



**UNIVERSITY OF KANSAS MEDICAL CENTER  
HUMAN SUBJECTS COMMITTEE**  
INSTRUCTIONS FOR THE **EXEMPT APPLICATION**  
TO CONDUCT HUMAN SUBJECT RESEARCH

These instructions outline the information that the Human Subjects Committee (HSC) will use in evaluating proposed human subjects research. In its review, the HSC must determine that the proposed research meets federal standards for the protection of human subjects. Those regulations, overseen by the federal Office for Human Research Protections (OHRP), are found in 45 CFR 46 at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

The federal regulations outline six categories of low risk projects that may qualify as “exempt” studies. Only the HSC may determine that a research project qualifies for Exempt status. The request for Exempt status must be approved prior to initiation of the study.

“Exempt” status means that informed consent is not required, and annual re-review is not required. Exempt research, as all research, must be conducted in an ethical manner. Respect for potential subjects and confidentiality must be maintained.

Although annual renewal is not required, investigators are responsible for notifying the HSC if any revisions are made to the project. The HSC must determine whether or not the revisions impact the risks to human subjects, thus affecting the project’s Exempt status.

The Exempt Application is designed to facilitate the review process and demonstrate that federal criteria are met. In addition to the regulations, OHRP has published an IRB Guidebook at [http://www.hhs.gov/ohrp/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/irb/irb_guidebook.htm) which provides helpful information about research ethics and the research review process.

It is important to understand that the review process is conducted on a case-by-case basis and is specifically tailored to the proposed methodology. Additional supportive information may be requested at the discretion of the HSC in an effort to assure regulatory compliance and protection of research subjects. If you have questions, please contact the KUMC HSC at (913) 588-1240.

## **SECTION I: STUDY INFORMATION**

Please provide all requested information about the Principal Investigator (PI) who will be conducting the human subject research. Note that students, residents, and fellows must have a faculty mentor as principal investigator. Ensure accurate contact information so that the HSC office can communicate with the PI in a timely manner.

In addition to Protocol Title, provide protocol number/version and date.

## **SECTION II: EXEMPT CLASSIFICATION**

In order for proposed research to be considered for exempt review, it must meet the criteria for at least one of the six (6) exempt categories as defined by the Office of Human Research Protection (OHRP). Each category is listed in detail on the *Application for Exempt Review of Human Subject Research*, however, if you have any questions as to whether your research qualifies under one or more of these exempt categories please contact the HSC Office at (913) 588-1240 or [humansubjects@kumc.edu](mailto:humansubjects@kumc.edu).

If your proposed research does not meet the criteria for exempt review, you must complete either the *Application for Full-Committee Review* or the *Application for Expedited Review*.

## **SECTION III: STUDY PERSONNEL**

List all individuals who have any role in the design or conduct of the study. The personnel section has two purposes. First, it assists the HSC in evaluating whether the principal investigator and other study personnel have the appropriate qualifications, experience, and facilities to properly conduct the study and provide for the safety and welfare of subjects. Second, HSC office staff reviews the list of study personnel to ensure that the named individuals have completed training in human subjects and HIPAA training and have filed an annual Conflict of Interest disclosure. Study approval will be withheld if the training and disclosure requirements are not met.

## **SECTION IV: FUNDING INFORMATION**

State whether the study is funded or unfunded or if the investigator is seeking funding. Funding information is used to identify potential data recipients, to determine whether there are adequate resources to conduct the study, and to evaluate available resources in the event of a subject's injury. When the proposal is part of a federal or non-federal grant application, investigators must submit the entire grant application for HSC review.

## **SECTION V: CONFLICT OF INTEREST**

This section asks *study-specific* questions on conflict of interest. Requirements for this information are separate from the requirement to complete the annual Conflict of Interest Form that is required of all KUMC employees.

In addition to reporting his/her own financial interest, the principal investigator is responsible for conferring with the study team to determine whether *any* team member has a reportable financial interest *related to the study*. Team members are not required to disclose confidential details of their interest to the principal investigator; they may simply inform the principal investigator that their interest is reportable. Financial interests are not necessarily prohibited, and not all financial interests impact the welfare of human subjects. If the principal investigator or a study team member has a reportable interest, the study will be referred to the KUMC Conflict of Interest (COI) Committee. The COI Committee will work with the team member on a confidential basis, to determine whether the financial interest requires a management plan. If the committee requires a management plan, HSC approval for the project will remain pending until the plan is implemented.

## **SECTION VI: PROJECT INFORMATION**

### **(a) Protocol**

A research protocol must accompany the application. The protocol should contain a full description of the proposed research methodology so that the HSC can adequately review the application in accordance with federal regulations. The full protocol will be screened by the HSC staff for administrative completeness and then reviewed by the HSC Chairman and a HIPAA representative. Researchers should provide as much information as possible to avoid unnecessary delays in the review process.

The protocol should cover the purpose, results of similar or related studies, rationale and specific aims, hypotheses, study design, participant selection criteria, study procedures, risks and benefits, confidentiality protections, statistical analyses, and record retention. The protocol should include a list of any instruments used in the study as well as the instruments themselves. If interaction with the subjects is planned, the HSC must review all information that will be used for the interaction (such as flyers, letters of introduction, surveys, tests, and interview questions). Data collection sheets also must be included in the application.

### **(b) Study Summary**

The study summary is reviewed by both the HSC and HIPAA reviewers, and will be reviewed by all members of the HSC if it is determined that the protocol must go to a convened HSC meeting. Describe the specific scientific objectives in language that can be understood by persons who are unfamiliar with your area of research, as follows:

#### **What is your research question (hypothesis)?**

State your research question (i.e., hypothesis) so that the HSC can understand your research intent.

#### **What study design will you use?**

The study design should demonstrate how you will answer your research question. HSC reviews the study design to ensure that the design adequately minimizes risk and that risks are reasonable in relation to potential benefits.

### **(c) Retrospective Chart Review**

Retrospective chart reviews involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are publicly available or recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. If the investigator accesses identifiable records or specimens to conduct the chart review and does not obtain written permission from the patients, then a waiver of privacy authorization must be approved. A request for a waiver is posted at:

<http://www.kumc.edu/hipaa/research/>

## **Section VII: Cancer and Cancer-related studies**

Please indicate whether the protocol relates to cancer or cancer prevention. All cancer-related studies must obtain prior approval from the Kansas Masonic Cancer Research Institute's Protocol Review and Monitoring Committee. Cancer or cancer related studies may include the following:

**Therapeutic/Treatment:** Studies that evaluate new treatments or new ways to use a current or new treatment such as drugs or combinations, therapies, surgical or radiation techniques, or methods of treatment for cancer.

**Prevention:** Studies that look at cancer prevention, high-risk characteristics, and recurrence.

**Ancillary or Companion:** Studies that are in addition to or related to another study in order to get additional information on a group of subjects or to look at a different set of variables collected, or a cancer-related study that involves management of disease, quality of life, or follow-up on survival.

**Correlative:** Laboratory based cancer research involving human participants, human tissue or related by-products.

## **Section VIII: Certifications**

Please obtain the appropriate signatures on your application prior to submission. Applications submitted without signatures will be returned. Department Chairs should sign applications for faculty members. If the principal investigator is the department chair, administrative certification should be obtained from the appropriate associate dean, dean, or other executive administrator.