

**INSTRUCTIONS FOR SUBMITTING APPLICATIONS TO  
THE UNIVERSITY OF KANSAS  
HUMAN SUBJECTS COMMITTEE LAWRENCE  
(HSCL)**

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**Email applications may be submitted. See page 8 for details.**

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## **Who Must Apply for HSCL Approval and Why?**

The National Research Act of 1974/1983 (PL 93-348) dictates that, in order for institutions to be eligible for behavioral or biomedical research grants from federal sources (e.g., The Department of Health and Human Services and its various research institutes), an Institutional Review Board (IRB) must be established and maintained to review research involving human subjects. The charge of this IRB is to protect the rights of those subjects participating in such research at this institution. The IRB for the University of Kansas is the Human Subjects Committee Lawrence (HSCL). The University must also have an approved Multiple Project Assurance which sets forth the responsibilities of the University, the researchers, and the IRB with respect to human subjects research. Our Multiple Project Assurance may be found at [www.research.ku.edu](http://www.research.ku.edu). HSCL must review applications for research involving human subjects if the research:

- (1) is in any way sponsored by the University (e.g., affiliated with the University in name), or
- (2) is conducted by, or under the direction of, any employee or agent of the University as part of their institutional responsibilities, or
- (3) is conducted by, or under the direction of, any employee or agent of the University using University facilities or property, or
- (4) involves the use of the institution's non-public information to contact or identify participants or prospective participants.

Investigators conducting research with human subjects that meet any of these conditions must prepare applications for that research and submit them to HSCL for approval. HSCL's review of the applications is guided by the Code of Federal Regulations (Title 45, Part 46), which sets the minimum standards for protection of human subjects.

### **When to Submit**

Applications for HSCL approval can be submitted at any time. HSCL works continuously on the review of applications and meets on a monthly basis, usually in the first week of each month. Research applications that are received by the 15th of each month will be acted upon at the following month's meeting.

For example, if a proposal needing a full committee review is submitted by October 15th, a committee decision concerning that proposal will be reached during the November meeting. A proposal submitted on the 16th of October, however, is not guaranteed committee action until the December meeting. Thus, the turnaround interval for committee action on a reviewed proposal can be as brief as three weeks, or as long as six weeks. Note that if the 15th of the month falls on a weekend or holiday, the deadline for receipt of a proposal is extended to 5:00 p.m. on the next full work day.

HSCL recommends that lead-time for committee approval be figured into the schedule for the conduct of research, especially since committee action (i.e., discussion and vote on approval of the project) is not necessarily equivalent to a guarantee of committee approval. Furthermore, it should be noted that the same turnaround schedule cannot be guaranteed during the summer months, because some of the committee members are on nine-month University contracts, and are thus unavailable to review projects or attend meetings.

### **What to Submit**

Applications are submitted using the HSCL application form. It is available from the HSCL office (235 Youngberg Hall; 864-7385), from your department, or at [http://www.rcr.ku.edu/hsc/hsc\\_handbook/app\\_b.shtml](http://www.rcr.ku.edu/hsc/hsc_handbook/app_b.shtml)

Applications submitted to HSCL typically consist of two parts.

Part 1: The HSCL application includes four pages, a face page, a checklist page, a description page, and an abstract page. A copy of the application follows the text of this manual. If you have difficulty downloading the Instructions or the Application, HSCL can send them to you via email upon your request.

Part 2: Appendices should also be submitted with the application. Appendices contain supplementary information regarding the application, which usually include (but are not limited to) a copy of the written consent form(s) (if

applicable) to be used in the conduct of the research, and copies of any additional supplementary materials (surveys, questionnaires, assessment materials, recruitment letters, etc.) that will be used in the conduct of the research. However, feel free to include any materials that you believe will assist the committee in evaluating the application.

Each of these two parts of an HSCL proposal is discussed in the sections that follow.

## **Part 1: The HSCL Application**

**Page 1.** The face page contains the formalities of the HSCL application. The space for the HSCL application number at the top right of the face page should be left blank.

1. Name of Investigator(s). All investigators should be listed here. In projects with more than one investigator, correspondence about the proposal will be addressed to the individual who signs as the first investigator. From here on, this person is referred to as the First Investigator (FI). The FI will be KU faculty, student, or staff. If the FI does not have "Principal Investigator" status as defined by the Principal Investigator policy found at <http://www.kucr.ku.edu/depts/proposals/policy/pi.shtml>, a KU faculty supervisor or individual with KU PI status will be needed to sign off on the form (see item 5 on the next page). Students, therefore, need to have a faculty supervisor or sponsor. The faculty supervisor/sponsor is considered to be ultimately responsible for the proper conduct of the project with respect to the protection of human subjects.

