Overview

- Types of Chart Reviews
- Exempt vs. Expedited
- Consent Requirements
- HIPAA
- Publishing
Chart Reviews

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.
Chart Reviews

Exempt
- Always retrospective
- Cannot maintain codelink
- Full HIPAA Waiver
- Consent waiver

Expedited
- Can be retrospective, prospective or both
- Can maintain codelink and identifiers
- May use any type of HIPAA authorization
- May obtain any type of consent (waiver or full)

Retrospective
- “On the shelf” at time of review
- May use codelink
- May use any type of HIPAA authorization
- May be Exempt (no codelink) or Expedited
- May obtain any type of consent (waiver or full)

Prospective
- May only be Expedited
- May use any type of HIPAA authorization
- May obtain any type of consent (waiver or full)
- Can be combined with retrospective charts
### Retrospective vs Prospective

<table>
<thead>
<tr>
<th>Retrospective</th>
<th>Prospective</th>
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<tbody>
<tr>
<td>• Retrospective can be exempt or expedited</td>
<td>• Prospective are only expedited</td>
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<tr>
<td>• Generally does not obtain consent (waiver)</td>
<td>• May use consent or waiver of consent</td>
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<tr>
<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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<tr>
<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 or Expedited?

How to Determine the Category of Review
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 may be required.
- For retrospective chart reviews, the investigator generally requests that the consent requirement be waived.
Is my chart review expedited?

- Chart reviews may be considered expedited if the following is occurs:
  - Researcher will be maintaining identifiable information
  - Creating a codelink or
  - Accessing both prospective and retrospective data.
DO I NEED TO GET CONSENT?
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:
  - The research involves no more than minimal risk to the subjects;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - The research could not practicably be carried out without the waiver or alteration; and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Verbal Consent

- 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;
- 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 is more often the case for prospective chart review studies, but sometimes occurs in retrospective chart review studies.
Protected Health Information

WHAT IS PHI?
HOW DO I ACCESS IT?
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.
Chart Review and HIPAA Waivers

- 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.
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; Publication is the most common, but it could be any time point (e.g., after data analysis, etc.).
# HIPAA Waivers

## Partial Waiver

- **Used:**
  - To obtain PHI and contact information, and from patients 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.

## Full Waiver

- **Used:**
  - Only for retrospective chart reviews when consent is not obtained.

- **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.
Be Advised!!

- If investigators who receive health information under a HIPAA Waiver disclose any PHI to other investigators, institutions, or agencies, the investigator is responsible for keeping an accounting of disclosures;
- Under HIPAA, subjects can request a record of how often their health information was released to others in the previous six (6) year period;
- For health information obtained under a HIPAA Waiver, it is the investigator’s responsibility to provide this record of disclosures.
Preparatory to Research

- Used to assess whether or not the study is feasible and 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.
Publishing Results of Chart Reviews

TOP TEN MISTAKES
Tope Ten Chart Review Mistakes

“The retrospective chart review: important methodological considerations”, Matt Vassar and Matthew Holzmann, Journal of Educational Evaluation for Health Professionals, 10(12);

- Top ten most common mistakes that will prevent your retrospective chart review abstract from publication:
  1. Failure to create well-defined, clearly-articulated research questions;
  2. Failure to consider sampling issues a priori;
  3. Failure to adequately operationalize variables in the study (identify study variables, do lit review);
  4. Failure to train and monitor data abstractors;
  5. Failure to use standardized abstraction forms;
  6. Failure to create an adequate procedural manual for data abstraction (can be protocol);
  7. Failure to explicitly develop inclusion and exclusion criteria;
  8. Failure to address inter-rater or intra-rater reliability;
  9. Failure to perform a pilot test (10% of sample);
10. FAILURE TO ADDRESS CONFIDENTIALITY AND ETHICAL CONSIDERATIONS.
Recap

- 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;
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