KEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

APPLICATION REQUESTING **EXEMPT REVIEW** OF A RESEARCH PROTOCOL
INVOLVING HUMAN SUBJECTS

Research studies involving children or vulnerable individuals must be submitted for full review.

All applicants **must** submit the following items to Townsend 130, ATTN: IRB

- A complete, signed copy of the application (faculty advisor must also sign if applicant is a student or an adjunct)
- Consent form or an Application for Waiver of Informed Consent
- CITI Human Subjects Training Certificate

If applicable, these items must also be submitted with the application for it to be considered complete:

- An additional Consent form for participants being photographed or recorded via digital media
- Copies of all survey instruments, interview questions, recruitment letters, emails, advertisements
- Site permission (if applicant is conducting research anywhere other than Kean University)

Complete answers to all questions must be provided and all necessary documentation submitted. Incomplete applications will be returned without review.

General Information

Applicant (PI) Name*: _____Today's Date: _____

_____Faculty _____Adjunct _____Lecturer _____ Tenured/Tenure-Track

_____Student _____Undergraduate Student _____Masters Student _____Doctoral Student

_____Staff _____ Full- Time _____ Part-Time

Department (do not abbreviate): _____

Home Address: _____

Email Address: _____ Day Phone: _____

Research Project Title: _____

Anticipated Start Date: ** _____ Anticipated End Date: _____

If project **was initially denied** and this is a resubmission, provide date of denial letter: _____

* *Co-PIs must complete the Co-PI section. Students applying for IRB review must complete the student section. NOTE: Student applications and Adjunct faculty applications that are not signed by the Faculty Advisor will not be reviewed.*

***** Kean University Policy on the Use of Human Subjects in Research prohibits the start of any research activity (including canvassing and recruiting of subjects) that has not been reviewed by, and received written approval without provisions from, the IRB.***

FOR IRB OFFICE USE ONLY

PROTOCOL #_____ DATE RECEIVED: _____

DATE REVIEWED: _____

_____APPROVED _____APPROVED WITH PROVISIONS _____DENIED

Guidelines for Exempt Review. There are eight specific categories of exemption. In order to receive an exempt review from the IRB you must fit into one of these categories. Common examples of exempt level research at Kean University are anonymous surveys; surveys or interviews of adults about non-sensitive topics; educational tests; or observation of public behavior. ***No research involving children or individuals from vulnerable populations is eligible for exempt status.***

Research exempt from IRB review MUST only involve one or more of the following research categories. Research that contains elements of exempt and non-exempt activities is NOT eligible for IRB exemption.

IRB Exempt Categories

☐ **XM1 Research conducted in established or commonly accepted educational settings involving normal educational practices that is not likely to have adverse impacts on students learning, required educational content, or involving assessment of educators who provide instruction** , such as: (i) Research on regular instructional strategies or (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples of research **NOT EXEMPT** via this criteria

- Research that involves evaluation of a radically new instructional strategy or use of random assignment of subjects to different instructional methodologies is not exempt because the methods employed deviate from normal educational practices.
- Educational research that involves deception or withholding of information from subjects
- Exemptions are not granted for research on physical education that involves exercise if the activity is altered in a significant way for the purposes of the research.
- Research that involves possible "adverse effects" on student learning of the required education content and/or on the assessment of educators.

☐ **XM2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.** In order for research to be considered exempt under this category one of the three following criteria must be met:

(i) Information obtained is not identifiable, directly or through identifiers linked to the subjects:
(ii) Any disclosure of the human subjects' responses outside the research would not reasonable place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation or
(iii) Information obtained can be identifiable but the IRB has done a limited IRB review in keeping with 46.111(a)(7), which relates to there being adequate provisions for protecting privacy and maintaining confidentiality

Examples of research **NOT EXEMPT** through this criteria

- Surveys or questionnaires that ask invasive questions of a sensitive or private nature that might be deemed to cause the subject some discomfort or distress. This includes but is not limited to questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.
- Research where subjects can be identified as participating in the study. This can be, but is not limited to collecting personal info such as name, SS#, or student ID number.

**Important: Research on sensitive or personal topics which may cause stress to participants are not exempt from review.

☐ **XM3 Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §_.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

The methods of data collection allowed under exemption category #3 are limited to verbal or written responses from subjects (e.g., surveys or interviews, test responses, or data entry), observation, and audiovisual recording. Data cannot be collected via physical procedures such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), eye trackers, and blood draws.

**Important: Deception is allowed if certain criteria are met. This exemption is only for benign behavioral research with adults and is not applicable to children

☐ **XM4 Secondary Research for which consent is not required. Secondary research of identifiable private information or identifiable bio specimens, if at least one of the following criteria is met:**

(i) The identifiable private information or identifiable bio specimens are publicly available;
(ii) Information, which may include information about bio specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note

☐ **XM5 Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.**

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ **XM6 Research involving taste and food quality evaluation and consumer acceptance studies. This IRB exemption category applies to Federal research only.**

(i) If wholesome foods without additives are consumed OR if a food is consumed that contains food ingredients, agricultural chemicals, and/or environmental contaminants at or below the level and for a use 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.

