination of collected data points or the retention of a correlation key (a list or table matching study identifiers to identifiable patient records).

Method 2: GVSU researchers only access **deidentified** patient data and **cannot reidentify** individual patients. This can involve use of an Honest Broker – an individual not affiliated with the research who has access to the necessary data as part of their regular job responsibilities. The Honest Broker creates a deidentified dataset and provides it to the researcher. The Honest Broker does not provide the correlation key or any way for the researcher to reidentify participants.

If an Honest Broker will be utilized to collect data from patient EHRs, an Honest Broker Attestation will need to be completed and submitted with the GVSU IRB protocol submission. Researchers may use either the [GVSU Honest Broker template](#) or analogous document provided by the CS.

3. **HIPAA Authorization**

Because patient health records are HIPAA-protected data, the researchers may either obtain HIPAA authorization from the patient participants, or a privacy board may issue a waiver of HIPAA authorization for the study. Ideally, the CS will have a privacy board that issues the waiver and document this waiver in the IRB approval letter. If it is unclear whether the CS issued the HIPAA waiver and it is deemed necessary, the GVSU IRB also has the authority to grant this waiver.

4. **GVSU IRB Personnel Training Requirements**

All GVSU personnel conducting research with human subjects must be named on the GVSU IRB submission and complete required training in Responsible Conduct of Research and Human Subjects Research before IRB approval can be granted; see *IRB Policy 310: Researcher Responsibilities, Qualifications and Training* for more information. These trainings are hosted online through CITI; access instructions can be found on the Office of Research Compliance & Integrity's (ORCI) website: <https://www.gvsu.edu/irb/training-requirements-74.htm>. **The faculty and/or CS advisor must also complete RCR and HSR training requirements and be named on the GVSU IRB submission if they will access identifiable patient information for research purposes.**

5. **Materials to Include with GVSU IRB Protocol Submissions**

The following documents and information should be provided when submitting a retrospective chart review research protocol to the GVSU IRB, as applicable:

- *CS IRB Protocol Submission*: A copy of the original research protocol approved by the CS's IRB.
- *CS IRB Approval Letter*: A copy of the letter documenting IRB approval by the CS's IRB. Include documentation that the GVSU researchers were added to the research protocol submitted to the CS's IRB, if possible.
- *Sample Data Collection Sheet*: Include information on data points being collected from individual patient EHRs, and who will be accessing this information.
- *GVSU Honest Broker Attestation*: If an honest broker will be utilized, include a signed Honest Broker Attestation.
- *HIPAA Authorization/Waiver*: Documentation of a HIPAA authorization/waiver approved by the CS's IRB, if applicable. This might be found in the *CS IRB Approval Letter*.

6. **GVSU IRB Protocol Submission Instructions and Tips**

The following instructions and tips are provided to help create a complete IRB protocol submission and facilitate an efficient review process.

- If the CS IRB has already reviewed this project or a larger "umbrella" project, select "Yes" to the first question on the IRB New Protocol Submission Form, in the section titled "Review by External IRB". If you would like GVSU to seek to rely on the CS IRB's review of this project, select "Yes" to the second question as well. The form will then ask you to provide the name of the CS and the CS IRB's decision on this protocol (Figure 1., below). This information can be found in the *CS IRB Approval Letter*.

- If requesting that GVSU seek to rely on the CS IRB’s review of this protocol, attach the *CS IRB Protocol Submission* and *CS IRB Approval Letter* documents to the form in the section titled “Reliance Agreement Request.”
- *GVSU Medical Dosimetry Graduate Students*: In the “Protocol Personnel” form section, please list Kristen Vu or Bethany Marshall as the Principal Investigator (College of Health Professions, School of Interdisciplinary Health). List yourself as a Co-Investigator or Research Assistant. **If your faculty and/or CS advisor will access identifiable patient information, they must also be included as a Co-Investigator and complete the GVSU IRB personnel training requirements.**
- In the form section titled “Additional Comments,” please include the following information, as applicable:
 - The contact information of the CS IRB, if requesting that GVSU seek to rely on the CS IRB’s review of the protocol.
 - Whether you and/or (if applicable) your faculty advisor will have access to identifiable information and/or a correlation key that would allow them to reidentify patients, if not stated elsewhere.
 - *GVSU Medical Dosimetry Graduate Students*: Please state if the CS IRB does not typically add student investigators to the IRB protocol as research personnel.
- If you are unsure where in the OneAegis submission form to attach a document, attach them to section 11b., “Additional Attachments.”

Figure 1. The "Review by External IRB" section of the IRB New Protocol Submission Form in OneAegis.

Review by External IRB
[Add Note](#) [View Audit](#)

In addition to the GVSU IRB, has or will another IRB review this study? *(Required)*

Yes
 No

GVSU can attempt to cede to the other institution's decision. Do you wish to rely on another institution's determination/review? *(Required)*

Yes
 No

Note that relying on the other institution's decision is often easier for the PI, as it does not require the PI to complete the full GVSU application form. Reliance agreements for projects approved under expedited or full board review require a signed agreement between institutions (exempt studies do not); if the other institution is willing to enter into the agreement, this process can usually be completed in less time than it would take to review the protocol internally as a new protocol. If the other institution refuses to enter into the agreement, the GVSU PI must submit the protocol through GVSU's IRB.

Indicate which site will be the IRB of Record for this study. This is the site that will provide initial review/approval of the study and will be responsible for post-approval monitoring of the protocol until it expires or is closed. *(Required)*

Mary Free Bed
 Mercy Health St. Mary's
 Metro Health
 Spectrum Health
 Other
 Not Yet Determined

If "Other" was selected, list the site: *(Required)*

Seattle Grace Hospital IRB

What was the outside IRB's decision for this protocol? *(Required)*

Exempt Determination
 Expedited Approval
 Full Board Approval
 Not Human Subjects Research Determination

Note: Do not submit this form until a formal decision has been made by the external IRB.

Table 1. GVSU IRB Review Pathways for Retrospective Chart Reviews

Will GVSU personnel access the EHRs of individual patients, or record identifiable patient data?	Will GVSU personnel be able to reidentify individual patients, or access a correlation key?	Clinical Site (CS) level of IRB review:	GVSU IRB review level:	Materials to include in the GVSU IRB protocol submission:
No	No	NR*, NHR**, Exempt, Non-Exempt***	NHR**	CS IRB Protocol Submission CS IRB Approval Letter GVSU Honest Broker Attestation
No	Yes	Exempt, Non-Exempt	Reliance; If unable, Expedited Cat. 5	CS IRB Protocol Submission CS IRB Approval Letter GVSU Honest Broker Attestation
Yes	No	Exempt	Accept determination; If no IRB documentation provided, Exempt Cat. 4	CS IRB Protocol Submission CS IRB Approval Letter Sample Data Collection Sheet
Yes	No	Non-Exempt	Reliance; If unable, Exempt Cat. 4	CS IRB Protocol Submission CS IRB Approval Letter Sample Data Collection Sheet
Yes	Yes	Exempt	Expedited Cat. 5	CS IRB Protocol Submission CS IRB Approval Letter Sample Data Collection Sheet
Yes	Yes	Non-Exempt	Reliance; If unable, Expedited Cat. 5	CS IRB Protocol Submission CS IRB Approval Letter Sample Data Collection Sheet

* NR = Not Research; ** NHR = Not Human Subjects Research; Non-Exempt = Expedited or Full-board review