

# **Human Subjects Research**

**Resources  
for KUMC Students, Residents  
and Fellows**

**January 2005**

# The University of Kansas Medical Center

Human Research Protection Program

December 1, 2004

TO: KUMC Students, Residents and Fellows

FROM: Karen Blackwell, MS  
Director, Human Research Protection Program/ Privacy Official

This packet of resources is designed to assist you as you enter the realm of human subjects research. All research that involves humans or their personal information must first be approved by the KUMC Human Subjects Committee. This review allows KUMC to ensure that the activities comply with multiple government requirements. More importantly, it ensures that our research meets the highest ethical standards.

The Human Research Protection Program has assembled these resources to assist you with the submission of your projects. On page 4, you will find a Checklist that outlines the essential steps for conducting research. Subsequent pages contain descriptions of the various types of research projects, HIPAA considerations, training websites, and submission requirements.

We welcome your questions and suggestions about these resources. Both the Human Subjects Office and the HIPAA Compliance Office are available for consultation about research projects. We would be happy to discuss your project before submission, in order to facilitate the review. You may schedule a consultation regarding HSC by contacting Daniel Voss at 588-5712; a pre-review for HIPAA is available with Tom Field at 588-0940.

## **Human Subjects Research Table of Contents**

Checklist for Conducting Human Research .....	4
Research Categories: Exempt, Expedited, and Full-Review Projects .....	6
KUMC Guidelines for Retrospective Chart Reviews .....	9
Elements of Protected Health Information .....	12
Quick Reference Guide on HIPAA Research Requirements.....	13
Application for Waiver of Privacy Authorization.....	14
Training Modules .....	16
HSC Submission Deadlines .....	21
Required Paperwork for Submissions.....	22
Web Resources .....	24
Contact Information .....	28

# Checklist for Conducting Human Subjects Research at The University of Kansas Medical Center

- Are you conducting research?**  
*Research is a systematic investigation, including protocol development, testing, and evaluation, designed to contribute to generalized knowledge.*
- Does your research involve human subjects?**  
*Human subjects are living individuals about whom the investigator obtains data through intervention or interaction with the individual, or obtains identifiable private information.*
- Is the research subject to HIPAA regulations?**  
*If your research involves individually identifiable health information, HIPAA applies. The PHI checklist [www.kumc.edu/hipaa/docs/PHIChecklist.pdf](http://www.kumc.edu/hipaa/docs/PHIChecklist.pdf) outlines the 18 identifiers that make patient data subject to HIPAA requirements.*
- Complete the Human Subjects/HIPAA training and file a Conflict of Interest Disclosure.**  
These items are accessed through the Chalk system at <https://www2.kumc.edu/chalk2/>
- Make a preliminary determination of the type of review that will be required. The Human Subjects Committee (HSC) will make the final determination and can provide guidance on these categories.**  
Exempt Review – Permitted when research meets one of six federally-defined categories (e.g., educational testing, retrospective review of existing data or samples, demonstration projects)  
Expedited Review – Minimal risk studies that may be reviewed by the HSC chair, or one or more experienced reviewers designated by the chair, rather than the full Human Subjects Committee.  
Full Committee Review – Any research that does not meet exempt or expedited criteria. Written informed consent is the default requirement, but this requirement may be waived when appropriate (e.g., telephone surveys, anonymous questionnaires, retrospective projects that require a limited linking list)
- Submit the application based upon the type of review you anticipate.**  
**Required application materials are listed at:**  
<http://www2.kumc.edu/researchcompliance/forms/HSC.Submission.Reg.05.19.2004.pdf>  
**Deadlines and meeting dates are listed at:**  
[http://www2.kumc.edu/researchcompliance/forms/HSC\\_MeetingDates\\_2005.pdf](http://www2.kumc.edu/researchcompliance/forms/HSC_MeetingDates_2005.pdf)
- Respond to any provisos (questions or conditions) from the HSC/HIPAA review. These are generally sent to the researcher three days after the meeting. Responses to provisos must be received within 45 days, or the application will be terminated.**
- Receive HSC approval before initiating the study. Use the current, stamped version of the consent form for all subjects (if applicable).**
- Report any unanticipated problems or adverse events on the adverse event form found at <http://www2.kumc.edu/researchcompliance/hscforms.htm>**
- Obtain HSC approval before implementing procedural changes**
- Annually re-certify the project, if required**

*For assistance at any time during your research project, from submission to closure, contact the Human Subjects Committee Office at 913-588-1240, located in G006 Sudler.*

# Information from the Human Subjects Committee Office

## **Research Categories: Exempt, Expedited, and Full-Review Projects**

Human research studies will fall into one of three categories for review: “exempt” research, expedited review allowed, or full committee review required.

