

## **Guidelines for Retrospective Chart Review Studies**

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While retrospective chart review research that involves only minimal risk to human subjects is sometimes exempt from full Institutional Review Board review, it is still subject to administrative review to determine eligibility for exemption. The IRB administrative office will decide whether the project qualifies as exempt, and the decision is confirmed in writing.

**\*\*Data or specimens must be existing (on the shelf) and may not be prospectively obtained to qualify for this exemption category. Prospective collection of data or specimens requires a higher level of review and consent from research subjects.**

**\*\*\*Identifiers and links to the subject's identity must be stripped from the data when it is collected. If a link must remain the research requires a higher level of review.**

### **General Principles**

"Retrospective Chart Reviews" of existing medical records that are intended as a systematic investigation designed to contribute to generalizable knowledge require prior IRB approval.

For this definition, "medical records" consist of information collected and generated for the purpose of providing health care for the personal benefit of the patient. It is usual that the information within medical records will have clinical validity and utility and that the collector of the information is a health care provider.

Medical records are distinguished from "research records" since the latter are collected and generated for the purpose of providing information about a research question. The intent in collecting research records is to conduct research and the collector of the information is a researcher.

Retrospective chart reviews of existing medical records do not require prospective IRB approval if any of the following intentions apply:

- 1) The intent is a non-generalizable investigative review such as for quality assurance or a review of a physician's competency
- 2) The intent is for quality management issues such as to ascertain the need for health care delivery
- 3) The intent is for compliance issues such as those of third party billing or investigator non-compliance
- 4) The intent is to obtain clinical information for teaching purposes.

If the intent of a retrospective review of medical charts does not fit those defined above, the retrospective chart review should be considered research and must receive prospective IRB approval.

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## Approval Categories for Retrospective Chart Reviews

No matter the review category, waivers of informed consent and HIPAA regulations may be requested. Such requests must be appropriately justified in writing.

1) **EXEMPT REVIEW:**

A retrospective chart review may receive IRB approval under the exempt process if the research fits both of the exempt criteria of 45 CFR 46.101(b)(4). These exempt criteria are:

- a. The research involves the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens; **AND**
- b. The data sources are publicly available or the data is recorded by the investigator in an anonymous manner such that subjects cannot be identified directly or through identifiers linked to the subject

Please note that for a chart review to receive concurrence of exemption from the IRB, it means that a **master list with a code number and identifiers cannot be kept.**

2) **EXPEDITED REVIEW:**

Retrospective chart reviews may qualify for expedited review according to 45 CFR 46.110 category 5 if:

- a. The research involves no more than minimal risk or minor changes in approved research; **AND**
- b. The research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as for medical treatment or diagnosis).

The expedited review procedure may not be used for studies in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Unlike exempt review, expedited review of retrospective charts does not require that the data be de-identified or anonymous. Expedited reviews can be given to studies in which the data already exists, but data may be prospectively collected. No matter whether the data exists or will be prospectively collected, the HIPAA "minimum necessary" rule applies.

Please note that when a chart review is appropriate for expedited review, **a master list can be kept** with identifiers and a code number throughout the research study.

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### **3) FULL BOARD REVIEW:**

Retrospective medical chart review studies that do not meet the criteria outlined in categories 1 and 2 must be approved by a convened meeting of the full IRB panel. Examples of such studies might be those in which the information contained in the medical records is of a sufficiently sensitive nature that additional safeguards are necessary to protect subjects' rights. In this case, the full IRB panel will make a determination of risk and the need for informed consent.

Retrospective research often requires the analysis of data that were originally collected for reasons other than research ([Hess, 2004](#); [Jansen et al., 2005](#)). This includes physician and nursing notes, ambulatory and emergency room reports, consultations, admission and discharge documentation, laboratory and diagnostic testing reports, and other clinical or administrative data.

## **Important Methodological Guidelines**

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### Elements in a Retrospective Study Design\*

1. Write the study question
2. Develop the hypothesis
3. Search the literature - This stage involves a systematic review of the literature pertinent to the study's area of focus, diagnoses, conditions, demographics, criteria, and populations. A review of the literature is a standard requirement for any research initiative, including retrospective chart reviews.
4. Consider the statistical issues, such as sample size and how the results will be analyzed
5. Write the protocol: where the data will be found, what data will be needed, how data will be collected, how data will be analyzed
6. Obtain permission: institutional review board (patient?), data source (eg, medical records department)
7. Collect the data
8. Analyze the data
9. Explain the results
10. Write the report