KEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

APPLICATION REQUESTING **EXPEDITED 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 by the deadline date:

- A complete, signed copy of the application (faculty advisor must also sign if applicant is a student or adjunct faculty)
- Active CITI Human Subjects Training Certificate
- Consent Form and Debriefing Form on Kean Letterhead

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

- Assent form (for participants under 18)
- An additional Consent form for participants being photographed or recorded via digital media
- Site permission (if applicant is conducting research anywhere other than Kean University)
- Copies of all survey instruments, interview questions, recruitment letters, emails, advertisements
- Permission to use measures created by a different researcher

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 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 Expedited Review. Federal and state guidelines dictate that in order for research to be considered eligible for expedited review, certain criteria must be met and maintained. In addition, Kean University policy requires that research involving children or vulnerable participants must be submitted for full review. In order to approve research designated as expedited, the IRB must determine that **ALL** of the following requirements are satisfied:

1. The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on subjects should be used.

2. The risks of the research must be reasonable in relationship to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may be gained.

3. Subject selection must be equitable, with all subjects having an equal opportunity to accept or decline participation.

4. Informed consent should be sought and documented unless a waiver of consent and/or documentation of consent has met the waiver criteria specified by the DHHS (45 CFR 46).

5. Where appropriate, there is a plan to collect and monitor data to ensure subject safety.

6. The privacy of subjects and maintenance of confidentiality of data are protected.

8. Research that is being conducted does not ask questions of a sensitive nature (e.g. questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.) Research does not allow for subjects to offer responses that could reasonably place them at risk for criminal or civil liability, be damaging to their financial standing, insurability, reputation, or be stigmatizing.

Expedited Categories. There are 8 categories of research that are eligible for expedited review status. Categories 1-4 deal with clinical studies of drugs, collection of blood samples, collection of biological samples, and collection of medical data though noninvasive means commonly used in clinical practice (e.g., x-rays). Indicate below the expedited category that relates to this research study.

☐ **EXP5** - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). *Research using the medical records of HIV-positive patients is an example of a study that should not be reviewed by the expedited method because of the sensitive nature of the research.*

☐ **EXP6** - Collection of data from voice, video, digital, or image recordings made for research purposes. *If information included in the recordings is considered sensitive or potentially damaging to the subject's financial standing, employability, insurability, reputation, or if the subject's voice or (still or moving) image could be identified then this research is not eligible for expedited review.*

☐ **EXP7** - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *Research studies on intelligence or other traits involving specific populations require careful analysis because this type of research, depending on the nature of the survey questions, could result in stigmatization of a segment of society.*

☐ **EXP8** - Continuing review of research previously approved by the convened IRB if certain conditions apply: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

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 (separate ICF is needed for the participant to indicate consent for digital recording)

☐ Use of existing/secondary data

☐ Medical procedures

☐ 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

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 and monitor the progress of the project throughout the approved duration.

_____ _____

Signature of Faculty Advisor Date

A. PROTOCOL DESCRIPTION

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

1. **PURPOSE** Briefly describe the context and goals of your research project. Summarize the background, nature, rationale and significance of the proposed study. In outline form, clearly state the objectives of the research, major hypothesis and research design. Provide three to five references. ***Please be advised that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.***

2. **SUBJECTS** Describe the involvement of the human subjects in this project. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant woman etc. should address their special needs. Clearly state the following: Who are the subjects? What will they be doing? How many subjects will be involved in the project? What is the relationship (if any) between the researcher and the subjects?

3. **RECRUITING** Specify how subjects will be recruited (e.g. advertisements, announcements in class, e-mail, internet, etc.). NOTE: Be aware of privacy provisions when designing recruitment activities. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects ***must be attached***.

4. **DESCRIPTION OF THE PROCESS AND DURATION:** Provide a description of the procedures to be followed. Include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of measures to allow the IRB to under the nature of human subjects participation. Indicate the duration of anticipated research as applicable **from the viewpoint of the participant** (the length of each session and the number of sessions).

5. **SETTING/LOCATION** 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).*

6. **OBTAINING CONSENT** State in detail your plans for obtaining each subject's informed consent to participate in this project Describe how this information will be conveyed to subjects. BE SPECIFIC! Outline the steps chronologically (attach copy of informed consent form). NOTE: *At least 2 copies of the forms should be handed out to participants, with one for them to sign, date and hand back and one for them to keep for their records.* **If research involves minors**, explain in detail the assent process. Attach copy of verbal assent script or written assent form.

7. **BENEFITS** Explain benefits of participating in the study **for participants**. If none, state this. Then explain the benefits of the study in general and to the public. List all possible or expected benefits.

8. **RISKS** One of the key elements of an expedited project is that there are minimal risks to the participants. First, describe any possible risks (physical, psychological, sociological, legal, financial, or other) that can result from participation in this project. Then, describe how there are only minimal risks to participants for taking part in your study.

9. **PRIVACY & CONFIDENTIALITY** These are separate issues. You must address both. **Privacy** applies to the person (e.g., how potential participants are identified and contacted; who is present during the research activities; how public is the setting; is the researcher accessing the minimum amount of information necessary). **Confidentiality** applies to the data (e.g., identifiable data; access to data; under what circumstances data may be shared).

10. **STORAGE** Specify how you will keep your data secure, and maintain confidentiality during and after the research. Be specific and describe how data will be stored throughout the duration of the project and upon its completion. PLEASE NOTE THAT ALL CONSENT FORMS AND DATA MUST BE KEPT UNDER LOCK AND KEY FOR 5 YEARS.

11. **DISPOSAL** Describe how you will ultimately dispose of your data after you have completed your research (e.g. shredding, deleting digital files). PLEASE NOTE THAT ALL RESEARCH RECORDS MUST BE MAINTAINED FOR AT LEAST FIVE YEARS AFTER THE COMPLETION OF THE RESEARCH.

12. **MEASURES** Are you using any scales or instruments you did not create yourself? If so, list the names of those scales and provide a copy of the permission to use the instrument. If it is in the public domain, please indicate below. If you purchased the scale, provide proof of purchase.

13. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred: 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

B. SUPPORTING DOCUMENTS

These three documents must be attached. If they are not included, the application will be returned without review.

- Consent form
- Debriefing form
- CITI Training Certificate

ADDITIONAL DOCUMENTS - 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
- Site permission (if applicant is conducting research anywhere other than Kean University)
- Copies of all survey instruments, interview questions, recruitment letters, emails, advertisements

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