Chart Reviews

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IRB FORUM
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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

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

Retrospective	Prospective
• Retrospective can be exempt or expedited • Generally does not obtain consent (waiver) • May use a full or partial HIPAA waiver • Information is already collected (“on the shelf”) prior to study submission	• Prospective are only expedited • May use consent or waiver of consent • May use full HIPAA authorization or waiver of HIPAA (full or partial) • Information has not yet been collected

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.

Consents

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.

HIPAA Waiver

- 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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