



**KEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

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

All applicants **must** submit the completed, signed application to Townsend 130, ATTN: IRB

General Information

Protocol # _____ Date of original IRB Approval: _____

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: _____

A. Provide the following information

Describe in detail proposed changes to the following sections:

- 1) Purpose
- 2) Subjects
- 3) Recruiting
- 4) Duration
- 5) Location
- 6) Obtaining Consent
- 7) Benefits
- 8) Risk
 - a) Risk Level (General)
 - b) Risk Level (Specific)
 - c) Procedures to Protect from Risks
- 9) Privacy
- 10) Data Storage
- 11) Disposal
- 12) Measures

If applicable, include as an attachment to this form copies of all revised survey instruments/permission letters, revised consent, assent, and debriefing forms and training certificates for new individuals who were not identified on your original application.

B. 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 PI

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