APPROVAL REQUEST FORM:

RESEARCH WITH HUMAN OR ANIMAL PARTICIPANTS

Cornerstone UNIVERSITY®
BUILD A LIFE THAT MATTERS

STUDY INFORMATION

Title of study: _____

Date research will begin: _____ **Expected completion date:** _____

If proposal for external funding:

Agency: _____ **Deadline:** _____

Department chair's signature, acknowledging awareness of study: _____

CU-IRB TRAINING

CU-IRB training is required of all investigators prior to review of the CU-IRB Approval Request Form.

Training is available for Cornerstone students, faculty and staff through Moodle. To access:

1. Type **"Protecting Human Research"** in the search box in Moodle and click "Go."
2. Click on "**IRB - PROTECTING HUMAN RESEARCH PARTICIPANTS TRAINING**" when it appears.
3. Enter "Cornerstone" as the Enrollment Key and then click "**Enroll Me.**"

After creating an account, begin with the introduction module and follow the instructions. Once you've completed all modules and all quizzes, print out the certificate and submit it along with this proposal form to the CU-IRB chair.

☐ All investigators have completed the required CU-IRB training within the last three years and a copy of the certificate has been submitted with this application.

INVESTIGATOR(S)

Name(s): _____

Department: _____

☐ **Student** ☐ **Faculty** ☐ **Other:** _____

Phone: _____ **Date:** _____ **Email:** _____

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APPROVAL INFORMATION

For research conducted by students or non-faculty staff:

This research involving human or animal participants, if approved, will be under the direct supervision of the following faculty adviser (considered the principle investigator):

Faculty Adviser: _____ **Department:** _____

Phone: _____ **Date:** _____ **Email:** _____

For research conducted by external investigators:

☐ This research **has been** approved by an external IRB. The approved proposal will be submitted with this application.

☐ This research **has not been** approved by an external IRB.

RESEARCH INFORMATION

Type of research:

Indicate by marking an [x] in the appropriate box below.

☐ **Human Subjects Research**

☐ **Animal Research *(Also Complete Question 7)***

About the research:

1. **PROJECT DESCRIPTION:** Provide a description of the proposed research by responding to each of the topics below.

   a. **Purpose of research.**

   b. **Method of selection/recruitment of targeted participants.**

   c. **Targeted participants age range:** Number: _____ Gender: _____

   d. **Targeted Participants in Special Consideration Categories:** *(Check all that apply.)*

   ☐ None
   ☐ Children (age range: _____)
   ☐ Cognitively impaired persons
   ☐ Prisoners
   ☐ Pregnant or lactating women
   ☐ Blind individuals
   ☐ Military personnel
   ☐ Wards
   ☐ Institutionalized individuals
   ☐ Non-English speaking individuals
   ☐ Students
   ☐ Other subjects whose life circumstances may interfere with their ability to make free choice in consenting to take part in research.

   Please specify: _____

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e. **Targeted participant incentives, follow ups, compensation to be used.**

f. **Nature of data to be collected and procedures (i.e., explain what data you will collect and how it will be collected). Be as explicit as possible about the steps involved.**

g. **Instruments to be used (i.e., include a complete copy of any interview or questionnaire instruments to the bottom of this document).**

h. **Describe how data will be analyzed.**

i. **Describe plan for data dissemination.**

2. **POTENTIAL RISK:** By marking "x" in the following box, the researcher(s) acknowledge that all research has the potential for risk.

☐ Yes

a. **All research entails some level of risk, though perhaps minimal. Below, describe in detail any psychological, social, legal, economic or physical risk that might occur to participants.**

b. **Illegal activities: Do the data to be collected relate to any illegal activities?** (Mark an "x" in the appropriate box below):

☐ No illegal activities are involved in this proposed research.

☐ Yes. (Please attach explanation of illegal activities in proposed research.)

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3. **POTENTIAL BENEFIT:** University policy requires that risk from and/or burden of participation be outweighed by potential benefits to participants and/or humankind in general.

   a. **Identify potential benefits to PARTICIPANTS resulting from this research.**

   b. **Identify potential benefits to HUMANKIND in general resulting from this research.**

4. **CONSENT:** All participants must know that their participation is completely voluntary; therefore, all studies must include informed consent.

   a. **What is the consent process to be followed in this study? Explain how you will be obtaining consent from participants.**

   b. **Is deception or incomplete disclosures involved in this study?**

   ☐ No.

   ☐ Yes. (If yes, please provide a justification as well as a plan for the debriefing process.)

5. **MINORS:** Will minors and/or other vulnerable participants be involved in the proposed research? (mark an "x" in the appropriate box below):

   ☐ No minors or other vulnerable participants are involved in proposed research.

   ☐ Yes. (Please attach procedures to be used in obtaining their agreement (assent) to participate, in addition to the consent of their authorized representative, such as parent or guardian.)

6. **SECURITY PROCEDURES:** Please describe how participants are protected from the potentially harmful use of the data collected in this research by responding to each of the topics below:

   a. **Describe measures planned to ensure anonymity or confidentiality.**

   b. **Describe methods for storing data while study is underway.**

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c. Check the box below that accurately describes how you plan to destroy data and media once study has been completed.

- ☐ After five years, the principal investigator will destroy the data on file.
- ☐ After five years, the faculty adviser will destroy the data on file.
- ☐ Other: Please explain below.

d. If audio, videotape or other electronic data are to be used, when will they be erased?

- ☐ After five years, the principal investigator will destroy the data on file.
- ☐ After five years, the faculty adviser will destroy the data on file.
- ☐ Other: Please explain below.

Do not forget to include a copy of:

- ☐ The Informed Consent. *(See question 4.)*
- ☐ All instruments to be used in this research (e.g., interviews forms, questionnaires, surveys). *(See question 1g.)*

*Only researchers utilizing **animal subjects** must complete this section:*

7. For research utilizing animal subjects, indicate by marking an [X] in the boxes below that the following conditions have been met:

- ☐ The study and its associated facilities meet all appropriate federal, state and local regulations.
- ☐ The study is designed to be conducted and terminated with due and acceptable regard for the welfare of the animal subjects.
- ☐ The study is designed to avoid inflicting needless pain and/or suffering. When required, the appropriate tranquilizers, analgesics and/or anesthetics will be used.
- ☐ Adequate safeguards have been made for the safety and comfort of the animal participants.
- ☐ The biomedical appropriateness of using the selected animal models in the research has been appropriate tranquilizers, analgesics and/or anesthetics will be used and justified.