

## **KUMC Guidelines for Retrospective Chart Reviews**

Retrospective chart reviews are considered to be human subjects research and must be approved by the KUMC Human Subjects Committee. As of April 14, 2003, retrospective chart reviews must meet both human subjects and HIPAA privacy requirements.

### **Human Subjects Requirements**

#### *Exempt Status*

Frequently, retrospective chart reviews qualify for “exempt” status under human subjects regulations. Exempt studies are not subject to certain federal research requirements and do not require yearly recertification. The KUMC Human Subjects Committee determines whether or not a project qualifies as exempt. In order to qualify as exempt, the retrospective chart review must meet two criteria:

1. The project must involve the use of existing data, documents, records, or specimens. “Existing” means that materials were already in existence at the time of the HSC application. The protocol must give a specific date, e.g., “This study will only collect information that has been recorded in charts prior to 6/1/03.”
2. Information recorded by the researcher must not identify the subject. Individually identifiable data elements may not be recorded. Additionally, the researcher is not allowed to keep a linking list of any sort. To be exempt, it must not be possible to figure out which data belong to a patient, once the data have been recorded by the researcher. The protocol must specifically state that no items of information that would enable the identification of any subject will be recorded, and that no linking list of any sort is being kept that would enable someone to look up the code number assigned to a subject and determine the identity of that subject.

#### *Waiver of Consent*

Certain retrospective projects may not qualify for exempt status, if partial identifiers are needed or if a linking list is desired. If a project does not qualify for exempt status, then all federal research regulations will apply to the project. In that case, informed consent of the participant is the default requirement. For retrospective chart reviews, the investigator generally requests that the consent requirement be waived. A waiver of consent may be approved by the KUMC Human Subjects Committee if the project meets these regulatory criteria:

- The research involves no more than minimal risk to the subject.
- The waiver will not adversely affect the rights and welfare of the subjects
- The research could not practicably be done without a waiver of consent.
- When appropriate, the subjects will be provided with pertinent information after the study.

Examples of retrospective studies that might qualify for a waiver of consent are those that collect dates of surgery, or studies that require a linking list to connect various components of data in Medical Records and Radiology or Pathology.

## **HIPAA PRIVACY REQUIREMENTS**

Retrospective studies must also meet privacy requirements. A retrospective chart review involves the use of medical information for research without seeking written permission from the patient. Therefore, the access to medical information must occur under a waiver of privacy authorization. In order to qualify for a waiver of privacy authorization, the following criteria must be met:

- There is an adequate plan to protect identifiers from improper use and disclosure.
- There is an adequate plan to destroy identifiers at the earliest opportunity
- Protected health information (PHI) will not be re-used or disclosed for another purpose.
- The research could not practicably be conducted without the waiver of privacy authorization.
- The research could not practicably be conducted without the use of PHI.

## **APPLICATION AND APPROVAL PROCESS**

Project applications should address both human subjects and HIPAA requirements. All application materials should be submitted to the KUMC Humans Subjects Committee (HSC). Include the following documents:

- 1) HSC application form<sup>1</sup>
- 2) Application for “Exemption Class”<sup>1</sup> or a submission letter that requests a waiver of informed consent and addresses the waiver of consent criteria.
- 3) Study protocol, including the data collection sheets.
- 4) Application for waiver of privacy authorization<sup>2</sup>
- 5) List of study personnel
- 6) Human Subjects Tutorial certificate: if not turned in previously

<sup>1</sup>Available at: <http://www2.kumc.edu/researchcompliance/hscforms.htm>

<sup>2</sup>Available at: <http://www.kumc.edu/hipaa/forms/>

At the time of application to HSC, please submit **one original and one copy** of the above materials. The project will be reviewed for both human subjects and privacy issues. Final approval will come from the HSC. Prior to approval, all study personnel must complete HIPAA Research Training. An on-line module is available for those who have not attended a live session.

## **ACCOUNTING REQUIREMENTS**

Under the HIPAA Privacy Rule, the holder of the medical record is required to account for disclosures made to a researcher under a waiver of privacy authorization. To fulfill this legal obligation, the researcher will be assigned a tracking number for the project. The holder of the medical record should use this tracking number to record the disclosure in each patient’s chart. The tracking may be electronic or paper, depending on the medical record system being used. In certain departments, the researcher may be required to assist in the accounting effort by placing in note in the records that are accessed for the project.