

CO-INVESTIGATOR

Name:
Email Address:
Correspondence Address:
Phone:

Is the principal investigator or co-investigator a student? ____Yes ____No
If the principal investigator is a student, Faculty Advisor name and contact information must be included.

FACULTY ADVISOR

Name:
Email Address:
Correspondence Address:
Phone:

EDUCATION AND TRAINING:

1. Provide a copy of your NIH Training Certificate. Do **NOT** submit this application if you have not attached a copy of the NIH Training Certificate for all investigators and the Faculty Advisor.

The training can be accessed at <http://phrp.nihtraining.com/users/login.php>

2. Faculty and graduate level students must provide a copy of your FCOI Training Certificate. Undergraduate level students do not need to provide proof of FCOI Training.

The training can be accessed at
<http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm>

Anticipated Start Date for Research:

Anticipated Ending Date for Research:

Indicate potential or confirmed funding sources for this research project.

Will the funding source regulate recruitment, data collection, analysis, or reporting of this research in any way? ____Yes ____No If yes, explain:

TYPE OF REVIEW:

The full committee or an expedited subset of the committee will be asked to review your application, depending upon the nature and circumstances of your research. Check the area that applies to your research. The IRB reserves the right to Full Review all applications.

_____ **EXPEDITED REVIEW**

Surveys considered minimal risk; research on individual or group behavior or characteristics where research does not cause stress to subject and confidentiality is maintained; research involving deception that poses no more than minimal risk; performance of non-invasive tests; collection of data using noninvasive procedures; collection of blood samples by finger stick or venipuncture by trained personnel; research using existing documents, records, pathological specimens, or diagnostic specimens.

_____ **FULL REVIEW**

Research with greater than minimal risk; research of a sensitive nature; research with vulnerable populations (children, prisoners, pregnant women, mentally disabled, elderly individuals [persons 55 and over], non-English or English as second language speakers, or economically/educationally disadvantaged individuals; research with students enrolled in a class in which the Investigator is the instructor); research involving invasive procedures; research including physical/psychological pain or potential injury.

PROJECT DESCRIPTION:

1. Describe the research question(s) and/or hypotheses.
2. Describe any relevant theory that supports this research. (This section should be between one and two pages in length. Any application stating “Not Applicable” in this section will be immediately returned to the investigator(s). Include citations where appropriate.)
3. Summarize how this research will contribute to your discipline or field of study.
4. Does the study require approval of another IRB? _____Yes _____No
If yes, provide the IRB application and approval letter from the non-Alvernia University IRB.

STUDY POPULATION:

1. How many subjects will participate in the research?
2. What are the ages of the potential participants? (Ages 0-7 require full review and a legal guardian informed consent form; ages 8-17 requires full review and a child assent form along with the legal guardian informed consent form; ages 18 and older require an adult informed consent form unless a waiver is indicated. Attach all applicable forms for review. Check all that apply.)

_____ 0-7 years _____ 8-17 years _____ 18-54 years _____ 55+ years

3. Some populations are considered “vulnerable” to coercion or undue influences. Will any of these populations be invited to participate in the research? Check all that apply.

- Children (under age 18)
- Prisoners
- Pregnant women
- Psychologically impaired individuals
- Elderly individuals (55 and over)
- Minorities
- Non-English speakers
- Economically/educationally disadvantaged individuals
- Students in a classroom in which the Investigator is the instructor
- No vulnerable populations (Skip to Question 5 if no vulnerable populations.)

4. Provide the rationale for using these vulnerable populations and detail the safeguards included in the research to protect their rights and welfare.

5. Is pre-existing data being used? Yes No If yes, describe the data source.

6. If pre-existing data is being used, is the data publically available? Yes No
“Publically available” means that the information is accessible to anyone without fees or authorizations. If pre-existing data is being used and is not publically available, a Site Permission letter is required to access the data.

PARTICIPANT IDENTIFICATION AND RECRUITMENT:

1. How will potential participants be identified and recruited? Provide a copy of all advertisements, bulletin board notices, telephone scripts and other recruitment materials.

2. Who is responsible to provide permission to access participants from this locale?

INSTRUCTIONS FOR WRITING A SITE PERMISSION LETTER: A permission letter must be prepared for each individual at a site requesting permission to conduct research at the specific site. Site permission letters must be submitted to the IRB **BEFORE** being sent to the site personnel. Site permission letters **MUST** contain the following elements: identification of investigator, purpose of research, how the identity and/or private information of the participants will be protected, level of risk to participants, how the name of the site will be protected, the fact that the research will be made public, full contact information for the Faculty Advisor (if applicable), full contact information for the Alvernia University IRB, the length of time the study will take participants and/or site personnel.

METHODS AND PROCEDURES:

1. Describe the research procedures. What will participants do in order to complete this study? List every task/activity that participants will be asked to complete. Include an estimate of the time it will take participants to complete the tasks/activities.

2. Describe analytical techniques used to analyze data. (Stating the use of SPSS, Excel, etc. is not sufficient. Supply specific analytical techniques.)

3. Will compensation be provided to participants? Yes No

If yes, describe what the compensation will be and how compensation will be handled in the event the participant withdraws from the study.

