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.

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.**

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 f3.9 (rt9.2 4502 183.4 m20.00 Bfh)10.4 (o4 (IRB i)-)3.3 (s10.4 (t)-3.3 (h.9 (rc)6Xm[(kn.9 (rc)6M3.5 (P)4

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.

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.

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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

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