Union Institute & University
Institutional Review Board

Human Subjects
Research Description

All research projects involving human subjects must submit an application for review and approval by the Institutional Review Board (IRB) prior to initiation of the research. Attach completed applications and research proposals and appendices to e-mail messages to mary.ginn@myunion.edu. Contact the IRB at 513.487.1153, or 800.486.3116, ext. 1153, with any questions or concerns.

Insert [Your Name, Union ID #, Study Title, and Page X of Y] on every page—header or footer (Select from Insert menu.).

1. **Principal Investigator (PI) Name & Contact Information** (mailing address—for approval letter, telephone numbers, e-mail addresses):
2. ☐ Graduate Student ☐ Undergraduate Student ☐ Faculty ☐ Staff
3. Researcher’s UI&U ID Number:
4. Degree program:
5. Student’s concentration/specialization; employee’s department name:
6. Faculty advisor/dissertation chair/supervisor:
7. Advisor/chair/supervisor e-mail address:
8. Second core reader:
9. PsyD Principal Faculty Investigator (PI) & Contact Information:
10. Date CITI Course Basic Modules Completed:
11. Other involved institution that requires IRB review/approval: (Submit copies of IRB approval letters from other institutions.)
12. Funding source:
13. **Attach** resumés of other individuals who will interact with subjects (assistants, co-researchers, collaborators).
14. **Attach** resumé for PI to verify experience and qualifications to conduct research with the study population.

**Project Description:**

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<th>Project Title:</th>
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| Projected Beginning Date: (after IRB approval) | Projected Ending Date: (12 months initially) |
This project makes use of the following types of subjects and/or locations: (Check all that apply.)

- [ ] Children
- [ ] Elementary and Secondary Schools
- [ ] Prisons/ Prisoners
- [ ] Children – More Than Minimal Risk
- [ ] International Research – In another country(ies)
- [ ] Pregnant Women, Neonates, and/or Fetuses
- [ ] Internet Research*
- [ ] Persons with Mental Illness
- [ ] Persons with a Physical Disability
- [ ] Persons with Illnesses or Disorders
- [ ] Non-English Speaking Participants
- [ ] Economically/Educationally Disadvantaged Persons
- [ ] Pregnant Women, Neonates, and/or Fetuses
- [ ] Research in a Hospital (HIPAA Required)
- [ ] Elderly Persons
- [ ] Students Used as Research Participants
- [ ] Other Location ________________________________

*Internet research involves research on Internet activities as well as using the Internet for a survey, interview, focus group, etc.

Take elective CITI Course modules associated with each study population included in your study.

The following media will be used in this study: (Check all that apply.)

- [ ] Audio recorder
- [ ] Digital audio recorder
- [ ] Video recorder
- [ ] Photographs
- [ ] Other (specify): ________________________________

Data Collection Method: (Check all that apply.)

- [ ] Interview
- [ ] Survey
- [ ] Questionnaire
- [ ] Purchased instrument
- [ ] Instrument used with author’s permission
- [ ] Other (specify):

Sensitive Data Collection: (Check all that apply.)

- [ ] Substance abuse
- [ ] Sexual behavior/ orientation/ abuse
- [ ] Criminal activities
- [ ] Other (specify):
- [ ] None

Number of Participants:

Principal Researcher’s Assurance Statement:

I have read Union Institute & University’s policy concerning research involving human subjects, and I agree to:

1. Accept responsibility for the ethical conduct of this research.
2. Obtain approval from the IRB prior to changing any procedures.
3. Submit a Progress Report describing the current status of the project as specified in the approval letter.

Student PIs: Send your application and all materials to your faculty advisor or dissertation chair for review and approval prior to sending to the IRB.

Faculty PIs: Submission by attachment using your Union e-mail address to the IRB serves as your signature and pledge to abide by the conditions stated above.

PSYD PRIMARY FACULTY INVESTIGATOR: Send an e-mail to mary.ginn@myunion.edu stating that you have reviewed and approved this student’s IRB application and research proposal.

Primary Student Investigator Signature __[TYPE NAME HERE]________ Date: __[TYPE DATE HERE]_____

Electronic signature ✗

ADVISOR/ CHAIR/ SUPERVISOR: Send an e-mail to mary.ginn@myunion.edu stating that you have reviewed and approved this IRB application and research proposal for your student.
Provide information on the following issues in nontechnical language. Refer to the General Application and Research Proposal Preparation Guidelines for issues to consider for each topic. Leading questions are not all-inclusive; you must provide a description of your project sufficient for reviewers to weigh the risks, benefits, and human protection provisions of your project. Refer to attachments/appendixes (e.g., consent form(s) and recruitment documents) in the descriptions. If you believe that a question is not applicable to your study, enter N/A.

