CAPE FEAR VALLEY HEALTH

IRB Guidance: Guidelines for Medical Record/Chart Reviews

Medical record/chart reviews of medical records that are intended as systematic investigations designed to contribute to generalizable knowledge require IRB determination or approval prior to conducting the project.

"Medical records/charts" consist of information collected and generated for the purpose of providing health care for the personal benefit of the patient. It is usual that the information within medical records/charts will have clinical validity and utility and that the collector of the information is a health care provider.

Medical records/charts are distinguished from "research records" since the latter are collected and generated for the purpose of providing information about a research question. The intent in collecting research records is to conduct research and the collector of the information is a researcher.

Medical record/chart reviews (both retrospective and prospective) do not require prior IRB approval if any of the following intentions apply:

1. The intent is a non-generalizable investigative review such as for quality assurance or a review of a physician's competency
2. The intent is for quality management issues such as to ascertain the need for health care delivery
3. The intent is for compliance issues such as those of third-party billing or investigator non-compliance
4. The intent is to obtain clinical information for teaching purposes.

If the intent of a medical record/chart review does not fit those defined above, the review should be considered research and must receive IRB determination/approval.

Determination/Approval Categories for Medical Record/Chart Reviews with No Subject (Patient) Contact

<u>Not Human Subjects Research</u>:

If you are receiving unidentifiable/de-identified or coded data (without access to the identifying code) from another source, your research may not be considered human subjects research. In such cases IRB approval is not required but the IRB will make a determination and continuing IRB oversight is not required.

Example:

A researcher requests de-identified data from a local clinic. The investigator is provided de- identified data report (contains none of the 18 PHI identifiers) in the form of a spreadsheet. This information is provided by the clinic's authorized IT person. The information in the sheet is not considered PHI because all 18 of the PHI identifiers have been removed. There is no requirement for consent of the subject and no requirement regarding HIPAA authorization because there is no identifiable private information being disclosed.

<u>Exempt Review, Category 4</u>:

A medical record/chart review of *identifiable private information* or *identifiable biospecimens* may receive IRB determination under the exempt process if the research fits one of the exempt criteria of 45 CFR 46.101(b)(4). These exempt criteria are:

a) The data sources are publicly available,

Example: Data or biospecimens purchased commercially (publicly available).

b) The information is recorded by the investigator in an anonymous manner such that the subjects cannot be identified directly or through identifiers linked to the subject.

In order for a medical record/chart review to be determined under b), you can have access to the records which include identifiers – such as name or date of birth – but you cannot record this information, even temporarily, while extracting the data you need. Therefore, a master list with a code number and identifiers cannot be kept.

Example: A doctor working at a hospital accesses medical records to collect information for a research project that includes patient age, type of trauma, medical tests conducted and if subject returned for follow-up procedures. All data is recorded without any of the 18 PHI identifiers.

c) The information is collected and analysis involving the use of identifiable health information regulated under HIPAA regulation, for the purpose of "health care operations" or "research", or for "public health activities and purposes." Meaning the information has been, will be collected solely for non-research purposes such as for medical treatment or diagnosis.

Example: A researcher wants to gather data on the use of a particular antibiotic by reviewing medical records from the years 2015 – 2020. The investigator requires recording the patients name, the initial date the antibiotic was provided and subsequent information regarding the administration of the antibiotic. The patient identifier is required in order to link patient information obtained from multiple databases, and/or link existing patient information with new patient information.

Note: Consent of the subject and/or Waiver of the Informed Consent Process are not required but the IRB must grant a Waiver of HIPAA Authorization if the researcher has not obtained a HIPAA Authorization. Justification for the Waiver of HIPAA Authorization (***Appendix A – HIPAA Use of Protected Health Information***) must be included with your IRB application.

Full Board (Non-Exempt) Review:

In very rare cases, full committee review may be required for medical record/chart reviews, even if there is no contact with subjects. Under federal regulation, exempt and expedited review cannot be used for research projects that pose greater than minimal risk to subjects.

Full committee review is required for medical record/chart projects where identification of the subjects and/or their responses would reasonably place them at risk for criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing. The IRB may review the project at the expedited level if the project team implements reasonable and appropriate protections to safeguard the subjects' privacy and confidentiality.