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

Not Human Subjects Research:

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.

FLEX Review:

Medical record/chart reviews that meet the criteria to be reviewed under **Campbell's HRPP policy, Registration Projects by FLEX Review**. FLEX Review categories are not defined in the federal regulations and they will be only applied to research projects that fall outside of the scope of Campbell University's Federalwide Assurance (FWA) for the Projection of Human Subjects.

FLEX Review categories may be used for research projects that would typically fall under Exempt, Category 4 *and* Expedited, Category 5 (see below), if the research is federally funded or the criteria for FLEX Review is not met.

Medical record/chart reviews may qualify for FLEX review according to Campbell's HRPP FLEX policy Category 3 or 8 if one of the following criteria is met:

a) The data sources are publicly available, **OR**
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, **OR**
c) If the identity of the subjects can readily be ascertained directly or through identifiers linked to the subjects and adequate provisions have been made to ensure the privacy and confidentiality of the subjects' data *(requires justification for Waiver of the Informed Consent Process to be included in the research plan)*.

This means that the research information may be collected in a de-identified, anonymous, coded, or identifiable manner. Collection may be retrospective and/or prospective. The HIPAA "minimum necessary" rule applies. A HIPAA authorization or waiver of HIPAA authorization is required for research meeting criteria c) listed above.

A clear explanation of the research methods that will guard against disclosure of private information; and justification for waiver of informed consent (if recording identifiers) and HIPAA authorization are required in your research plan and *Appendix A – HIPAA: Use of Protected Health Information*.

IF YOUR RESEARCH IS FEDERALLY FUNDED OR DOES NOT MEET THE CRITERIA FOR FLEX REVIEW, YOUR PROJECT MUST BE REVIEWED UNDER THE FEDERAL REGULATIONS.

Exempt Review, Category 4:

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,

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 exempt, 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.

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 submission.

A medical professional or staff member who normally has access to medical record/chart information by virtue of their patient care responsibilities can conduct the record/chart review. Students in the health care professions can conduct medical record/chart reviews under the supervision of an appropriately credentialed professional employed by the "covered entity."

Examples:

1. *Data or biospecimens purchased commercially (publicly available).*
2. *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.*

Expedited Review, Category 5:

Medical record/chart reviews of *identifiable private information* or *identifiable biospecimens* may receive IRB approval under the expedited review process according to 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 materials (data, documents, records, or specimens) that have been, will be collected or will be collected solely for non-research purposes such as for medical treatment or diagnosis.

The expedited review procedure may not be used for studies where identification of the subjects and/or their responses would reasonably place them at risk of criminal, civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.

Unlike exempt review, expedited review of medical records/charts does not require that the data be de-identified or anonymous. Data collection can be retrospective or prospective. The HIPAA "minimum necessary" rule applies.

A clear explanation of the research methods that will guard against disclosure of private information; and justification for waiver of informed consent and HIPAA authorization are required in your research plan and *Appendix A – Use of Protected Health Information*.

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.

Full Board 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.

Special Considerations

Most medical record/chart reviews are not conducted at Campbell University. Due to Campbell's unique teaching relationships, most of these research projects are conducted at external institutions such as local medical clinics, hospitals, and pharmacies. These external institutions or sites are considered "covered entities" under HIPAA regulations and typically do not have an IRB. If the site does have an IRB you will need to contact the external site's IRB to discuss your research project. If the external site does not have an IRB, the Campbell IRB *may* be willing to extend our Federalwide Assurance (FWA) to the external site. Extending Campbell's FWA requires a reliance agreement, specifically an Individual Investigator Agreement (IIA) to be executed between the external site without its own IRB and Campbell University. Therefore, your research project will be reviewed as either exempt or expedited as determined by the IRB.

The Campbell IRB does not execute an IIA for projects that are approved by FLEX review because these projects are not covered by Campbell's FWA. Registration Projects by FLEX review will require the submission of a Letter of Support (LOS) from the external institution.

Please contact the IRB if you have questions around the role of your collaborating site **before** submitting your protocol for IRB review.

Medical Records/Charts Review Involving Subject Contact

Research involving subject contact requires informed consent, no matter the level of the review.

Medical record/chart review in combination with subject contact requires the following:

1. The consent form should include the following information:
    - A statement regarding the purpose of the medical records review (i.e. for screening, for ongoing review or to meet follow-up requirements)
    - A statement informing subjects their medical records will be reviewed by others besides the “covered entity” researchers (i.e., sponsor, etc.)

    Both these statements can be found in the Campbell IRB informed consent templates.
2. HIPAA Requirements: In addition to obtaining informed consent, HIPAA authorization or an approved waiver is also required.