Examples of research NOT EXEMPT through this criteria

- Studies that involve consumption of alcohol, vitamins, or supplements such as protein power, creatine, and glucosamine chondroitin sulfate should not qualify for exempt status.

☐ **XM7 Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).**

☐ **XM8 Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:**

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Subject/Participant Number: #_____ Adults (18 or older) #_____ Minors (under 18)

Research site(s): State where project will take place: _____

Time commitment for each subject/participant: _____

Project Attributes (check all that apply)

☐ Use of recruitment materials (flyers, emails, letters, advertisements)

☐ Questionnaires or Surveys ☐ In-person ☐ Phone ☐ Mail ☐ Email ☐ Online

☐ Interviews ☐ In-person ☐ Phone ☐ Skype (or similar)

☐ Observation

☐ Focus groups

☐ Administration of tests, inventories, self-reports, measuring instruments, etc.

☐ Photography, Audio or Video recording (separate Informed Consent form is needed for the participant to indicate consent for digital recording)

☐ Use of existing/secondary data

☐ Other (explain) _____

Co-PI (complete if applicable)

Co-PI Name: _____

☐ Faculty ☐ Undergraduate Student* ☐ Graduate Student* ☐ Staff

Department (do not abbreviate): _____

Home Address: _____

Email Address: _____ Day Phone: _____

☐ Proof of successful completion of CITI Human Subjects Training is attached.

Student Applicants – Complete this section

Is this research/student project required to fulfill requirements of a course? ☐ Yes ☐ No

If yes, course title _____ and course ID _____

Will this research/student project be published or presented? ☐ Yes ☐ No ☐ Unsure

Faculty Advisor Name: _____

Department (do not abbreviate): _____

Email: _____ Office phone: _____

Signatures:

The undersigned accept(s) responsibility for the study, including adherence to DHHS regulations, New Jersey law, and Kean University policies relative to the protection of the rights and welfare of subjects/participants in this study. In the case of student applications, the Faculty Advisor and the student share responsibility for adherence.

By signing this form, I certify that I am familiar with Kean University policies and federal and state regulations regarding the protection of human subjects in research. I will not begin this study until I receive a written notice of approval, without provisions, from the IRB. I will conduct this study following the approved protocol. I will report any adverse events or emergent problems to the IRB; will obtain IRB approval before implementing any modifications of protocol; and, will request continuing review and approval for any activities beyond the study end date.

_____ _____

Signature of Applicant Date

_____ _____

Signature of co-PI (if applicable) Date

By signing this form, I attest that I have read/reviewed this application for quality, completeness, and accuracy**.** I certify that I am familiar with Kean University policies and federal and state regulations regarding the protection of human subjects in research. This study meets the guidelines and requirements of the IRB and has my endorsement.

I agree to provide appropriate education and supervision of theadvisee/applicant and any listed co-PI and also monitor the progression of the study for the entireduration.

_____ _____

Signature of Faculty Advisor Date

A. PROTOCOL DESCRIPTION

(Note: incomplete or handwritten responses will be returned without review)

1. Briefly describe your proposed research project, and describe your research goals/objectives.

2. Explain how you will recruit subjects into the research (including when and where recruitment will be conducted and methods of recruitment (e.g. flyers, email, social media, face-to-face).

3. Briefly describe the nature of the involvement of the human subjects (observation of postsecondary student behavior in the classroom, personal interviews, mailed questionnaire, survey, chart review, etc.).

4. Describe the setting (e.g., a classroom) and the location (e.g., name of school) where the research will be conducted. (NOTE: *If research is to be conducted at another institution or facility (e.g. a school, community center, place of business, etc.) a signed copy of the permission letter from that institution authorizing the researcher to collect data on its grounds must be attached).*

5. Explain how records will be kept; who will have access to the data and how it will be stored.

6. Explain how the data or records will be deleted or destroyed

7. Explain why you think this protocol should be considered exempt. Address all known or potential risks to subjects/participants.

B. SUPPORTING DOCUMENTS

- Attach a copy of all data collection tools: survey questions, interview questions, data collection sheets, etc.
- Attach a copy of any recruitment letters, recruitment emails, flyers or advertisement
- Attach a consent form or an Application for Waiver of Informed Consent (If Applicable)
- Attach an additional consent form for audio/video or photographs (If applicable)
- Site permission (If applicant is conducting research anywhere other than Kean University)

Direct questions about the IRB application and review process and schedule to irb@kean.edu or visit the IRB website at https://www.kean.edu/offices/research-and-sponsored-programs/irb-research-compliance