*Tutorial: All researchers, including the faculty supervisor for a project, must complete the online tutorial for conducting research involving human subjects before the project can receive HSCL approval. You may access the tutorial at <http://www.rcr.ku.edu/hscl/tutorials.shtml>*

2. Department Affiliation. Please indicate the campus department with which the FI is affiliated.

3. Campus or Home Mailing Address. This is the address to which correspondence concerning the proposal will be sent. If possible, please give a campus address, so that HSCL may use campus mail for delivery of this correspondence. If you give a home mailing address, please indicate the city and zip code. If you have an email address please provide that also, as email correspondence allows much faster turnaround on project review and approval.

4. Phone Number(s) and Email(s). Please provide a campus number and home telephone number and email at which the FI can be reached. These allow the coordinator to contact the FI in case there is a technical problem with the application.

5. Name of Faculty Member Responsible for Project. Research projects submitted to HSCL must have a KU faculty sponsor. If the FI is a student, please indicate the KU faculty member who will be sponsoring the research.

6. Type of Investigator and Nature of Activity. If the FI applying for HSCL approval is KU faculty or staff, the top part of this item should be filled out, indicating the status of the FI and whether the research is to be submitted for internal or external funding. If a KU/KUCR account number has been assigned to this project, please provide that number. If the FI is a student, fill out the bottom part of this item.

7. Title of Investigation. Please give a brief title for the project. Brief titles facilitate correspondence and record keeping. If this is a funded project or an application for a funded project, is the HSCL project title the same as that submitted to the funding organization? If not, please give that title as well.

8. Individuals Other Than Faculty, Staff, or Students at Kansas University. If applicable, check the box and indicate the names of other non-KU personnel that may be participating in the conduct of this research.

9. Certifications. The FI and any other personnel involved in the conduct of the research are required to sign the bottom of the face page, thus affirming familiarity with the policies of HSCL and the professional codes of ethical conduct with respect to human subjects. This is an important step. HSCL cannot process applications that are not signed by the faculty sponsor and all participating investigators. Please note that by submitting the application via email or hard copy you are certifying that you have read, understand, and will comply with the policies and

procedures of the University of Kansas regarding human subjects in research and that you subscribe to the standards and will adhere to the policies and procedures of the HSCL.

**Page 2.** Please fill out the name of the FI and the proposal title at the top of this page. The space following the "HSCL #" is for office use and should be left blank.

10. Checklist. The checklist allows HSCL to rapidly screen applications for possible expedited or full board conditions. Please read and answer Yes or No to #10 items carefully. Failure to do so accurately may result in delays in the processing or approval of your proposal. The section "Other Supporting Materials," should be noted if item 10.c., about cooperating institutions, is checked "yes." If item 10k is marked "yes," then copies of the instruments to be used in the research (or a detailed description of the instruments) must be attached as an appendix. These materials will be retained in HSCL files concerning this project.

### **Use of Audio and Video Recording**

For projects in which audio and/or video recording is intended, your abstract and consent form should explain who will have access to the tapes, security measures you will take to protect the privacy of subjects recorded, and what you will do with the tapes upon completion of your project (e.g. erase them, retain them for future research, etc.).

### **Payment to Subjects**

Please note that if the research involves payment to subjects (i.e., if item 10b is marked "yes"), such payment is considered to be appropriate only if it is meant to compensate subjects for costs incurred as part of participation in the research. (e.g. travel, time, etc.) FI's should not use payment schemes that may be potentially coercive.

### **Medical/Health Information**

The Health Insurance Portability Accounting Act (HIPAA) mandates special precautions to be taken when dealing with individual medical information or Protected Health Information (PHI). Most research on the Lawrence campus does not involve use of medical information. However, as indicated in items 10.o and 10.n, some research may recruit individuals with a medical diagnosis, such as cancer, autism, mental retardation, physical injury, etc and the research may also involve periodic requests for medical information to determine how individuals respond over time to an intervention dealing with a medical condition. In accordance with HIPAA, HSCL has developed sample HIPAA health information forms designed for Protected Health Information. HSCL also may require researchers to use a PHI Addendum for existing research projects which involve Protected Health Information. These forms may be found under "Researcher forms".

### **Deception**

Investigators proposing research to HSCL in which participants are misinformed concerning the study's procedures or purposes during the course of data collection must address how their applications meet these conditions. This requirement may be met in a number of ways. However, in order to address these issues and facilitate review of such applications, HSCL recommends that applications for research involving deception include the following elements: Justification for the Deception and Explicit Statement of No Risk/Minimal Risk.

Debriefing. Subjects should be informed that deception took place, and should be appropriately informed as to the actual purpose of the research, and the role of the deception in protecting the integrity of the research. Finally, subjects should also be reminded of their right to withdraw from the study at this time; this can be accomplished through a range of various procedures, extending from the inclusion of a simple statement to that effect in the debriefing, to having the participant sign a second informed consent form at the end of the study.

