

UNIVERSITY OF KANSAS
Human Subjects Committee Lawrence
Application for Project Approval

- 1. Name of Investigator(s) _____
- 2. Department Affiliation _____
- 3. Campus or Home Mailing Address: _____
 - a. Email address: _____
 - Phone Number(s): (a) Campus: _____ (b) Home _____

5. Name of Faculty Member Responsible for Project: _____
HSCL must receive faculty approval via email notification or hard copy signature before a student application may be processed.

a. Email address of Faculty Member: _____

6. Type of investigator and nature of activity. (Check appropriate categories)
- Faculty or staff of University of Kansas
 - Project to be submitted for extramural funding; Agency: _____
 KU/KUCR project number: _____

(HSCL must compare all protocols in grant applications with the protocols in the corresponding HSCL application)

- Project to be submitted for intramural funding; Source: _____
- Project unfunded
- Other: _____
- Student at University of Kansas: Graduate Undergraduate Special
- Class project (number & title of class): _____
- Independent study (name of faculty supervisor): _____
- Other (please explain): _____
- Investigators not from the Lawrence campus but using subjects obtained through the University of Kansas

Activity to be registered with clinical trials.gov (when registered, notify HSCL of registration number)

- 7.a. Title of investigation: _____

- 7.b. Title of sponsored project, if different from above: _____

8. Individuals other than faculty, staff, or students at Kansas University.
 Please identify investigators and research group:

9. Certifications: By submitting this application via email or hard copy I am certifying that I have read, understand, and will comply with the policies and procedures of the University of Kansas regarding human subjects in research. I subscribe to the standards and will adhere to the policies and procedures of the HSCL, and I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of study. I also certify that I have verified and disclosed any potential conflict of interest between myself and/or my team members and the project sponsor (if applicable). **Type or write name(s) in the signature lines below depending on your electronic or hard copy submission.**

Date: _____
 Signature: _____
 First Investigator

Date: _____
 Signature: _____
 Faculty Supervisor

Date: _____
 Signature: _____
 Second Investigator

Date: _____
 Signature: _____
 Third Investigator

First Investigator:

Project Title:

10. Please answer “Yes” or “No” for the following questions about the proposed research activity. (Provide details about questions checked “Yes” on the last page of the application.)

Does the research involve:

___ a. drugs or other controlled substances?

___ b. payment of subjects for participation?

___ c. access to subjects through a cooperating institution (other than KU)?

___ d. substances taken internally by or applied externally to the subjects?

___ e. mechanical or electrical devices (e.g., electrodes) applied to the subjects?

___ f. collection of fluids (e.g., blood, urine, etc.) or tissues from subjects or exposure of subjects to hazardous materials (chemical, biological, radiation, etc.)?

Environment Health & Safety (EHS) Approval number (required):

___ g. subjects experiencing stress (physiological or psychological)?

___ h. omission of information concerning any aspect of purposes or procedures (misleading or withheld information)?

___ i. deception of subjects (active misinformation or false feedback provided)?

___ j. subjects who could be judged to have limited freedom of consent (e.g., minors, developmentally delayed persons, or those institutionalized)?

___ k. any procedure or activities that might place the subjects at risk (psychological, physical, or social)?

___ l. use of participant observation interviews, focus groups, questionnaires, audio or video recordings? (check all that apply)

___ m. data collection over a period greater than one year?

___ n. indicate the consent procedure(s) to be used signed, oral, information statement, parent/guardian, assent procedure for minors or the cognitively impaired (Check all that apply) Note: HSCL makes the final determination on waiver of a signed consent form or consent. Justification must be provided for waiver of signed consent form or consent.

___ o. indicate the type of data you will be acquiring in this project private health information academic records, social security information, KU ID number

___ p. other data that may increase participant risk (46.101 (b) (2) (ii) in the areas listed criminal civil, financial, employment, reputation

11. If any of the key personnel or research team members of this project have a financial interest* in a project sponsor or a provider of goods or services to the project, the individual and the relationship must be disclosed.

Neither I nor any member of the research team has a financial interest in the project sponsor or a provider of goods or services to this project.

I am disclosing the following financial interest(s)** :

Name of Individual	Role on Project	Financial Interest Entity

* An individual's financial interests include those of the individual, his or her spouse, dependent children, and other members of the personal household (i.e., ownership, compensation received or anticipated, a position of officer or director, or receipt of fees or commissions).

** If this financial interest has not already been disclosed on a Conflict of Interest report, an ad hoc disclosure via the Conflict of Interest reporting form may also be required. Direct inquiries to coi@ku.edu. COI resource information is also available at the following link: <http://www.rcr.ku.edu/coi/index.shtml>

Additional COI Notes:

Complete the following questions on this page. Please do not use continuation sheets.

12. Approximate number of subjects to be involved in the research:

13. Project Purpose(s):

14. Describe the proposed subjects (age, sex, race, or other special characteristics). If there is a physical or mental health condition that characterizes the subjects to be included in the study, please indicate this here as well.

15. 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 poster, newspaper ads, public or private membership or employee lists, etc. Drawings/raffles are not permitted for payment or recruiting. (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.)

16. Abstract of the proposed procedures in the project. You are limited to the rest of this page. (The abstract should be a succinct overview of the project without jargon, unexplained abbreviations, or technical terminology. Here is where you must provide details about Yes answers to items under question 10.a through 10.p of the application: drugs, cooperating institutions, medical information requested, security measures and post-project plans for tapes, questionnaires, surveys, and other data, and detailed debriefing procedures for deception projects.)