



Sam Houston State University

A Member of The Texas State University System

INSTITUTIONAL REVIEW BOARD

SHSU IRB Guidance: Help with IRB Applications for a Retrospective Chart Review

IRB Considerations for a Retrospective Chart Review

The information in this guidance is designed for medical students. The purpose is to help guide students through the key steps of preparing and submitting an IRB application for a retrospective chart review. This is a quick guide and is not intended to provide guidance on formulating a research question, literature searching, data analysis, or presentation/publication of results.

What is a retrospective chart review?

A retrospective chart review is a type of clinical research study in which data is collected solely from the medical record or another patient database. As a result, there is no intervention with research subjects and no interaction with research subjects. Importantly, the medical treatment or care provided to patients who are subjects in a retrospective chart review is NOT directly related to the research study. In other words, the medical care was provided to patients regardless of whether the study was being done or not, thus the methods of a retrospective chart review are only related to identifying subjects and extracting their information from the medical record. As a result, any medical treatment, and risks/benefits thereof, have nothing to do with your study from the IRB's perspective.

Note that a retrospective chart review is NOT a study design, rather it is a study methodology. The study design for a retrospective chart review is always observational, and can be a case series, a case control study, a cohort study, or a cross-sectional study.

A chart review can be paired with a survey or an experimental (intervention) arm of a study. **This quick guide only deals with the IRB considerations for the chart review portion of the study.**

How do I get access to medical records?

The first step in conducting a chart review is to have a research mentor who already has access to the medical record. It is extremely unlikely that any health system will allow a medical student to run their own chart review, and most IRBs require a principal investigator that is a physician or faculty member. Thus, to conduct a chart review, which will require access to medical records, you will need a research mentor who has access to the medical records.

What is the IRB?

The IRB is a committee of faculty, staff, and laypersons that oversees human subjects research. For the purposes of this guide, be aware that medical records are considered human subjects, as a result, **retrospective chart review studies require IRB review because they are considered human subjects research.**

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Do chart reviews require IRB review?

Yes, chart reviews must be reviewed by the IRB if they are research. Even chart reviews that you know will fall into the EXEMPT category. Chart reviews can only be determined EXEMPT by the IRB. As a result, chart review protocols must still be submitted to the IRB for this exempt determination. “Exempt” merely means that the study is minimal risk such that it does not require ongoing oversight by the IRB.

What category of exempt is a chart review?

There are different categories of Exempt status for research studies. Chart reviews generally fall under Exempt Category 4(ii) or 4(iii). These are:

4(ii) Secondary research uses of identifiable private information or identifiable biospecimen – information recorded by investigator in manner that identity of subjects cannot readily be ascertained.

4(iii) Secondary research uses of identifiable private information or identifiable biospecimen – use of identifiable information regulated under HIPAA

Note that the **data to be collected for a chart review is considered a “use of identifiable private information”**. Because medical records exist for clinical, and not research, purposes, the use of this data for research is considered a “secondary use”.

The choice between Exempt category 4(ii) and 4(iii) depends on whether you will collect identifiers (such as MRN) as part of your study. This will be described in further detail below.

Training

All investigators listed on an IRB application must be up to date with human subjects research training per your institution’s requirements.

At SHSU, this training can be found here: www.citiprogram.org. Review IRB-SOP-018.01 Training and Education for more details on SHSU’s IRB training requirements.

At other institutions, this training requirement may be different.

Online Form

All IRB requests for approval are prepared and submitted through Cayuse Human Ethics. The “IRB Protocol Elements” information below is a combination of the types of information being requested by the IRB.

At SHSU, Cayuse Human Ethics can be found by clicking this link: <https://shsu.app.cayuse.com/>. Click [here](#) for guidance on navigating to Human Ethics.

Note that every member of the research team who is to be added to an IRB Protocol at SHSU must have a Cayuse profile. If you or someone on your research team is unable to add a person to the

Cayuse Human Ethics application, this means that those individuals do not have a Cayuse profile. Click [here](#) to complete the Cayuse Registration Form. Be sure to select Institutional Review Board, so the compliance office will know which Cayuse profile to create.

IRB PROTOCOL ELEMENTS (Note: this is not an all-inclusive listing of sections; this only highlights the sections affecting a secondary use request)

Objectives (Section 2.A.)

The objectives of your study are the main outcomes of your study as you define them. They are not broad goals, such as “to cure cancer”, or vague ideas, such as “to see if drug A works”. Instead, they are specific outcomes that you will measure.