**The committee has directed the Coordinator to refrain from sending applications to them that are not complete. Therefore, applicants submitting deception research applications without adequate debriefing procedures will be asked to provide them before the applications are sent on to the committee for review.**

11. Approximate number of subjects to be involved in the research. Please indicate the number of subjects from whom you are planning to collect data.

**Page 3.** Information about the project purpose, proposed subjects, and selection procedures helps the committee discern the potential benefits to be derived from the research, whether the proposed population is especially vulnerable or at risk, and whether the processes for subject selection are equitable and sensitive to issues of confidentiality and privacy.

12. Project Purpose(s). Please describe briefly, and without jargon, the purpose of the project described in the application. Please use only the space provided.

13. Describe the Proposed Subjects. Please indicate any special criteria for including or excluding subjects involved in the proposed research. For example, if subjects are to be included in the project only if they are from a particular age group, racial group, or gender, please indicate this here. Additionally, if there is some medical attribute (e.g., Alzheimer's Disease, heart disease, etc.) or physical (e.g., marathon runners, bicyclists, weight lifters) that characterizes the subjects to be included in the study, please indicate this here as well.

### **Subject Selection Considerations**

14. Describe how the subjects are to be selected. Please indicate how you will gain access to, and recruit these subjects for participation in the project. That is, will you recruit participants through word-of-mouth, fliers or posters, newspaper ads, public or private membership, employee lists, etc? (If subjects are to be recruited from a cooperating institution, such as a clinic or other service organization be aware that subjects' names and other private information, such as medical diagnosis, may not be obtained without the subjects' written permission.) If subjects are to be recruited randomly (by mail or telephone), through one of the on-campus subject pools, through PSYCH. 104 mass screening, or through a cooperating institution, please indicate the particulars here. Please note that investigators who wish to recruit subjects who are clients of an organization (clinic, hospital, etc.) should have that organization ascertain subjects' interest rather than just obtain a list of client names from the organization without the consent of the clients. Investigators may ask the organization to distribute the consent form or introductory letter and have interested subjects contact the investigator directly or through the organization. This method protects the privacy of prospective subjects.

**Page 4.** This is an important part of the application. Although applications assigned to committee review will be read and considered in their entirety by only three members of HSCL, the entire application is distributed to all members of the committee prior to the monthly meeting. Thus, it should be complete and provide an accurate description of the proposed project. Many of the problems the committee encounters in evaluating applications arise from difficulties in understanding what is being proposed. Often, the committee must request clarification before reaching a final decision with respect to a proposal. With clear abstracts and generic language, many of these problems can be avoided.

15. Abstract of the proposed procedures. The abstract should be a succinct overview of the project. Please describe the procedures to be employed in the project. The HSCL committee is comprised of professionals from various academic and nonacademic fields. Therefore, it is important that the procedures be described in terms that can be understood by such an audience. Describe the procedures in the space provided, without jargon, abbreviations, or technical terminology. If you must use technical terms, please define or explain them so that someone not knowledgeable about your field can understand them.

### **Part 2: Appendices**

Supplementary materials should be attached to the applications as appendices. These supporting materials often include the following items:

#### **Copies of Research Instruments**

If applicable (usually, if item 10k on the page 2 of the application has been checked "yes"), copies of instruments (assessments, scales, questionnaires, surveys, protocols, etc.) that are to be used in the proposed research are attached in appendices. If the instruments or protocols cannot be attached themselves, a detailed description of the instruments may suffice.

## **Informed Consent Form**

If written informed consent is being used, a copy of the consent form that will be used in the research should be attached. According to the federal code of regulations (45 CFR 46), the consent form must include the following items when appropriate and applicable:

If oral informed consent is being proposed for use, the FI should consult directions and regulations for documenting oral consent in the Federal Regulations (45 CFR 46.117.b.2). This typically involves submission of a text or script of the consent procedures, the presence of a witness, and a summary description of the research provided for subjects. Consent form examples are located under "Researcher forms".

### **Consent Form Requirements**

These are reprinted here for your convenience. Sample consent forms are found under "Researcher forms". The consent form must include the following items when appropriate and applicable:

