GW OHR Guidance:

Chart Reviews

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

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

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

1. Where the data are coming from
2. How the data are accessed, transferred, and/or extracted, and
3. How the data are protected and stored during and after extraction for analysis

**Chart reviews don’t usually involve contact with subjects- do I need consent?**

There are two forms of consent necessary for chart reviews; informed consent for the research and HIPAA authorization for the research team to access participant medical records. Both forms of consent can be waived when the research team will have no contact with participants. However, for some chart reviews (especially prospective chart reviews), there will be contact with potential participants and therefore consent should be obtained.

Generally, if you have the opportunity to obtain consent from participants then you should do so. Additionally, when informed consent is sought from participants you can also include HIPAA authorization language to gain permission to access participants’ medical records.

When requesting a waiver of consent, you will need to request a waiver of informed consent for research and a waiver of HIPAA authorization. You will need to justify the following:
Tip: If you are accessing data prospectively, consider if obtaining consent would be possible.

REQUIRED: Once the IRB approves your HIPAA waiver request, you will need your privacy officer to approve and sign the waiver before you can begin your research.

### CHECKLIST FOR CHART REVIEW STUDIES

There is a special, focused IRB application for chart review studies. When you are creating an IRB application for a chart review study, **you must complete sections 1 – 8**, making sure to **mark section 8.7 “yes”** – you are conducting a chart review only:

- Section 8.7 select “chart review only”

Then, complete the rest of the IRB application, paying special attention to the following items:

- Make sure all study personnel are listed consistently between sections 3 and 4
- Make sure all study personnel are up to date on their CITI training
- Do not leave any questions blank, particularly about *where and how* data will be accessed, and *where and how* data will be stored
- Make sure that data security measures are clearly stated, such as “all medical charts will be accessed and analyzed on MFA (or GW Hospital) servers, computers, and devices,”
and “data will be de-identified and a code link document linking codes to identifying information stored separately from data”

**Tip:** As per MFA requirement, you may not take identifiable data home on a laptop or flashdrive

If you are requesting a waiver of consent and HIPPA authorization:

- [ ] Section 12.1 Request a waiver of consent *process*
- [ ] Section 15.2 Request a HIPAA *Full* Waiver
- [ ] Upload a completed full HIPAA Authorization waiver with PI signature as a study document (found here: https://humanresearch.gwu.edu/hipaa-forms-0)

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**Questions?**

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