### **“Exempt” Studies**

Exempt studies are low risk studies that fall into one of six categories delineated by the federal government. Exempt research, as all research, must be conducted in an ethical manner; “exempt” status simply means that annual re-review is not required. Researchers should note that only the Human Subjects Committee (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.

The federal criteria for exemption are listed below. Most exempt projects at KUMC fall into Category 2 or Category 4.

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (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) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) 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 if the information is recorded by the investigator in such a manner that 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 Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

After receiving Exempt approval, 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. Projects that do not meet the “exempt” criteria must comply with all federal regulations regarding research.

## **Expedited Review**

Expedited review is a process through which certain kinds of studies are reviewed by the HSC chair, or one or more experienced reviewers designated by the chair, rather than the full Human Subjects Committee. Expedited review is permitted only when the project involves no more than minimal risk and when the study procedures fall into one or more of the eligible categories listed by the federal government. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Categories of Expedited research are summarized as follows:

- Under certain conditions, clinical studies of drugs and medical devices.
- Under certain conditions, the collection of blood samples.
- Prospective collection of biological specimens for research purposes by non-invasive means, e.g., hair and nail clippings, deciduous teeth, saliva, dental plaque, mucosal cells.
- Under certain conditions, the collection of data through non-invasive procedures routinely employed in clinical practice.
- Research involving materials collected for non-research purposes.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics employing survey, interview, oral history, focus groups (if not exempt).
- Research in which the primary risk is breach of confidentiality and the risk has been managed so that it is no more than minimal.

A complete list of research categories that may be reviewed with an Expedited procedure is found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> The submission requirements for Expedited studies are identical to the requirements for research requiring Full Review. Submissions should include any applicable data collection tools or questionnaires. Requirements for written informed consent may apply.

### *Waivers of Consent*

- Expedited projects may also include those for which the investigator requests a waiver of informed consent. A request for a waiver of consent should be made on a separate letter that is included in the submission packet.
- The request to waive consent must demonstrate that:
  - the research involves no more than minimal risk to the subjects;
  - the waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - the research could not practicably be carried out without the waiver or alteration; and
  - whenever appropriate, the subjects will be provided with additional pertinent information after participation.

### **Full Review Projects**

Any research involving human subjects that does not fall into an Exempt or Expedited category must be reviewed by the full Human Subjects Committee at a convened meeting. Full review is required when the study poses greater than minimal risk or when an external granting agency requires full review. Research reviewed by the full committee usually involves significant physical, psychological, economic, legal or social risks. Common examples are clinical trials and behavioral studies.

## 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. 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 also must 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.

# Information from the HIPAA Compliance Office

## The Health Insurance Portability and Accountability Act (HIPAA) governs Protected Health Information (PHI)

If any of the following demographic characteristics are paired with information about past, present, or future physical or mental health, or information about the payment of health care, the resulting information is **Protected Health Information** under federal law.

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code

***To qualify as de-identified data, each of the elements listed above must be removed.***

- Note: a de-identified data set may include a tracking code or other numbering system, provided that:
- a. the tracking code is not related to information about the individual
  - b. the re-identification algorithm is not disclosed to the data recipient

