Kansas Department of Health and Environment
Institutional Review Board

NEW PROJECT REQUEST

Date:

Name of project:

Type of Application: ☐ New ☐ Revision (to a pending New Application)
☐ Modification (to an existing #_____ approved application)
☐ Renewal (Name of Liaison _____)
If a Revision, Modification or Renewal, please attach document that highlights any changes or modifications to procedures or staffing

Name of investigator: Phone number:

Bureau and agency: Email:

Name of co-investigator: Phone number:

Bureau and agency: Email:

Have you viewed the Video on the Common Rule requirements at:
https://www.youtube.com/watch?v=Sptom2vU924&feature=youtu.be ? ☐ Yes ☐ No

What are you requesting? ☐ Board Review ☐ Exemption
(Only the IRB has the authority to determine that a project is exempt from IRB review)
If requesting exemption, which can be submitted at any time, which exemption are you claiming for the project (Board Consent exemptions 46.101(b)(7) and (8) are not given by KDHE IRB):
(List of exemptions can be found at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html)

☐ Exemption CFR 46.101 (b)(1) For Educational Settings
☐ Exemption CFR 46.101 (b)(2) or (b)(3) Tests, Surveys, Interviews, Public Behavior Observation
☐ Exemption CFR 46.101 (b)(4) Existing Data Documents, Records and Specimens
☐ Exemption CFR 46.101 (b)(5) Public Benefit or Service Programs
☐ Exemption CFR 46.101 (b)(6) Food Taste and Acceptance Studies
☐ Exemption Approval from another IRB?
If yes, please provide the IRB name and protocol number for this specific project and attach documentation of project approval.
IRB Name:
Protocol Number:

Does the project enroll or collect data from any of the following:

☐ Children - Under 18 years of age (these subjects require parental or guardian consent)
☐ Over 65 years of age
☐ Physically or mentally disabled
☐ Economically or educationally disadvantaged
☐ Unable to provide their own legal informed consent
☐ Pregnant females as target population
☐ Victims
☐ Subjects in institutions (e.g., prisons, nursing homes, halfway houses)

Will you be collecting personal identifiers? ☐ Yes ☐ No
Personal identifiers include any of the following: name, address, phone number, person number (e.g., SSN, hospital number), or anything that can be linked to an identifier.

Will data be collected that might be reasonably considered sensitive? ☐ Yes ☐ No
Sensitive data would include but not be limited to the following: drug or alcohol use, sexual behavior, victimization or abuse, criminal activity, mental illness.

Will the protocol require anything besides participant provision of information? ☐ Yes ☐ No
(e.g., specimen collection, physical examination, treatment)

Risk Protection Benefits: The answers for the three questions below are central to human subject research. You must demonstrate a reasonable balance between anticipated risks to research participants, protection strategies, and anticipated benefits to participants or others.

Risks for Subjects (Identify any reasonably foreseeable physical, psychological, or social risks for participants. State that there are "no known risks" if appropriate)

Minimizing Risk (Describe specific measures used to minimize or protect subjects from anticipated risks.)

Benefits (Describe any reasonably expected benefits for research participants, a class of participants, or to society as a whole.)

In your opinion, does the research involve more than minimal risk to subjects? ("Minimal risk" means that "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")
☐ Yes ☐ No

Please attach a brief narrative description of the proposed project (no longer than one page), in terms that will allow the IRB or other interested parties to clearly understand what it is that is proposed to do that involves human subjects. This description must be in enough detail so that the IRB members can make an informed decision about the proposal.
☐ Yes Attachment Included ☐ No Attachment

☐ Attach a copy of the written research protocol. If renewal or modification, please provide tracked changes to the protocol.

☐ Attach a copy of the grant application that will or is funding the research project.

☐ Attach copies of Human Subject Protection Certificates for the Principal and Co-Principal investigators.

Are you using a written informed consent form?
☐ Yes – Include a copy with this application
☐ A waiver or alteration of informed consent elements – Include a copy of alternatives
☐ No

☐ Attach a copy of data collection instruments.

☐ Attach a copy of documents to be used in participant recruitment (marketing/promotion)

Other documents may be required by the Board and must be included in this application.