Guidance on Request for Retrospective Review of Data or Specimens

To submit a project involving only medical record (chart) review, submit the following forms:

HPR-211 Application for Human Research

HRP-503 Protocol Template

Request for Waiver of HIPAA Authorization (If HIPAA applies – you are accessing, recording, or disclosing PHI) Most of the time if you are requested a waiver of informed consent (which most medical record review research does) you will need this waiver.

Filling out the protocol template may be a little different than completing it for other, non-chart review projects. In particular:

- #3 – Specify where the records you are reviewing will come from, such as: Dr. Brown’s surgery records, Faculty Practice Associates medical records, etc.
- #5a – This answer will generally be similar to that for #3.
- #5b – This would address the variables of interest. For example, “Records of patients with ICD-9 code X will be reviewed.
- #5c – This should indicate the number of records to be reviewed.
- #5d – This should indicate the time period of the records to be reviewed (e.g., “Records from 1/1/01 through 12/31/09 will be reviewed.”) as well as the expected amount of time the researcher expects the project will take to complete.
- #5f – Procedures will generally involve medical record review and analysis of the data collected from those records.
- #5h – In order for the IRB to appropriately categorize the research (exempt, expedited, not human subjects research) this section must be carefully completed, focusing on:
  1. What identifiers, if any, the researchers (a) can see when they are in the medical record and (b) what will be recorded with the data gathered from the medical record.
  2. If the data is or will be coded, specify who keeps the code and how, and who has access to it. Aside from these points, the instructions in the protocol template should be followed.
- #5i and j – Will generally not be applicable.
- #6 – The primary risks to subjects in medical record review is breach of confidentiality/privacy risks. The way to prevent these is to appropriate protect the data, which you will have addressed in #5h.
• **#12** – Generally, a waiver of informed consent will be sought for medical record review research. That such a waiver is being sought should be stated here. Then you should review (you don’t have to fill it out or submit it) HRP-415 Waiver or Alterations of the Consent Process to make sure you qualify for a waiver of consent.

• **#13** – Generally not applicable since most medical record review research involves a waiver of consent.