CHART REVIEW: RETROSPECTIVE AND PROSPECTIVE

The George Washington University
Office of Human Research
IRB Forum
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OVERVIEW

- Types of Chart Reviews
- Exempt vs. Expedited
- Protected Health Information
- Consent Requirements
- HIPAA
Chart reviews are a common method of gathering information on a specific medical condition or set of patient characteristics. Chart reviews can also include school records and employment records (usually for social science researchers). Chart reviews fall under IRB review because they involve viewing or obtaining private information about human subjects.
## Retrospective vs Prospective

<table>
<thead>
<tr>
<th>Retrospective</th>
<th>Prospective</th>
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<tr>
<td>Retrospective can be exempt or expedited.</td>
<td>Prospective are only expedited.</td>
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<td>Generally does not obtain consent (waiver).</td>
<td>May use consent or waiver of consent.</td>
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<td>May use a full or partial HIPAA waiver.</td>
<td>May use full HIPAA authorization or waiver of HIPAA (full or partial).</td>
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<td>Information is already collected (“on the shelf”) prior to study submission.</td>
<td>Information has not yet been collected.</td>
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WHAT IS RETROSPECTIVE?

- The project must involve the use of existing data, documents, records, or specimens (shelved or frozen specimens).
- “Existing” means that materials were already in existence at the time of the IRB application.
- The protocol must give a specific date range, e.g., “This study will only collect information that has been recorded in charts 6/1/99-6/1/03.”
EXEMPT VS. EXPEDITED
IS MY CHART REVIEW EXEMPT?

- To be exempt, it must not be possible to figure out which data belong to a subject, once the data have been recorded by the researcher.

- Information recorded by the researcher must not identify the subject. Individually identifiable data elements may not be recorded.

- Additionally, the researcher is not allowed to keep a linking list of any sort.

- This must be stated in the protocol, application, and HIPAA waiver, if applicable.
IS MY CHART REVIEW EXEMPT?

- Certain retrospective projects may not qualify for exempt status, if partial identifiers are needed or if a linking list is desired.
- If a project does not qualify for exempt status, then all federal research regulations will apply to the project. In that case, informed consent of the participant is the default requirement.
- For retrospective chart reviews, the investigator generally requests that the consent requirement be waived.
Chart reviews may be considered expedited if the following occurs:

- Researcher will be maintaining identifiable information,
- Creating a codelink, or
- Accessing both prospective and retrospective data.
PROTECTED HEALTH INFORMATION (PHI)
Generally speaking, chart reviews involve the use of medical information for research without seeking written permission from the subject.

Therefore, the access to medical information must occur under a waiver of privacy authorization.

In order to qualify for a waiver of privacy authorization, the following criteria must be met:
There is an adequate plan to protect identifiers from improper use and disclosure.

There is an adequate plan to destroy identifiers at the earliest opportunity.

Protected health information (PHI) will not be re-used or disclosed for another purpose.

The research could not practicably be conducted without the waiver of privacy authorization.

The research could not practicably be conducted without the use of PHI.
WHAT CONSTITUTES PHI?

- Names
- All geographic subdivisions smaller than a State
- All elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/License numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, code, or combination that allows identification of an individual.
What Do I Need?


**WAIVER OF CONSENT**

- Waiver of consent process is the most frequently requested type for both retrospective and some prospective chart reviews. In order for the IRB to approve a waiver of consent process, the IRB must be able to make the following determinations:

  A. The research involves no more than minimal risk to the subjects;

  B. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

  C. The research could not practicably be carried out without the waiver or alteration; and

  D. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
In certain instances the IRB may determine that consent is required if the investigator is unable to justify why it’s impracticable to conduct the research without a waiver. This consent can be verbal and conducted via telephone.

This is more often the case for prospective chart review studies, but sometimes occurs in retrospective chart review studies.
Verbal consent is also known as waiver of documentation of consent.

Consent is still obtained but a signature may not be required. The study team would document in the research files that subject granted verbal consent.

This may be used if:
- Research presents no more than minimal risk.
  - AND
- Research involves procedures that do not require written consent when performed outside of a research setting.
HIPAA WAIVERS

What Type and How?
The requirement to obtain Authorization may be waived if all of the following criteria are met:

Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on:

- An adequate plan to protect the identifiers from improper use and disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless a health or research justification for retaining the identifiers exists or retention is required by law)
- Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity (except as required by law for authorized oversight of the research) or for other research for which use/disclosure of PHI would be permitted

Waiver will not adversely affect the privacy rights and the welfare of the individuals

The research could not practicably be conducted without the waiver

The research could not practicably be conducted without access to and use of the PHI.
HIPAA WAIVER

- If you are conducting research for which you cannot obtain consent or get written authorization for various reasons
  - That involves collection of *existing* data.
    - Data/ specimens previously collected for standard of care or other research purposes
    - Not reasonable to contact patients for consent (large numbers, some may be deceased)
  - That involves collection of *prospective* data.
    - This involves *minimal risk* interactions
    - PHI needed from critical care, intubated, patients; emergency research, etc.
- Health care providers may release their patient records to a researcher, if the researcher obtains a waiver of authorization from an IRB and/or Privacy Board.
- The IRB approves a waiver; however, you cannot access the charts until you have approval from *the institution’s privacy officer*!!
Privacy officers will ask for a time frame of destruction.

In other words, the identifiers will be destroyed 24, 48, 72 hours after publication.

The time frames are not specified in the HiTECH Act, but they must provide a time frame.

Publication is the most common, but it could be any time point (e.g., after data analysis, etc.).
PREPARATORY TO RESEARCH

- Used to assess whether or not the study is feasible.
- Approval must be obtained from the privacy officer.
- NOT the same as recruitment (partial waiver) or data collection (full waiver)
Example of Prep to Research:
- Requiring access to medical records to determine if enough potential subjects are available for research to be considered valid.

You may be required to obtain IRB review and approval.

Example:
- Recording information for recruitment or data purposes.
You need to explain:

- Plan to *protect the identifiers* from improper use and disclosure

- Plan to *destroy the identifiers* at the earliest opportunity (within Institutional requirements)

- Written assurances that PHI will not be reused or disclosed except as permitted under HIPAA
When to Use

- To obtain PHI and contact information, and for study recruitment.

- When identifying PHI information is required to make initial contact with a person for participation.

- When PHI is required to conduct pre-screening and determine eligibility of potential subjects before recruitment.

- To disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals for a study.

- To conduct IRB-approved recruitment activities so eligible patients could directly contact the researcher.
Explain:
- How the use or disclosure of PHI involves no more than minimal risk
- The research could not practicably be conducted without access to and use of PHI
- How the subjects will be identified
- Plans to *protect the identifiers* from improper use and disclosure, and confidentiality of subjects and
- Plans to *destroy the identifiers* at the earliest opportunity (within Institutional requirements)
- Written assurances that PHI will *not be reused or disclosed* except as permitted under HIPAA
Retrospective chart reviews can be exempt or expedited, often use consent and HIPAA waivers.
Retrospective data must exist prior to study submission.
Exempt chart reviews MUST NOT have links to identifiable data.
Prospective chart reviews may require written consent and HIPAA authorization.
HIPAA waivers may be full or partial.
## Privacy Officers

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