INSTITUTIONAL REVIEW BOARD
APPLICATION FOR RESEARCH STUDIES with HUMAN PARTICIPANTS

Directions: *Fill out the questions as appropriate. Send questions and comments to Alvernia.irb@alvernia.edu.*
Note: If your research involves the use of ONLY archival, existing, de-identified dataset, DO NOT submit this application. Refer to *Research Determination Tool.*

REVIEW CATEGORIES (45 CFR 46)
Select one

Category A: Exempt Review :

☐ A1 ☐ A2 ☐ A3 ☐ A4 ☐ A5 ☐ A6 ☐ A7 ☐ A8

Category B: Expedited Review:

☐ B1 ☐ B2 ☐ B3 ☐ B4 ☐ B5 ☐ B6 ☐ B7 ☐ B8 ☐ B9

Category C: Full Review: ☐ Greater than minimal risk

GENERAL INFORMATION

1. **APPLICATION:** ☐ Initial Submission ☐ Resubmission
2. **APPLICATION TYPE:**
   ☐Undergraduate ☐Master's ☐Doctoral ☐Faculty/Staff ☐Institutional
   ☐Other (Please specify):

3. **INVESTIGATOR(S) CONTACT:**
   PRINCIPAL INVESTIGATOR
   Name:
   Email Address: Phone:

   CO-INVESTIGATOR(S):
   Name:
   Email Address: Phone:

   CO-INVESTIGATOR(S):
   Name:
   Email Address: Phone:

   Note: Students need to include the names and contact information of Faculty Advisor(s) or Committee Members:
   Name: Contact information:
   Name: Contact information:
   Name: Contact information:

4. **EDUCATION AND TRAINING:**

Note: Principal investigator(s) need to provide the CITI training certificates of all parties involved in the project (including other researchers, advisors, and dissertation/thesis committee members) as attachments. Some studies may also require FCOI certificates.

5. **Project Title:**

PROJECT/STUDY INFORMATION

6. **TYPE OF RESEARCH:** Other:

7. **PROJECT DESCRIPTION:**

   a. Describe the research question(s) and/or hypotheses.

   b. Attach a copy of the full research proposal for reference during IRB deliberations. Include Participant Packet.

8. **STUDY POPULATION:**

   a. How many subjects will participate in the research?
   b. How many potential participants do you need to reach study goals?
   c. Gender: Male Female Other
   d. Indicate research participant(s) (mark all that apply):

      ☐ Adult volunteers (may include those listed below as part of the public not specifically targeted or identified).
      ☐ Minors (under age 18)
      ☐ Prisoners
      ☐ Pregnant women
      ☐ Impaired individuals (physically, psychologically, socially, or other)
      ☐ Adults requiring a guardian
      ☐ Minorities and/or Non-English speakers
      ☐ Economically/educationally disadvantaged individuals
      ☐ Students in an educational setting
      ☐ Participants who may become coerced or compromised by the study
      ☐ Other:

   e. What characteristics/attributes are needed to be part of the study?

f. What characteristics will exclude participants from the study?

9. RECRUITMENT

a. List site where participants will be recruited:

b. Procedures used for recruitment (attach any handouts/brochures)

c. List site where research will be performed (if other than recruitment):

d. Who is responsible to provide permission to access participants from this site?

10. MATERIALS

☐ Created by researcher (attach it, if not in proposal)

☐ Public domain

Reliability:

Validity:

☐ Permission to use material(s). If yes, attach.

☐ Permission to adapt/modify material(s). If yes, attach.

☐ Translation. If yes, describe process:

MM◊ **TYPE OF DATA COLLECTED** (Mark all that apply)

☐One-on-one interviews

☐Focus Groups

☐Questionnaires/surveys

☐Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)

☐Ethnographic observation

☐Physiological measurements (e.g., EEG, EKG, MRI)

☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)

☐Behavioral decision-making tasks (e.g., puzzles, interactive games, etc.)

☐Physical activities such as walking and other forms of exercise

☐Clinical trial/procedures

☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above):

MH **METHODS OF DATA COLLECTION, STORAGE, RETENTION** (Mark all that apply)

☐ Data will be collected anonymously and will not include ANY identifiers.

☐ Data will be linked to participants (through code numbers, pseudonyms, etc.).
Provide plan to maintain confidentiality and privacy:

☐ Data will be stored anonymously

☐ Data will be stored with participants' identity.
Provide data storage plan:

☐ Other data collection, storage, and/or retention. Explain:

How long and where data will be stored:

13. CONSENT

Type of consent
Other consent (explain)

How is consent obtained (explain, if not on proposal attached)

Who will provide consent to participants

How do you know participants understood consent

14. DATES

a. Anticipated Start Date for Data Collection:
b. Anticipated Ending Date for Project:

15. STUDY FUNDING AND CONFLICT OF INTEREST:

a. Is this research funded? ☐No ☐Yes List funding:

If YES, will the funding source regulate	Yes	No
Recruitment	☐	☐
Data collection	☐	☐
Data analysis	☐	☐
Reporting	☐	☐

b. If yes, explain your plan to manage financial conflict:

c. Is there any other conflict of interest in study? ☐Yes ☐No

If yes, explain how it will be addressed.

RISKS/BENEFITS/INFORMED CONSENT

Does the study involve any of the following?	Yes	No	N/A
More than minimal risk	☐	☐	☐
Deception	☐	☐	☐
Use of protected health information (PHI)	☐	☐	☐
Names or other identifiers that indicate who is in the study	☐	☐	☐
Covert observation	☐	☐	☐
Mental/Physical stress or harm	☐	☐	☐
Information related to			
• sexual attitudes/preferences/practices	☐	☐	☐
• alcohol, drugs, or other addictive product	☐	☐	☐
• health status	☐	☐	☐
• social unacceptable behavior	☐	☐	☐
• an individual's mental health	☐	☐	☐
• illegal activity/conduct	☐	☐	☐
• invasion of privacy	☐	☐	☐
• potential to damage one's financial standing, employability, or reputation.	☐	☐	☐
Compensation/ benefits	☐	☐	☐

If yes (to any item), explain the risk/benefits and how they will be addressed, any precautions to minimize risks, and how the benefits of this project outweigh the risks.