# KEAN UNIVERSITY
# INSTITUTIONAL REVIEW BOARD

APPLICATION TO REQUEST **CONTINUING REVIEW** OF A RESEARCH PROTOCOL
INVOLVING HUMAN SUBJECTS

All applicants must submit a completed, signed hard copy of this form and any required additional information to: Townsend 130, ATTN: IRB.

**Submission of this application must occur 60 days prior to expiration of currently existing research protocol to avoid the possibility of a lapse in IRB approval.** Any research study that has not received continuing review and written approval by the end of its current approval period is automatically considered expired and all research and research-related activities must cease.

**Background:**
In accordance with DHHS Guidance on Continuing Review, the IRB starts with the working presumption that the research, as previously approved, does satisfy all of the criteria for IRB approval of research. The IRB will focus on whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects. The IRB will also assess whether there is any new information that would require revision of the protocol and/or the informed consent document.

**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: _____

Current Approval End Date: _____ Protocol# (from current approval letter):_____

*Students applying for IRB continuing review must complete the student section. NOTE: Student applications that are not signed by the Faculty Advisor will not be reviewed.*

**FOR IRB USE ONLY**

PROTOCOL #_____ DATE RECEIVED: _____

DATE REVIEWED: _____

_____APPROVED _____APPROVED WITH PROVISIONS _____DENIED

**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: _____

## A. PROTOCOL DESCRIPTION FOR CONTINUING REVIEW

Provide responses to the following:

1. A brief summary of the protocol currently being used. HIGHLIGHT any changes to methodology that have occurred since data collection started, and any amendments or modifications to the research since the last IRB review.
2. The number of subjects enrolled to date. Explain any variation from the number of subjects in the original application.
3. A summary of any unanticipated problems and available information regarding adverse events. If there have not been any unanticipated problems, state this.
4. A summary of any withdrawal of subjects from the research since the last IRB review.
5. A summary of any complaints about the research since the last IRB review.
6. Any other relevant information, especially updated information about risks associated with the research.
7. A summary of any recent literature that may be relevant to the research.

## B. REQUIRED ATTACHMENTS

If you are proposing changes to *any* of the currently approved documents (consent form, debriefing form, recruiting materials, surveys, etc.), a copy of the current document as well as the newly proposed document must be attached.

## C. SUBMITTING YOUR REVISED APPLICATION

In addition, use your original application to create a REVISED application. Highlight (in yellow) the changes that were made and submit it along with this form.

**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

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