KEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

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

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

- A complete, signed copy of the application (faculty advisor must also sign if applicant is a student)
- 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 ☐ Undergraduate Student* ☐ Graduate Student* ☐ Staff

Department (do not abbreviate): _____

Home Address: _____

Email Address: _____ Day Phone: _____

Research Project Title: _____

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

If project was initially denied approval 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 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 USE ONLY

PROTOCOL #_____ DATE RECEIVED: _____

DATE REVIEWED: _____

_____APPROVED _____APPROVED WITH PROVISIONS _____DENIED

Guidelines for Exempt Review. There are six 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.***

Exempt Categories.

☐ **XM1 Research conducted in established or commonly accepted educational settings, involving normal educational practices**, 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.

☐ **XM2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior** unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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 found in the forms of collecting personal info such as name, SS#, or student ID number.

☐ **XM3** Research on elected or appointed public officials or candidates for public office.

Examples of research NOT EXEMPT through this criteria

- Research where the public official's participation is revealed or identifiable.

☐ **XM4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens**, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Examples of research NOT EXEMPT through this criteria

- Research where materials will be collected after IRB approval
- Research where there are direct or indirect subject identifiers attached to the specimens that can be traced back to the respondent

☐ **XM5** Research and demonstration projects that are designed to evaluate public benefit or service programs, such as Welfare, Medicaid, Unemployment, and Social Security.

☐ **XM6** Taste and food quality evaluation and consumer acceptance studies

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.

Subject/Participant Information: #_____ Adults (18 or older)

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 (an additional ICF is needed for the participants 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 the advisee/applicant and any listed co-PI.

_____ _____

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

3. 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).*

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

5. 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: surveys, interview questions, data collection sheets, etc.
- Attach a copy of any recruitment letters, recruitment emails, flyers or advertisements
- Attach a consent form or an Application for Waiver of Informed Consent
- Site permission (if applicant is conducting research anywhere other than Kean University)
- If applicable, an additional Consent form for participants being photographed or recorded via digital media

Direct questions about the IRB application and review process and schedule to irb@kean.edu or visit the IRB website at http://compliance.kean.edu