1. A statement of the purpose of the research and a brief description of procedures to be followed. Identify any procedures that can be classified as experimental in nature; that is, not well proven or established.
2. A description of any reasonably foreseeable discomforts or risks to the subjects (psychological, sociological, or physical).
3. Inclusion of the Kansas Tort Claims Act statement when more than minimal risk is involved. The statement to be included if the risk is more than minimal is as follows: "In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment."
4. A description of benefits for the subjects or others which may be reasonably expected from the research.
5. A disclosure of alternative procedures that would be advantageous to the subject. (Usually applicable only to research involving medical treatments.)
6. An offer to answer any inquiries concerning the project and whom to contact, including phone number and address. (questions concerning the procedures, purpose or subject's rights).
7. A statement that participation is voluntary, that participation may be discontinued at any time and that refusal to participate or the decision to discontinue participation will be without penalty or loss of benefits to which the subject is otherwise entitled.
8. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
9. Name of first investigator(s) (FI), their department(s) and telephone number(s).
10. Name of subject if other than the one giving consent. (i.e. if subjects are not capable of giving informed consent.)
11. Signature of subject (if appropriate).
12. If subjects are under 18 years of age, or have limited capacity to give informed consent, consent from the parent/guardian is required.
13. Reference to any written explanations given to subjects of procedures to be followed if this explanation does not appear on the consent form.
14. An indication of the time commitment for participation in the study.
15. If the subject pool is likely to have individuals under the age of 18 and they are not to be included, the following shall appear below the signature:  
"With my signature I affirm that I am at least 18 years of age."
16. The Committee requires that the following should be included:  
"With my signature I acknowledge that I have received a copy of this consent form to keep."  
This could be placed under the signature line.
17. When the length of a consent form exceeds one page, a page number format indicating the total number of pages of the consent form (e.g., "1 of 3," "2 of 3," "3 of 3") should be used.
18. The consent form must include the KU faculty supervisor's name, department, and department phone number.

## **Assent Procedures**

In research with children or other participants for whom the ability to give informed consent is otherwise compromised, it is usually appropriate to obtain some form of agreement, or "assent" to participate in the data collection sessions. For example, even though children or individuals with developmental disabilities cannot provide informed consent for participation in research, a researcher must describe the procedures in language that can be understood by the subjects, and obtain their verbal "agreement" to participate. If an assent procedure is to be used, a prototype of the "script" of this procedure should be included in the appendices of the application. A sample assent form is found under "Researcher forms".

## **Surveys and Questionnaires**

For mail surveys or questionnaires that are completely anonymous in nature, signed informed consent can often be waived. However, in the place of informed consent under such circumstances, an appropriate "letter of introduction" should accompany the survey. The letter of introduction should include the critical aspects of the informed consent form (e.g., risk- benefit statements, assurances of voluntary participation and confidentiality of responses, etc.). The letter should also include a statement that, by returning the questionnaire, the respondent indicates his or her consent to participate in the study. A copy of the letter of introduction should be included in the appendices.

If investigators wish to use the Internet or electronic mail to conduct surveys some extra precautions are necessary. Because respondents' electronic addresses are typically provided when they return such surveys by e-mail, FI's should devise a plan for stripping such information to maintain the confidentiality and anonymity of respondents' names. Also, it is possible that, through intent or accident, someone other than the intended recipient may see the subject's response. The investigator should therefore inform subjects that, while effort will be made to protect subjects' privacy, security and confidentiality of participants' responses cannot be guaranteed.

## **Other Supporting Materials**

Often, some of the concerns of the committee can be addressed by the inclusion of supporting letters from responsible individuals at institutions (schools, clinics, health care facilities, branches of law enforcement, etc.) that are involved or cooperating in the research. These letters might provide an indication of their willingness to cooperate in the conduct of the research, or their granting of permission to project personnel for access to subject populations located at such institutions. The letter may also indicate that such individuals have reviewed or (if applicable) have secured approval of the research protocol within that institution.

## **How Much To Submit**

Investigators must submit: **ONE** copy of the entire completed HSCL application (pages 1-4) plus consent form(s) and all appendix materials.

## **Where to Submit**

**Email applications may be submitted.** Student researchers must email their application documents to their KU faculty supervisor, who must approve it and forward to: mdenning@ku.edu. Please note that supporting materials that cannot be emailed must be provided to the HSCL office by hand delivery or surface mail.

If submitting applications by U.S. mail, send them to HSCL, 235 Youngberg Hall, 2385 Irving Hill Road, Lawrence, KS 66045-7563. For campus mail, send to HSCL, 235 Youngberg Hall. Applications may be delivered directly to Ms. Denning in her office at 235 Youngberg Hall, (785) 864-7385. Do not send HSCL submissions to the chair of the committee as this will result in a delay of processing the proposal.

## **The Review Procedure**

Over 500 applications for research are received by HSCL each calendar year. About 40% to 50% of these projects arrive at the start of each of the semesters. That is, in the first two months of each semester, HSCL may process up to 200 applications. The remaining applications are processed over the course of the rest of the year. When HSCL

applications are received, they go through a review process that is detailed in the Assurance Statement filed by the University with the U.S. Department of Health and Human Services.

### **Initial Screening of Applications**

The HSCL Coordinator, Associate Coordinator and/or the HSCL Chair first screens the applications to determine whether they fit the description of projects that qualify for an expedited review, or if they must receive full board review. Notification of the application status is sent out immediately to the FI.