

**University of Kansas
Human Research Protocol**

**For use with** [**eCompliance**](http://ecompliance.ku.edu/) **only**

# PROJECT INFORMATION

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| **Project Title** |  |
| **Investigator Name** |  |
| **Faculty Supervisor (Students Only)** |  |

This form must be used to submit an application through the eCompliance system.

**No other methods of submission will be accepted.**

Access the system at [ecompliance.ku.edu](http://ecompliance.ku.edu/)

For faster processing, ensure all study staff have all completed the required [Human Research Training](https://www.citiprogram.org/Shibboleth.sso/Login?target=https%3A%2F%2Fwww.citiprogram.org%2FSecure%2FWelcome.cfm&entityID=https%3A%2F%2Fshibidp.ku.edu%2Fidp%2Fshibboleth).

Contact irb@ku.edu with any questions.

# 1. Subject Information

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| **1.1 Number of Subjects**:  |

Click here to enter text.

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| **1.2 Subject Age (*Check all that apply*)** |

[ ]  0-7

[ ]  8-17

[ ]  18-65

[ ]  65+

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| **1.3 Special Populations (*Check all that apply)*** |

[ ]  Minors

[ ]  Non-English speaking

[ ]  Mentally or developmentally disabled individuals

[ ]  Pregnant Women

[ ]  Prisoners

[ ]  Individuals with diminished capacity for consent

[ ]  Individuals with a Legally Authorized Representative

[ ]  Other vulnerable population (describe below)

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| **1.4 Describe any specific populations targeted for inclusion or exclusion.** |

Click here to enter text.

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| **1.5 Describe target demographics of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.** |

Click here to enter text.

# 2. RECRUITMENT

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| **2.1 Describe the recruitment process for the study. Explain how you will gain access to and recruit the subjects for participation in this project.** |

Click here to enter text.

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| **2.2 Identify any cooperating institutions by name.**  |

Click here to enter text.

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| **2.3 External Study Team Members**  |

[ ]  **External study team members (individuals NOT currently affiliated with KU) will collaborate on this project.**

**If yes, explain external study team member’s roles in the projects. Explain if they will be involved in a) obtaining consent of participants, b) interacting or intervening with participants, or c) have access to identifiable data.**

Click here to enter text.

[ ]  **External study team member’s home institution has an Institutional Review Board that is currently registered with OHRP**

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| **2.4 Where will the research activities take place? List all off campus locations. Explain if this study will take place at more than one location/institution.**  |

Click here to enter text.

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| **2.5 Identify all applicable recruitment methods.** |

[ ] Flyers

[ ]  Letter

[ ]  Telephone

[ ]  Newspaper

[ ]  Poster

[ ]  Departmental Communication

[ ]  Purchased sample list

[ ]  Personal or Professional contacts

[ ]  Internet

[ ]  E-mail

[ ]  Online crowdsourcing sites (e.g., Amazon MTurk, Prolific, Qualtrics Panel)

[ ]  Social Media

[ ]  SONA

[ ]  Third party (Professional or Charitable Organization)

[ ]  Other

***\*\*Please upload copies of materials in the "Recruitment Documents" section in eCompliance.\*\****

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| **2.6 Are you recruiting students from a class you teach or for which you have a responsibility?** |

Choose an item.

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| **2.7 Are you recruiting employees who directly or indirectly report to you?** |

Choose an item.

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| **2.8 If yes to 2.6 or 2.7, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.**  |

Click here to enter text.

# 3. COMPENSATION

[ ]  **Subjects will not receive compensation**

[ ]  **Students will receive extra credit or course credit**

[ ]  **Subjects will receive monetary compensation**

[ ]  **Subjects will receive another form of compensation.** *Please explain in 3.1*

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| **3.1 Describe the compensation or credit, including amount, scheduling, and method (e.g. ClinCard). Explain what will happen if subjects withdraw from the study.** |

Click here to enter text.