1. **Purpose of Research:** Provide a description of the nature, purpose, and potential value of the proposed research; include research question(s) and/or hypotheses:

   How will the resulting information contribute to the existing knowledge base? What do you expect to learn and how will it be of value to participants and others?

   How will the resulting information be disseminated? Include degree program final document, thesis, dissertation, as well as journal articles, professional presentations, website(s), and any other potential uses and/or media:

2. **Subject Population Description:** Provide age range(s), gender, ethnicity (if applicable), occupations, and other important descriptors relevant to your recruitment and data collection:

3. **Research Procedures/Methods.** Provide a description of each activity, discuss human subject protection issues—identities and data—refer to attached materials (consent forms, surveys, scripts for recruitment e-mails, presentations, telephone calls, etc.):

   a. **Recruitment and Selection of Subjects:** Describe how study location administrators and potential participants will be contacted and informed about the study; provide scripts of recruitment messages for administrators and participants (e-mails, flyers, online posted messages, presentations, letters, etc.). Describe how you want potential participants to contact you to ask questions and/or volunteer:

   b. **Describe the research activities and the order in which they will take place:** Explain what participants will be asked to do; if more than one activity (e.g., pre-test/survey/interview/post-test, etc.), state the estimated amount of time devoted to each activity, including reviewing transcripts. Attach surveys, focus group and interview questions, etc., as appendices.

   c. **Describe the research (data collection) method and analysis:** Describe clearly the collection method(s) clearly (e.g., quantitative analysis, grounded theory, ethnography, etc.) and the analysis process.

   d. **Research Location(s):** Where will research take place? Whom (position title) will you contact to obtain permission to conduct all or portions of your study at all identified locations? How will you obtain permission to utilize that location? Attach approval/permission letter(s) from study locations.

   e. **Consent (Adults)/Assent (Children) Process Description (attach forms & scripts as appendices and refer to them):** Provide a clear description of the process for obtaining consent/assent of subjects or their representatives—initial contact with potential participants such as a group meeting, classroom, etc.; when, where, and how consent/assent forms will be presented to participants; how consent/assent forms will be kept separate from surveys, interview notes, or other collected data:

   f. **Procedures for Safeguarding Confidentiality of Information:** Who, such as transcribers, assistants, and statisticians, will have access to confidential data in addition to the researcher?

Where and how will data be stored securely during the study and after the study is completed, including audio and video tapes, photographs, transcripts, and/or digital recordings? (e.g., in a locked file cabinet in a locked
closet; electronic files in a password-protected computer in researcher’s home) State that all study data will be retained in a secure location for a minimum of three years after the study is completed and then destroyed.

g. **Deception and debriefing:** If used, provide justification for deception (anything intentionally not telling participants about the study) and describe the debriefing process; attach debriefing script. (See IRB Handbook for information about deception in research and debriefings.)

h. **Research resources:** Describe individuals who will assist in the consent process, survey distribution and collection, data analysis, etc.

4. **Potential Risks and Discomforts.** Describe potential risks, such as loss of confidentiality of data, loss of privacy related to participant identity, embarrassment, emotional reactions, etc., to subjects. Include high risks such as those that may be associated with criminal activities:

What action will be taken to minimize the effect of all identified potential risks? How will you handle emotional reactions? What resources will be available for participants who become emotional?

5. **Potential Benefits.** Briefly discuss any identifiable benefits that subjects “may” (not will) receive now or in the future:

Describe the benefit to the community and society (e.g., students, academic field, research, etc.):

Describe how potential benefits to participants, community, and society outweigh identified risks:

6. **Context of Study – Brief Literature Review – no more than five pages:** (Include reference list and/or bibliography.)

7. **Attach/ append additional materials below (X all that apply, add appendix number or letter):**

   - Recruitment Materials (ads, fliers, letters, posters, scripts for e-mail messages, telephone and/or presentations, Web site postings, etc.)
   - Consent Forms(s)—for all groups of participants; may include separate video- and/or audio-recording forms
   - Assent Forms/ Scripts for Children
   - Confidentiality Agreements (if used) for individuals who will assist in the collection, synthesis, and/or analysis of data; e.g., transcribers, statisticians, data-entry persons
   - HIPAA documents—authorization/ permission forms in medical and/or hospital settings
   - Questionnaires/ Surveys
   - Interview/ Focus Group Questions/ Interview Guide
   - Permission Letters for Use of Facilities/ Locations
   - IRB and/or Research Committee, and/or Administrator Approval Letters from all Study Locations and Other Institutions
   - Researcher and Assistant Resumés
   - Researcher’s Professional Association Ethical Guidelines