GW OHR Guidance:

Chart Reviews

This guidance document will outline general best practices and requirements for conducting research that solely involves chart reviews (retrospective or prospective). This document should be used by investigators and research team members who are planning a study that will involve review and extraction of medical record chart data for research purposes.

What does the IRB look for when reviewing a chart review?

The IRB focuses on the following when reviewing a chart review study:

- Whether or not there is personally identifiable information being obtained
- If *retrospective and/or prospective data are to be included
- Where the data are coming from
- Outcome variables to be included
- How the data are accessed, transferred, and/or extracted
- How the data are securely protected and stored during and after extraction for analysis

*Retrospective: All data accessed for this research must be in existence at the time of the initial IRB submission date in order to meet the definition of "retrospective." In the IRB application, researchers will be asked to provide the exact date range (MM/DD/YYYY- MM/DD/YYYY) from which data will be accessed.

Do I need consent for a chart review?

Two forms of consent are necessary for consideration for chart reviews:

- (1) Informed consent for the research
- (2) HIPAA authorization for the research team to access participant medical records

Research team members have the option to either (a) obtain informed consent and a HIPAA authorization from participants, or (b) request a waiver of consent and HIPAA authorization waiver for participants. In order to waive informed consent, the research team must meet the criteria for waiver of consent per the federal regulations (45 CFR 46.116(f)(3)). In order to waive the HIPAA authorization, the research team must meet the criteria in the HIPAA Full Waiver Request Form.

For prospective chart reviews in particular, whenever possible, informed consent and the HIPAA authorization should be obtained. The IRB application requests that researchers explain this.

What is a HIPAA authorization?

A HIPAA authorization in research is permission granted from a participant to allow the disclosure and use of their protected health information (PHI) from a covered entity or business associate for research purposes. This allows the research team to view/extract/use/analyze protected health information from a participant's medical records for research purposes.

What is the difference between a HIPAA Partial Waiver and a HIPAA Full Waiver?

HIPAA Partial Waiver

A research team should request the HIPAA Partial Waiver when they are accessing PHI for recruitment purposes *only*. This means the researcher is only going into the medical records to view/obtain the minimum amount of PHI in order to identify eligible participants for one's research and this information will not be used for any other purpose in the research. The HIPAA Partial Waiver Request Form must be completed, signed and dated by the Principal Investigator, and attached in the IRB submission.

HIPAA Full Waiver

A research team should request the HIPAA Full Waiver when they are accessing PHI for use in the research (i.e., data analysis). It is important the research team only collects the minimum amount of PHI that will help meet the research objectives to help reduce the risk to loss of confidentiality. The HIPAA Full Waiver Request Form must be completed, signed by the Principal Investigator, and attached in the IRB submission.

HIPAA Forms can be found here on the GW OHR website.

REQUIRED: Once the IRB approves your HIPAA Waiver Request as part of your IRB submission, the research team must reach out to the site's privacy officer/board to approve the waiver before one can begin their research.

TIP: The site's privacy officer/board from which a research team is obtaining permission to use the PHI is a great resource for researchers!

CHECKLIST FOR CHART REVIEW STUDIES

There is a specialized IRB application for studies only involving a chart review or secondary analysis of pre-existing data.

- ☐ If you are solely conducting a chart review, select "yes" in section 8 of the IRB Application for the question that says "Are you only conducting a chart review or does the research consist only of secondary analysis of an already existing dataset?"
- ☐ Ensure all study personnel are listed in section 3 of the IRB application and are up-to-date on their CITI training
- ☐ Complete every question. Do not leave any question blank. If a response is not applicable, mark it as such.
- ☐ Be clear about the data security measures and make sure this information is consistent across the IRB application and all documents.

- Note: Check with the site regarding any site-specific requirements; e.g., the MFA has site-specific requirements (i.e., you may not take identifiable data home on a laptop or a flashdrive).

☐ If requesting a waiver of consent and a HIPAA authorization waiver, be sure to:
- Select "Waiver of Consent" and complete this section
- Select "Yes" to the question that asks if PHI will be accessed/obtained/analyzed and then select "HIPAA Full Waiver"
- Complete the HIPAA Full Waiver and upload with your IRB submission. Be sure to complete in full and include the IRB #, PI name and contact information, and the PI signature.

☐ If including a HIPAA authorization in the consent form, please reference the content in the consent template **here**.

Questions?

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