[ ]  By checking this box, I understand that the HRPP is NOT granting approval for a specific method of payment and that I may need additional fiscal approval from the Office of Fiscal Affairs in order to pay research participants (Contact Karen Schaller at kschaller@ku.edu for questions about participant payment).

***\*\*Drawings and raffles may not be permitted for payment or recruitment; See HRPP website for detailed guidance.\*\****

# 4. PROJECT INFORMATION

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| **4.1 Expected study time period.** |

**From**: Click here to enter text.

**To**: Click here to enter text.

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| **4.2 Do you currently have funding or expect to obtain funding in the future?** |

Choose an item.

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| **4.3 Select type of funding.** |

Choose an item.

**If yes to 4.3, what is your award’s current status?**

Choose an item.

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| **4.3a If this is an unfunded study and will provide compensation, describe the funds to be used (e.g., faculty start-up account, facilities and administration [F&A overhead] account, department account, or personal funds).** |

Click or tap here to enter text.

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| **4.4 Describe the purpose of the research. Explain what is intended to be discovered; include goals, aims, and objectives and/or state the hypothesis to be tested.** |

Click here to enter text.

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| **4.5 Research Topic Background: Provide a brief scientific or scholarly background for the research activities, address gaps in current knowledge.** **\*\*Please include background information of your research topic. Do not submit personal background or resume/CV information.\*\*** |

Click here to enter text.

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| **4.6 The revised Common Rule definition of a “Clinical Trial” is the following:** *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.***Does your study meet the definition for a “Clinical Trial?”** |

Choose an item.

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| **4.7 Does your project include community engaged collaborators (community-engaged research)?** *Community-engaged research (CEnR) is defined as:* *a cooperative approach that includes partnerships and collaboration among researchers and community organizations/agencies. This includes, but is not limited to, involving community partners in the design and implementation of research objectives. Simply enrolling members of the community as research participants in study activities does not constitute community-engaged research.*  |

Choose an item.

***\*\*Community collaborators who are engaged with human subjects may need to complete CITI training and be listed on the study team.***

# 5. RISK & BENEFITS

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| **5.1 Does this study involve any of the following? (*Check all that apply*)** |

[ ]  Deception

[ ]  Omission

[ ]  Misleading information/false feedback

[ ]  Physical or mental stress

[ ]  Collection of fluids or tissue

[ ]  Genetic information

[ ]  Substances taken internally or applied externally

[ ]  Mechanical or electrical device applied to subjects

[ ]  Information pertaining to illegal activity

[ ]  Information pertaining to substance use

[ ]  DXA Scan, X-RY, MRI

[ ]  Information relating to sexual attitudes, orientation or practice

[ ]  Private identifiable information

[ ]  Personal or sensitive information

[ ]  Private records (academic or medical)

[ ]  Social or economic burden to participants

[ ]  Exposure to hazardous materials

[ ]  Information that if released could damage an individual’s financial standing, employability, reputation, or cause social stigmatization or discrimination

[ ]  Other

[ ]  None of these

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| **5.2 Describe the nature and degree of the risk or harm checked above. If using deception or omission, include a justification for the deception or omission.** |

Click here to enter text.

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| **5.3 What steps will be taken to minimize the risks or harm and to protect the subject’s welfare (when risk is greater than minimal)?** |

Click here to enter text.

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| **5.4 Describe the anticipated benefits of the research for individual subjects.** |

Click here to enter text.

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| **5.5 Describe the anticipated benefits of the research for society or science, and explain how the benefits outweigh the risks.** |

Click here to enter text.