4. Will electronic equipment (audiotape, videotape, etc.) be used to collect data?

Yes No

If yes, describe in detail how the electronic equipment will be used, including who will be using the equipment.

5. Will survey or interview methods be used in the research? Yes No

If yes, provide a copy of the survey instrument and interview questions. If the material is copyrighted, provide evidence you have permission to use the materials. Provide reliability and validity data for any instrument you are using.

6. How will the data (including, photo, audiotapes or videotapes) be collected, recorded, and stored? Describe in detail the program/software/survey technology if using a web-based survey and how participant identity will be protected. Who has access to this data? (The answer to this question may **never** be “not applicable”. The answer to this question must state that the IRB will have access to the data as well as the faculty advisor [if applicable].)

7. Will the data include names or other identifiers that indicate who is in the study?

Yes No

If yes, justify why these names or identifiers are being used. Describe how the data will be cleansed of the names and/or identifiers.

8. If codes are used to substitute for participant names, describe the process for assigning the codes. Who will have access to the codes, and who will secure and maintain the code list?

9. The raw data and coding key will be destroyed:

when the study is complete

within three (3) years

other

Provide a rationale for the length of time indicated above.

RISKS AND BENEFITS:

Minimal risk is defined as that in which the harm or discomfort anticipated in the research is no greater than that encountered in daily life or during routine physical/psychological examinations or tests. Examples of risks include: Use of confidential records (e.g. educational or medical records), manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stressors; any probing for personal or sensitive information especially in surveys or interviews; presentation of materials which participants might consider sensitive,

offensive, threatening, or degrading; invasion of privacy of participant or family; social or economic risk; risk associated with exercise or physical exertion; legal risk.

1. Will the research present more than minimal risk to participants? _____Yes _____No
2. Describe the actual and potential risks, discomforts, and inconveniences for the participants.
3. Describe the precautions that will be taken to minimize or prevent potential risks, inconveniences, and discomforts.
4. Will deceptive techniques be used in the study? _____Yes _____No
If yes, describe the deception, when and how deception will be revealed to participants and provide the debriefing statement that will be used.
5. Describe the potential benefits participants may experience as a result of participating in the research.
6. Describe potential benefits to society that may be expected from this research.

INFORMED CONSENT:

If applicable, attach an Informed Consent document to this application. Use the template on the IRB website that includes all essential elements of consent.

If the participants are anonymous, use the Anonymous Survey template on the IRB website.

If a survey is being used, attach the cover letter for the survey and a copy of the survey instrument.

CERTIFICATION STATEMENT

By signing below, I certify/agree:

- The information provided in this application is correct.
- I understand that as Principal Investigator, I have the responsibility for the conduct of the study, the ethical performance of the project and protection of the rights and welfare of human participants.
- I agree to comply and assure that all affiliated personnel comply with all Alvernia University IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research.

- I assure that no modification to the approved protocol and consent materials will be made without first submitting for review and approval by the Alvernia University IRB an amendment to the approved protocol.
- I agree to obtain legally effective informed consent from the research participants as applicable to this research and as prescribed in the approved protocol.
- I will promptly report unanticipated problems to the Alvernia University IRB by using the appropriate form.
- I will adhere to all requirements for continuing review.
- I will file the appropriate form when I have completed the study.
- I will advise the Alvernia University IRB of any change of address or contact information as long as this protocol remains active.
- I assure that I have obtained all necessary approvals from entities other than Alvernia University IRB that are necessary to conduct this research.
- I will not begin any part of the research until final written approval from the IRB is granted.

By my signature on this research application, I certify that I am knowledgeable about the regulations and policies governing research with human subjects and have sufficient training and experience to conduct this particular study in accordance with the research protocol.

Principal Investigator

Date

Co-Investigator

Date

Faculty Advisor

Date

STUDENT AS PRINCIPAL INVESTIGATOR

This project has been reviewed to determine that the scope, anticipated risks and benefits, and methodology are appropriate for this research by:

- Approval of thesis/dissertation proposal by faculty committee
- My personal review and approval of research proposal
- Other. (Describe below.)

FACULTY ADVISOR'S ASSURANCE

By my signature as advisor on this research application, I certify that the student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the research protocol. Additionally,

- I hereby confirm that I have thoroughly reviewed this IRB application, including the protocol narrative, and verify that it is complete and the research is appropriate in design.
- I agree to meet with the investigator on a regular basis to monitor study progress.
- I assure that the investigator will promptly report unanticipated problems and will adhere to all requirements for continuing review.
- If I will be unavailable, e.g., sabbatical leave, vacation, or resignation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Alvernia University IRB, in writing, of such changes.
- If the student leaves the university, I will provide all necessary documents for terminating the study or continuing review.

Faculty Advisor Name:

Faculty Advisor Signature

Date

DISSERTATION COMMITTEE MEMBERS' ASSURANCES

(To be signed by dissertation committee members for doctoral dissertation proposals.)

By my signature as committee member on this research application, I confirm that I have thoroughly reviewed this IRB application, including the protocol narrative, and verify that it is complete and the research is appropriate in design.

Date _____
Dissertation Chair Signature

Date _____
Dissertation Member Signature

Date _____
Dissertation Member Signature

Date _____
Dissertation Member Signature