**Quick Reference Guide on HIPAA Research Requirements**

<b>Research Examples</b>	<b>Investigators should:</b>
A clinical trial involving written informed consent.	Incorporate the required elements of the privacy authorization into the informed consent document, using the appropriate HSC consent template <sup>1</sup> .
A clinical trial in which research personnel, who do not have a treatment relationship with the patients, will access medical records or lab results to screen for subjects.	<p>a. Incorporate the required elements of the privacy authorization into the informed consent document, using the HSC consent template</p> <p>b. Contact the HIPAA Compliance Office for an application for a Partial Waiver of Privacy Authorization for the recruitment activities. The waiver application should be included in the submission to HSC.</p>
Prospective use of clinical records or biological materials to create a database or specimen repository for future research.	Submit the project to Human Subjects Committee for review. If informed consent is required by HSC, incorporate the required elements of the privacy authorization into the informed consent document.
A telephone survey for which written consent is not practicable.	Submit the project to HSC; include an application for a Waiver of Privacy Authorization <sup>2</sup> .
Retrospective research, involving access to medical records or identifiable lab samples held by a health care provider.	Submit the project to HSC; include an application for a Waiver of the Privacy Authorization <sup>2</sup> .
A study in which the investigator receives a data set or tissue samples that have some identifiers removed, but not enough to meet HIPAA de-identification standards. (For example, research that requires dates of surgery, subject's zip code, or subject's initials)	Submit the project to HSC; include an application for a Limited Data Set <sup>2</sup> . Negotiate a Data Use Agreement <sup>2</sup> , in cooperation with the HIPAA Compliance Office.
A project in which the researcher receives data or specimens that meet HIPAA de-identification standards.	Submit the project to HSC with an "Exempt" application; alternately, submit the project under a master plan for de-identified research (available in late Fall 2004)
Request for summary statistics on various diagnostic codes, in order to prepare a research protocol.	Request information directly from Hospital Medical Records Department. No privacy or human subjects requirements apply.

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

<sup>2</sup> Available on the HIPAA Compliance Website at <http://www.kumc.edu/hipaa/forms/>

**KUMC HUMAN SUBJECTS COMMITTEE**  
Application for Waiver of HIPAA Privacy Authorization for Studies Using PHI\*

**SUBMIT TWO COPIES OF THIS FORM TO THE HSC OFFICE**

**HSC#**

**Project Title:**

**Responsible Investigator:**

**Department/School:**

**I. Please describe the protected health information that you wish to access or use.**

**II. Who holds the records you wish to access?**

**III. Subject information:**

*How many subjects do you plan to study?*

*Approximately how many charts do you need to review in order to complete the project?*

**IV. To obtain approval for a waiver or alteration of the HIPAA privacy authorization, the research project must meet the federal regulatory criteria listed below. Please describe how your study meets these criteria.**

a) There is an adequate plan to protect subject identifiers from improper use and disclosure.

b) **There is 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.**

c) **Protected health information (PHI) will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which use or disclosure of PHI would be permitted under HIPAA regulations.**

d) **The research could not practicably be conducted without the waiver or alteration.**

e) **The research could not practicably be conducted without access to and use of PHI.**

---

**Principal Investigator**

**Date**

# Training Modules

# CHALK

**All Chalk users please log in here:**

[Information on recent improvements to Chalk.](#)

**Institution:**

**Username:**

**Password:**

[Enter Training](#)

**[I am a new user.](#)**

**[I have an account but I've forgotten my login information.](#)**

[Logout](#)

[Modules](#)    [Training History](#)    [Announcements](#)    [Reports](#)

**Click on module title to begin:**

[Animal Welfare Resources On-Line Training](#)

[Computer Security Awareness Training](#)

Informs users about computer policies and strategies to address common security threats. **This course is designed for users on the Kansas City campus; a course for Wichita users is coming soon.**

[Conflict of Interest Disclosure](#)

All KUMC unclassified personnel AND all those involved in research, regardless of their affiliation, are required annually to disclose any potential conflicts of interest.

[Human Subjects Protection](#)



All personnel involved in research at KUMC, regardless of affiliation, are required to initially certify with this 7 module tutorial in human subjects protection and to renew that certification annually with the refresher tutorial.

[IR Employee Skills & Goals Profile](#)

Employees of Information Resources should follow this link to create/update their employee skills & goals profile.

[KUMC University HIPAA Training](#)

This site contains multiple tutorials related to HIPAA compliance. Users should choose the tutorial that relates to their institutional role. For more information about tutorial(s) that may be required, please contact the HIPAA Compliance Office (913.588.0942).