# 6. DATA COLLECTION & SECURITY

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| **6.1 Data Collection & Security** |

[ ]  Observation

[ ]  Interviews

[ ]  Focus groups

[ ]  Surveys/Questionnaires

[ ]  Psychological tests

[ ]  Educational tests

[ ]  Internet based methods

[ ]  Blood draw, saliva swabs, or other biological sampling

[ ]  Tissue biopsies

[ ]  Audio recording

[ ]  Video recording

[ ]  Previously collected data (no individual identifiers)

[ ]  Previously collected data (with individual identifiers)

[ ]  Other

***\*\*Upload all data collection documents (surveys, specimen protocols, interview questions, etc) in the eCompliance "Supporting Documents" page.\*\****

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| **6.2 Procedures (Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a time line or step by step listing.)** |

Click here to enter text.

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| **6.3 Sharing the results with Subjects or Others. (Indicate if results like tests or incidental findings will be shared with the subject or others and if so, indicate how it will be shared.)** |

Click here to enter text.

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| **6.4 Withdrawal of Subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)** |

Click here to enter text.

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| **6.5 Protected Data to be Collected (*Check all that apply*)** |

[ ]  Protected Health Information

[ ]  Unique ID number (e.g. employee/student ID, driver’s license number)

[ ]  Academic records

[ ]  Social Security Number

[ ]  Other personally identifiable information

[ ]  Data collected from participants located in the European Union

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| **6.6 Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, what safeguards are in place for data with identifying information. Include a description of physical and electronic security.**  |

Click here to enter text.

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| **6.7 Identify any direct identifiers like name, unique identifier, address, e-mail, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.**  |

Click here to enter text.

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| **6.8 If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, and how it will be stored.** |

Click here to enter text.

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| **6.9 Do you plan to make a de-identified version of the dataset public, provide the dataset to a publisher, or use the de-identified data for future research? If so, see** [**consent templates**](https://research.ku.edu/human-subjects-research-forms) **for specific language to be included in the consent form.**  |

Choose an item.

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| **6.10 If using audio and video recording, describe how the recordings will be used, how confidentiality will be maintained, and how and when the recordings will be destroyed or completely deidentified.** |

Click here to enter text.

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| **6.11 As part of the study will you:** **a. Obtain protected health information (PHI) from a third party (such as a hospital or doctor's office)** **b. Have access to PHI in the subject's records?****If yes to either a or b, please describe how you will satisfy the HIPAA requirements for authorization to use PHI in research below. (Submit the Statement on Use of Protected Health Information (PHI) form)** |

Click here to enter text.

# 7. INFORMED CONSENT

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| **7.1 Specify the type of informed consent you will use with this research project.** |

***\*\*Consent form templates can be found on the HRPP website. Please upload all consent form drafts to the "Consent Form" section in eCompliance.\*\****

[ ]  Signed Consent

 Type of Consent

 [ ]  Adult

 [ ]  Parent/Guardian

 [ ]  Assent Script/Procedures

 [ ]  Foreign Language version

[ ]  Oral Consent ([Waiver of documentation of consent](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-30), upload script in eCompliance)

[ ]  A signed consent form would be the only record linking the subjects to the research, and the principal risk of signing a consent form would be potential harm resulting from a breach of confidentiality

[ ]  The research presents no more than minimal risk of harm to subjects and involves no

procedures for which written consent is normally required outside the research context

[ ]  Information Statement

[ ]  Debriefing Statement

[ ]  Waiver of Consent is requested

**A waiver of consent requires all five of the criteria below to be true. If a waiver of consent is requested, then provide a rationale for how your study meets each of the criteria.**

1. The research involves no more than minimal risk to the subjects

Click or tap here to enter text.

1. The waiver or alteration will not adversely affect the rights and welfare of the subjects

Click or tap here to enter text.

1. The research could not practicably be carried out without the waiver or alteration

Click or tap here to enter text.

1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Click or tap here to enter text.

1. If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format.

Click or tap here to enter text.

*See OHRP* [*waiver of consent*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-22) *FAQs.*

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| **7.2 Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)** |

Click here to enter text.

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| **7.3 Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place and how you will ensure the subject’s understanding.** |

Click here to enter text.