For example, if you were doing a Covid-19 vaccine trial, your objectives would be something like, “The primary objective of this study is to determine if patients who received the experimental vaccine were diagnosed with Covid-19 at a lower rate than patients who received placebo as determined by RT-PCR testing.” You can add secondary objectives as well, such as “Secondary objectives include assessing severity of illness in the vaccinated vs. placebo group. Severity is to be measured as presence of symptoms, hospitalization rate, rate of admission to ICU, and death rate.”

Background & Significance (Section 2.B.)

IRB protocols should contain a background and significance section where the investigators outline for the IRB the basic background of the study along with its significance. Remember, the IRB committee and the IRB analysts reviewing and processing your requests are not necessarily experts in your field, so you must provide them with adequate background on your study, along with the significance of the study. This will establish the importance of doing the study in the first place. It is within the rights of the IRB to decline approval of a study if they feel the risk of doing the study, no matter how minor, is more than the benefit of having the study results. That’s why it’s important to clearly explain the background and significance.

References (Section 2.B.)

Include a list of references in your protocol.

Study Design (Section 3)

All questions in this section will describe the study design. Below is information that may assist the PI in completing this section:

Population of Focus in Chart Review (Section 3.B.)

The IRB will ask you to describe your research subjects—**PI’s can include this in Section 3, Item B.1.—select Other and briefly describe.** Inclusion criteria refers to the characteristics of patients that make it so they may be included in your study. Here is an example:

“Patients aged 18 and older who received Roux en Y gastric bypass surgery at Smith Memorial Hospital between the dates of January 1, 2019, and January 1, 2022.”

Note that description includes location and dates, along with the clinical and patient characteristics that qualify the patient for inclusion. There may be quite a few criteria in this list.

Exclusion criteria are characteristics of the patients that would exclude the patient from the study EVEN IF they meet the inclusion criteria.

Example: “Patients who received prior weight loss surgery” or “Patients who did not have a follow-up visit at 6- and 12- months post-surgery”.

Vulnerable Populations

Describe any vulnerable subjects that are purposely included in your study. Here is a list of potential vulnerable subjects:

Children
Pregnant women
Prisoners
Students
Human fetuses
Neonates
Individuals with physical disabilities
Individuals with mental disabilities or cognitive impairments
Note that this is not a comprehensive list.

In the IRB application, you must describe vulnerable populations if they are purposely included. Thus, if you are doing a study on pregnant women and their exposure to environmental pollutants at work, you would describe this population. However, if your study was on adults 18-65 years old who have asthma, you may have pregnant women as part of your study, but you do not have to describe them as a vulnerable population because you are not purposely including them in your study.

Vulnerable populations are described here because they are vulnerable to coercion or undue influence, and you are being asked to explain any additional safeguards to protect them. In the case of a chart review, if you have vulnerable populations, there are generally no additional safeguards in place. This is because you are not interacting with subjects or intervening in any way. As such, simply state that no additional safeguards are in place beyond the data protection procedures already described.

Data Collection (Section 3.B.)

Select the option, Analysis of Secondary Use Data (including chart reviews).

Study Endpoints (this information can be included as a separate paragraph in Section 3.A.2. when the PI selects “Review of medical/mental health records/medical treatment/criminal records”)

For a chart review, the study endpoint is simply the measurement you are using for the primary (and

secondary, if necessary) outcomes in your study. For example, let's say you were doing a retrospective study in a cohort of patients with Parkinson's disease, and you were interested in seeing if their exercise level helped in slowing progression of disease. Assume that you have a log of physical activity for these patients over a period of time. The endpoints in this study would be the measures of clinical progression of Parkinson's in these patients. There could be multiple endpoints, as Parkinson's has both motor and cognitive symptoms. As such, endpoints may be stability or balance, tremor, or measures of dementia.

Data Analysis (Section 3.C.)

In this section, you will have to describe your statistical analysis plan for the study, which can include a discussion or rationale for your sample size determination. If you need help with this section, please work with your faculty mentor (if a student). For this question, it asks about stopping rules. Simply state "Retrospective chart review, no possibility of subject withdrawal."

Provisions to Protect the Privacy of Subjects (Section 3.E.2.)

There are no privacy risks with a retrospective chart review. Privacy = people. State something like this in your application, "This is a retrospective chart review, there are no privacy risks because there will be no interaction or intervention with subjects."