[Safety Training](#)

All personnel, regardless of affiliation, are required annually to complete safety training specific to their role.

[School of Nursing Clinical Orientation Module](#)

Annual Clinical Orientation certification for Greater Kansas City nursing students.

---

Powered by **CHALK**

©2004, The University of Kansas

Developed by

**NetLearning**

design, development & multimedia



Health Insurance Portability &  
Accountability Act  
at the University of Kansas Medical Center

## New Federal Regulations Governing Patient Privacy

Select the HIPAA training module you wish to complete:

- HIPAA Training for Classified and Unclassified KUMC Employees  
This training is for classified and unclassified KUMC employees whose duties do not involve clinical care or human research.
- HIPAA Training for KUMC Deans, Basic Scientists, and Department Directors  
This tutorial gives an overview of the HIPAA Privacy Rule and discusses its impact on the clinical, education, and research missions of KU Medical Center. It is targeted for deans, chairs and faculty in the basic sciences, and directors of non-clinical units at KUMC.
- HIPAA Training for KUMC Providers  
This tutorial is required for health care providers at KUMC, including physicians, residents, physician assistants, nurse practitioners, and allied health professionals who bill for their services.
- HIPAA Training for KUMC Students  
This tutorial provides training on the HIPAA Privacy Rule for KUMC students in the School of Medicine, School of Nursing, and School of Allied Health.



HIPAA Research Training is now Module 7 of the Human Subjects Tutorial. Any research personnel who have already completed the full Human Subjects tutorial, but need to complete HIPAA research training, may select the Human Subjects Tutorial and complete only Module 7. Completion of that module will be confirmed in the user's personal Training History and will be viewable by staff in the Human Subjects and HIPAA offices.

Have questions or comments about this training?  
E-mail [HIPAA Compliance](mailto:HIPAA@kumc.edu)

© 2004 The University of Kansas Medical Center

# HSC Submission Process



**Research Compliance  
Human Subjects Committee  
Meeting/Deadline Dates 2005**

<b>Deadline (Noon)</b>	<b>and</b>	<b>Meeting</b>	<b>Deadline (Noon)</b>	<b>and</b>	<b>Meeting</b>
December 30*		January 11	July 1		July 12
January 14		January 25	July 15		July 26
January 28		February 8	July 29		August 9
February 11		February 22	August 12		August 23
February 25		March 8	September 2		September 13
March 11		March 22	September 16		September 27
April 1		April 12	September 30		October 11
April 15		April 26	October 14		October 25
April 29		May 10	October 28		November 8
May 13		May 24	November 10 *		November 22
June 3		June 14	December 2		December 13
June 17		June 28			

**The deadline for submitting protocols is  
FRIDAY AT NOON  
Seven business days before the meeting**

\* Denotes Thursday deadline days for holiday observance

## Required Paperwork for Submissions to the KUMC Human Subjects Committee

*If more than 1 copy is required, submit as COLLATED packets.*

I. What paperwork do I need to submit a new study that requires full review?		
2 packets as described below		
HSC packet	HIPAA HSC packet	Total # of copies/item
1. HSC application (2)	1. HSC application (1)	3
2. Protocol summary (2)	2. Protocol summary (1)	3
3. Protocol (2)	3. Protocol (1)	3
4. Investigator's drug or device brochure (when available)		2
5. KUMC consent form (2)	4. KUMC consent form (1)	3
6. Sponsor's sample consent form (when available) (2)		2
7. Institutional Research Safety Form (2)		2
8. List of Personnel (2)		2
9. Tutorial certificates from outside personnel (when applicable) (2)	5. Tutorial certificates from outside personnel (when applicable) (1)	3

II. What paperwork do I need to submit a new exempt study?		
2 packets as described below		
HSC packet	HIPAA HSC packet	Total # of copies/item
1. HSC application (1)	1. HSC application (1)	2
2. Exempt application (1)	2. Exempt application (1)	2
3. Application for HIPAA waiver – retrospective chart review only ( 1)	3. Application for HIPAA waiver – retrospective chart review only (1)	2
4. Protocol summary (1)	4. Protocol summary (1)	2
5. Protocol (1)	5. Protocol (1)	2
6. List of Personnel (1)		2
7. Institutional Research Safety Form (2)		2
8. Tutorial certificates from outside personnel (when applicable) (2)	6. Tutorial certificates from outside personnel (when applicable) (1)	2

