

St. David's HealthCare Institutional Review Board

Guidance Document Regarding Retrospective Chart Reviews

I. Retrospective (Medical) chart review or data Collection

Retrospective chart reviews or data collection processes are considered research when they attempt to answer a research question. Research is defined in the Federal regulations (45 CFR 46.102) as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Human subjects are defined as living individuals about whom an investigator conducting research (1) obtains data through interaction or intervention, or (2) their identifiable private information. Therefore, medical chart reviews that incorporate data collection and data analysis to answer a research question must undergo IRB review.

II. Types of chart, or medical records, review

In general, there are two primary types of chart review. A Retrospective Chart Review evaluates patient data that is existing at the time the project is submitted to the IRB for initial review. A Prospective Chart Review includes at least some patient data that does not yet exist at the time the project is submitted to the IRB for initial review; retrospective data may be included in a prospective chart review study.

III. Questions to consider:

a) Are chart review studies Exempt from IRB review?

"Exempt" research refers to research that is exempt from the regulations in the United States Code of Federal Regulations (CFR) that pertain to human subject research. While many investigators may believe their studies are Exempt from these regulations, the IRB should make the determination that a research project meets the criteria for Exemption. Research studies that are exempt from IRB review must (i) pose less than minimal risk to the research participants AND (ii) must fit into at least one of six categories of research defined specifically in the regulations (45 CFR 46.101b). The six categories of exempt research are:

1. Research conducted in established or commonly accepted educational settings.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the collection methods could lead to identification of subjects.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph # 2 (above) if: (1) the human subjects are elected or appointed public officials or candidates for public office, or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate or otherwise examine generally public services or benefit programs.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the FDA, EPA, and/or USDA.

Retrospective chart reviews may be exempt under Category 4 of the Federal Regulations. However, in order for the research to be exempt, the information being collected must be in existence prior to the study **AND** the information must be recorded in such a manner that the subjects cannot be identified directly or indirectly through identifiers. Therefore, if a temporary identify link is retained by the investigator(s) to reconnect patients with their medical record (e.g. for additional data gathering at a later time), then the study cannot be exempt from IRB review. There are provisions for an intermediary (i.e. an honest broker) to retain the identifying link(s), such that the data is de-identified the investigator(s) and the research study adheres to the Exempt criteria. If the criteria to be Exempt cannot be met, the research may be eligible for an Expedited IRB Review.

b) Are chart review studies eligible for Expedited IRB review?

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. The FDA and OHRP regulations (21 CFR 56.110) permit, but do not require, an IRB to review certain categories of research through an expedited procedure if the research involves no more than minimal risk to human subjects. Examples for which expedited approval may be appropriate include;

1. Research on drugs for which an investigational new drug application (NDA) is not required. Although, if marketed drugs are used in a manner that significantly increases the risks associated with the use of the product, expedited review is not appropriate.
2. Research on medical devices for which an investigational device exemption (IDE) is not required **OR** the medical device is cleared/approved from marketing and the medical device is being used in accordance with its cleared/approved labeling. Studies intended to evaluate the safety and effectiveness of the medical device are not eligible for expedited review, including studies of approved medical devices for new indications.
3. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture (there are specific guidelines regarding weight, age & limits regarding how much blood can be drawn and over what period of time).
4. Prospective collection of biological specimens for research purposes by non-invasive means (i.e., hair & nail clippings, secretions, swabs)
5. Collection of data through non-invasive procedures routinely employed in clinical practice (x-rays are excluded).
6. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (i.e., treatment or diagnosis).
7. Collection of data from voice, video, digital, or image recordings made for research purposes.
8. Research on individual or group characteristics or behavior or research involving survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Most chart reviews are therefore eligible for Expedited Review under Category 6, above. Unlike Exempt Review, Expedited Review of retrospective charts does not require that the data be de-identified or anonymous. Expedited reviews can be given to studies in which the data already exists, and also to studies in which some or all of the data may be prospectively collected. No matter whether the data exists or will be prospectively collected, the HIPAA "minimum necessary" rule applies. Expedited Review **may not** be used for studies in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or 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 no greater than minimal.

IV. Medical records review for quality and non-research activities

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

Retrospective chart reviews of existing medical records do not require prospective 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 retrospective review of medical charts does not fit those defined above, the retrospective chart review may be considered "research" and must receive prospective IRB approval.

V. Waiver of consent

Waiver of consent is frequently requested for both retrospective and prospective chart reviews. In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the following criteria are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If all of the criteria above are not satisfied, then the Investigator may apply for a Waiver of Documentation of Consent, where the investigator does not need to obtain a signed consent from each subject, although consent (e.g. verbal consent) must be obtained from all subjects. In order for the IRB to grant a Waiver of Documentation of Consent, the following criteria must be met:

1. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
2. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

If a Waiver of Documentation of Consent is approved by the IRB, each subject will be asked whether they want to execute written consent documentation linking the subject with the research, and the subject's wishes will govern.

VI. Waiver of HIPAA Authorization

A Waiver of HIPAA Authorization allows researchers to use HIPAA Protected Health Information (PHI), such as names, dates of birth, etc. in their research study. The HIPAA "minimum necessary" rule always applies. The criteria that must be satisfied for a Waiver of HIPAA Authorization are:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - a. an adequate plan to protect the identifiers from improper use and disclosure;
 - b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. The research could not practicably be conducted without the waiver; and
3. The research could not practicably be conducted without access to and use of the protected health information.

Examples of research studies where a request for a Waiver of HIPAA Authorization may be appropriate include:

1. research on using existing health information, e.g., medical records research and chart reviews
2. research where a waiver of informed consent is also being requested, e.g., survey research via phone