Secondary Use Data (Section 8)

In Section 8, Item A, describe the procedures of a chart review. This description should include:

- How the patients will be identified
- Who will collect the data and from where (i.e., the Emergency Medical Record (EMR))
- Whether identifiers will be collected, and which identifiers
- Where the data will be stored (i.e., spreadsheet, database, etc.), this includes where both the data sheet AND identifiers are stored
- How you will protect the data (i.e., password protected, secure storage drive), including both data sheet and identifiers (if applicable)
- Who will have access to the data
- How data will be shared with others (such as statisticians, if applicable)
- Some notes on the above items: The procedures of a chart review are mostly grabbing data from the EMR or other source of data and storing this data securely somewhere. This can occur by hand (i.e., student collects data directly from the EMR), with the help of the Health IT department, and so on.

Provisions to Protect Confidentiality of Data (Section 8.C—if PI selects the last option in Item B)

There are data confidentiality risks. In this section, you would describe how you are protecting the data. Some key things to mention include:

Data will be stored securely (password protected, secure storage drive, use of, etc.)

Only investigators listed on the IRB will have access to data files

Correlation tool (or key to identifiers) will be used and stored separately from data files

Correlation tool will be destroyed at final publication/presentation of study (if you plan to do this)

Regarding Identifiers (Section 8.B. & 8.C.)

Of particular importance is the issue of identifiers. When it comes to chart review studies, the term “identifiers” refers to HIPAA identifiers. Here is a list of them, per the HHS (<https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>):

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
- All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- Telephone numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Fax numbers
- Device identifiers and serial numbers
- Email addresses
- Web Universal Resource Locators (URLs)
- Social security numbers
- Internet Protocol (IP) addresses
- Medical record numbers
- Biometric identifiers, including finger and voice prints
- Health plan beneficiary numbers
- Full-face photographs and any comparable images
- Account numbers
- Certificate/license numbers
- Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section “Re-identification”]

Be aware that if you have a data sheet with protected health information (PHI) and identifiers, and you let someone not authorized view this sheet, you have committed a HIPAA violation. Because of this, a strategy to protect data must be part of your research protocol.

There are two ways to protect confidentiality of patient data in a chart review (**note:** this will never be anonymous, so do not select the first option in Section 8.B.):

1. Do not collect identifiers (second option in Section 8.B.)
2. Utilize codes to allow re-identification (third option in Section 8.B.)

If you collect data without identifiers (#1 above), this is called safe harbor de-identification. If there are no identifiers in your data set, and the covered entity (hospital, clinic, practice...) has no

reasonable basis to expect that individual patients can be identified from the data, then it is not subject to HIPAA privacy rules. This type of data can be shared with statisticians.

If you do collect identifiers (#2 above), you do not want to include those in the same data sheet as the health information. You would instead utilize a “correlation tool” or “key to identifiers”. In this strategy, you remove identifiers from the data, and place them in a separate file which only has identifiers. You then give each subject a code (i.e., P1, P2, P3...) which you enter into both sheets. On one sheet, you have a patient code linked to identifiers, in the other sheet you have a patient code linked to the patient’s health and demographic data. In this way, you can utilize the code to re-identify the patient.

Here is a link to an example of a basic correlation tool and data collection sheet to illustrate this concept: [Sample Correlation Tool and Data Collection Sheet](#). If you wish to collect identifiers using this tool, attach this tool in Section 8.C.2.c.

If you want to use codes, you need to explain why you should be allowed to do this. Here is some sample language that explains why one might want to re-identify subjects in a chart review (**include this description in Section 8.C.2.a.**):

“The use of a correlation tool is being requested to allow re-identification of subjects. This request is being made for two main reasons. 1) In the case of data transcription errors (e.g., age of 350 years), researchers will be allowed to go back into the EMR to correct the errors. 2) Upon submission of the work for publication, it is often a reviewer request to strengthen the study by the inclusion of additional data in the study. With a correlation tool, investigators can go back into the EMR to collect additional data to improve the study.”

Attachments (throughout the submission)

Attach all documents requested by the IRB. This may include a blank version of your data collection sheet or a blank version of your correlation tool (if applicable). Since this is a secondary use request, you will not have to attach an informed consent form. Likewise, you will not have to attach any recruitment materials or messages to participants, because you will not be interacting with subjects.

After Submission to the IRB

Once submitted, follow IRB-SOP-046.01 Tracking Cayuse IRB Submissions for tracking your IRB submission through the routing and review process and IRB-SOP-001.01 Pre-Review Procedures for details on the review process performed by the IRB office.

Source: [Michigan State University's Office of Research, College of Human Medicine: Help with IRB Applications for a Retrospective Chart Review](#).

<https://research.chm.msu.edu/students-residents/retrospective-chart-reviews#:~:text=The%20IRB%20is%20a%20committee,are%20considered%20human%20subjects%20research.>