OFFICE *of* RESEARCH & GRADUATE STUDIES

IRB Guidance for Retrospective Chart Review Studies

Retrospective research often requires the use of data that were originally collected for reasons other than research, such as information contained in medical records. Medical records consist of information that has clinical validity and utility, being generated for the purpose of providing health care by health care providers. Examples include physician notes, ambulatory reports, admission and discharge documentation, laboratory test reports, and administrative data.

Retrospective chart reviews of existing medical records do not require IRB approval if any of the following apply:

1. The intent is to obtain clinical information for teaching purposes.
2. The intent is for quality management issues such as the need for health care delivery.
3. The intent is a non-generalizable investigative review such as for quality assurance.
4. The intent is for compliance issues such as third-party billing or other non-compliance scenarios.

Note: If the intent does not fit these definitions, the retrospective chart review is considered research and must receive prospective IRB approval.

Although retrospective chart review research may be exempt from full Institutional Review Board review, it is always subject to administrative review to determine eligibility for exemption. The Office of Research and Graduate Studies Research Compliance services will decide if the project qualifies as exempt. The decision will be confirmed in writing.

Approval Categories

1. Exempt Review:
   A retrospective chart review may receive approval under the exempt process if the research fits both the Exempt criteria of 45 CFR 46.101(b)(4):
   a. The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens; **AND**
   b. The data sources are publicly available, or the data is recorded by the investigator in an anonymous manner such that subjects cannot be identified directly or through identifiers linked to them.

   Note: This means that a master list with a code and identifiers cannot be kept.

2. Expedited Review:
   Retrospective chart review may qualify for expedited review under 45 CFR 46.110 category 5 if:
   a. The research involves no more than minimal risk or minor changes in approved research; **AND**
   b. The research involves data, documents, records, pathological specimens, or diagnostic specimens that have been collected, or will be collected, solely for non-research

purposes (such as for medical diagnosis or treatment).

Unlike exempt review, expedited review does not require that the data be anonymous or de-identified. Expedited reviews can be given to studies where data may be prospectively collected. The HIPAA "minimum necessary" rule applies, whether the data exists or will be prospectively collected.

Note: This means that a master list with a code number and identifiers can be kept during the research study.

3. Full Board Review:
   Retrospective chart review studies that do not meet the criteria outlined in Approval Categories 1 and 2 must be approved by a convened meeting of the full IRB. Examples include studies of medical records requiring additional safeguards to protect participant rights, determination of risk, and the need for informed consent.