III. What paperwork is needed to re-certify a study?	
A summary progress report (SPR) will be sent to the PI by the HSC office or the RI (if set up by Clinical Trials Division)	
HSC packet	# of copies per item
1. SPR: signed and completed	2
2. Protocol summary	2
3. List of Personnel	2
4. Current consent form (a. One with HSC approval stamp b. clean copy without stamp)	1
5. Tutorial certificates from outside personnel (when applicable)	2
6. Application for HIPAA waiver – retrospective chart review only ( 1)	1

#### IV. What paperwork is needed to submit a response to proviso(s)?

1. Cover letter: 2 copies
2. Current consent form with changes highlighted (when applicable): 2 copies
3. Current consent form WITHOUT approval stamp (when applicable): 1 copy

#### V. How do I submit a Serious Adverse Event (SAE) and when (1 copy of the entire packet)?

1. Complete and sign a HSC- Adverse Event Form.
  - For KUMC enrolled subjects: provide a copy of the case report form/progress note  
\*Blacken subject's name, record initials and/or subject number
  - For private sponsor or coordinating center reports: attach Medwatch report and/or sponsor report
2. If the consent is revised as a result of the SAE:
  - Submit a cover letter stating the change
  - Submit revised consent

Revised 05-19-2004

<http://www2.kumc.edu/researchcomp/humans.htm>,  
HIPAA templates are found at <http://www.kumc.edu/hipaa/research/>

## Required Paperwork for Submissions to the KUMC Human Subjects Committee

*If more than 1 copy is required, submit as COLLATED packets.*

- Submit the HSC Adverse Event Form
3. Submit promptly

### VI. How do I submit an Investigator's Brochure (IB) or revised IB or DSMB report (data safety monitoring board (1 copy)?

1. Prepare a cover letter identifying the product, date of the IB, and summary of changes (if revised). If the summary is included, state the pages where it can be found.
2. Attach the IB, rev IB or report.

### VII. How do I submit a revised protocol (amendment) and/or revised consent to the HSC?

Submit the following information:

- Cover letter summarizing the revisions: 2 copies
- Amendment: 2 copies
- Revised consent(s) with highlighted changes, when applicable: 2 copies
- Revised consent without highlights (if the consent was revised): 1 copy

### VIII. How do I close a study with the HSC?

1. Request an SPR from the HSC office
2. Complete and sign a Summary Progress Report
3. Attach the HSC Approved Consent Form utilized at the time of closure (stamped)
4. Attach any letters from sponsor regarding study closure

# Web Resources



# Kansas University Medical Center Research Compliance

Research Compliance

KUMC Research  
Compliance Areas

Research  
Compliance Educat

- Research Compliance Staff
- Policies and Procedures
- Roles and Responsibilities
- FAQ's
- Hot Topics
- Research Compliance Home

## Human Subjects Committee (HSC)



The University of Kansas Medical Center (KUMC) is engaged in research involving human subjects. The Human Research Protection Program (HRPP) has been developed to ensure the rights, safety and welfare of all subjects recruited or enrolled in research projects, regardless of funding source. The purpose of this program is to monitor, evaluate and improve the protections of human research participants. KUMC is responsible for assuring that all involved in research activities understand and comply with the ethical standards of research.

The Human Subjects Committee (HSC) is designated as the institutional review board for the University of Kansas Medical Center. The HSC is responsible for reviewing, approving, modifying, rejecting and monitoring research involving human subjects. The purpose is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as research subjects. To accomplish this purpose, the HSC uses a group process to review research protocols and related materials.

Purpose	
Membership	<a href="#">Roster Revised 09/28/2004</a> <a href="#">Identification and Selection of Members</a> <a href="#">Composition</a> <a href="#">Roles and Responsibilities</a>
Policies	<a href="#">KUMC Policies</a> <a href="#">Federal Regulations</a> <a href="#">Assurance of Compliance with DHHS</a>
Submission Process	<a href="#">2005 Deadlines &amp; Meeting Dates</a> <b>NEW:</b> <a href="#">HSC Announces Change in Deadline Dates</a> <a href="#">Protocol Submission for 2005</a> <a href="#">Submission Requirements</a> <a href="#">Initial Review</a> <a href="#">Continuing Review</a> <a href="#">Protocol Summaries</a>
Forms	
Committee Support	

### Additional Resources

- [Human Subjects Research Compliance Checklist Revised 09/14/2004](#)
- [KUMC Decision Tree](#)
- [Human Subjects Protection Tutorial](#)
- [Printer-Friendly Version of HS Tutorial](#)
- [Printer-Friendly Version of HS Refresher Tutorial](#)

- [HIPAA Research Training](#)
- [KUMC Guidelines for Retrospective Chart Reviews](#) 
- [Office for Human Research Protections \(OHRP\)](#)
- [Food and Drug Administration \(FDA\)](#)
- [Fact Sheet: Kansas Law on Surrogate Consent for Research](#) 

**Additional Guidelines**

- [Information Sheets Guidance for IRBs and Clinical Investigators](#)
- [Information for Submitting Investigational New Drug Application](#)

**Contact In**

KUMC Human Subjects  
G  
Mai  
3901 Rainbow  
Kansas City  
Phone: 91.  
Fax: 91.

---

[Compliance Department](#) | [KUMC Research Institute](#) | [KU Medical Center](#) | [University of Kansas](#) |  
[KUMC Research Advisory Council](#)

If you have questions, comments, or updates to this website, please email Sharon Cooper at [scooper@kumc.edu](mailto:scooper@kumc.edu).

Page Last Updated: Tuesday January 25 2005



# Kansas University Medical Center Research Compliance

Research Compliance

KUMC Research  
Compliance Areas

Research  
Compliance Educat

Research Compliance  
Staff

Policies and Procedures

Roles and  
Responsibilities

FAQ's

Hot Topics

Research Compliance  
Home

## Human Subjects Committee Forms

[Required Paperwork for Submission to the KUMC Human Subjects Committee](#)  
(Rev. 05-19-2004)

[Application for Review of Research Involving Human Subjects](#)

[HSC 1-83](#)

[HSC-1-83](#)

[Examples of Items to Submit to HSC](#)

[Consent Form Template 1](#)

This template is appropriate for clinical trials using an investigational drug or device, recommended for any other study in which external parties (such as sponsors or collaborators) will receive study data that has not been fully de-identified according to HIPAA standards.

[Consent Form Template 2](#)

This template should be used for internal studies and for other projects where all data to external parties has been de-identified according to HIPAA standards. \*

\* For more information about HIPAA requirements for de-identification, please refer to the PHI checklist, located at <http://www.kumc.edu/hipaa/forms/>

[Consent Template for Surrogate Decision-Makers](#)

This template is appropriate for persons who are consenting to research on behalf of an adult who does not have decisional capacity.

[Application for Exemption Class](#)

[Adverse Event Report Form](#)

[List of Study Personnel](#)

[Protocol Review Guide](#)

[Protocol Template](#)

[Institutional Research Safety Form \(IRSC 01-10/00\)](#)

« [Back to Human Subjects Committee](#)

# CONTACT INFORMATION

Karen Blackwell, MS  
Director, Human Research Protection Program/ Privacy Official  
G004 Sudler  
913.588.0942  
[kblackwe@kumc.edu](mailto:kblackwe@kumc.edu)

Tom Field, MS  
Manager, HIPAA Compliance Office  
1040 Dykes Library  
913.588.0940  
[tfield@kumc.edu](mailto:tfield@kumc.edu)

Dan Voss, MS, JD  
HSC Administrator  
G006 Sudler  
913.588.5712  
[dvoss@kumc.edu](mailto:dvoss@kumc.edu)

Human Subjects Office  
G006 Sudler  
913.588.1240  
[humansubjects@kumc.edu](mailto:humansubjects@kumc.edu)