



Office of Research and Creative Scholarship
Institutional Review Board
 (269) 471-6361 Fax: (269) 471-6246 E-mail: irb@andrews.edu
 Andrews University, Berrien Springs, MI 49104-0355

APPLICATION FOR APPROVAL OF HUMAN SUBJECTS RESEARCH

Please complete this application as thoroughly as possible. Your application will be reviewed by a committee of Andrews University IRB, and if approved it will be for one year. Beyond the one year you will be required to submit a continuation request. It is the IRB's responsibility to assign the level of review: Exempt, Expedited or Full. It is your responsibility to accurately complete the form and provide the required documents. Should your application fall into the exempt status, you should expect a response from the IRB office within one (1) week; Expedited within two (2) weeks and a Full review 4-6 weeks.

Please complete the following application:

1. Research Project	
a) Title:	
Will the research be conducted on the AU campus? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, please indicate the location(s) of the study and attach an institutional consent letter that references the researcher's study. <hr/> <hr/> <hr/>	
b) What is the source of funding (please check all that apply)	
<input type="checkbox"/> Unfunded	
<input type="checkbox"/> Internal Funding	Source:
<input type="checkbox"/> External Funding	Sponsor/Source:
Grant title:	Award # / Charging String:
<i>If you do not know the funding/grant information, please obtain it from your department</i>	
2. Principal Investigator (PI)	
First Name:	Last Name:
Telephone:	E-mail:
<input type="checkbox"/> Yes I am a student. If so, please provide information about your faculty advisor below.	
First Name:	Last Name:
Telephone:	E-mail:
Advisor's signature:	
Department:	Program:

3. Co-investigators (Please list their names and contact information below)			
First Name:	Last Name:	Telephone:	E-mail:
First Name:	Last Name:	Telephone:	E-mail:
First Name:	Last Name:	Telephone:	E-mail:
First Name:	Last Name:	Telephone:	E-mail:
4. Cooperating Institutions			
Is this research being done in cooperation with any institutions, individuals or organizations not affiliated with AU? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please provide the names and contact information of authorized officials below.			
Name of Organization:		Address:	

First Name:	Last Name:	Telephone:	E-mail:
_____	_____	_____	_____
First Name:	Last Name:	Telephone:	E-mail:
_____	_____	_____	_____
Have you received IRB approval from another institution for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please attach a copy of the IRB approval.			
5. Participant Recruitment			
Describe how participant recruitment will be performed. Include how and by whom potential participants are introduced to the study (<i>please check all below that apply</i>)			
<input type="checkbox"/> AU directory <input type="checkbox"/> Postings, Flyers <input type="checkbox"/> Radio, TV			
<input type="checkbox"/> E-mail solicitation. Indicate how the email addresses are obtained:			
<input type="checkbox"/> Web-based solicitation. Specify sites:			
<input type="checkbox"/> Participant Pool. Specify what pool:			
<input type="checkbox"/> Other, please specify:			
<i>Please attach any recruiting materials you plan to use and the text of e-mail or web-based solicitations you will use.</i>			
6. Participant Compensation and Costs			
Are participants to be compensated for the study? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, what is the amount, type and source of funds?			
Amount:	Source:	Type:	
_____	_____	_____	
Will participants who are students be offered class credit? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA			
Are other inducements planned to recruit participants? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.			
Are there any costs to participants? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain.			
7. Confidentiality and Data Security			
Will personal identifiers be collected? <input type="checkbox"/> Yes <input type="checkbox"/> No		Will identifiers be translated to a code? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Will recordings be made (audio, video)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe.			
Who will have access to data (survey, questionnaires, recordings, interview records, etc.)? Please list below.			

8. Conflict of Interest

Do you (or any individual who is associated with or responsible for the design, the conduct of or the reporting of this research) have an economic or financial interest in, or act as an officer or director for, any outside entity whose interests could reasonably appear to be affected by this research project: Yes No
If yes, please provide detailed information to permit the IRB to determine if such involvement should be disclosed to potential research subjects.

9. Results

To whom will you present results (highlight all that apply)

Class Conference Published Article Other If other, please specify:

10. Description of Research Subjects

If human subjects are involved, please highlight all that apply:

Minors (under 18 years) Prison inmates Mentally impaired Physically disabled
 Institutionalized residents Anyone unable to make informed decisions about participation
 Vulnerable or at-risk groups, e.g., poverty, pregnant women, substance abuse population

11. Risks

Are there any potential damage or adverse consequences to researcher, participants, or environment? These include physical, psychological, social, or spiritual risks whether as part of the protocol or a remote possibility. Please highlight all that apply (Type of risk): Definitions of risks can be found at the end of the application form.

Physical harm Psychological harm Social harm Spiritual harm

12. Content Sensitivity

Does your research address culturally or morally sensitive issues? Yes No If yes, please describe:

13. Please provide (type in or copy - paste or attach) the following documentation in the boxes below:

Protocol :

Survey instrument or interview protocol:

Institutional approval letter (if off AU campus):	
Consent form (for interviews and focus groups):	
Participants recruitment documents:	

Principal Investigator's Assurance Statement for Using Human Subjects in Research

_____ I certify that the information provided in this IRB application is complete and accurate.

_____ I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB approved studies, the ethical performance of protocols, the protection of the rights and welfare of human subjects, and strict adherence to the study's protocol and any stipulation imposed by Andrews University Institutional Review Board.

_____ I will submit modifications and / or changes to the IRB as necessary prior to implementation.

_____ I agree to comply with all Andrews University's policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research.

_____ My advisor has reviewed and approved my proposal.

Types of risk¹

Risk is the Probability that a certain harm will occur.

1. **Physical Risk:** Physical risks may include pain, injury, and impairment of a sense such as touch or sight. These risks may be brief or extended, temporary or permanent, occur during participation in the research or arise after.
2. **Psychological Risk:** Psychological risks can include anxiety, sadness, regret and emotional distress, among others. Psychological risks exist in many different types of research in addition to behavioral studies.
3. **Social Risk:** Social risks exist whenever there is the possibility that participating in research or the revelation of data collected by investigators in the course of the research, if disclosed to individuals or entities outside of the research, could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals.
4. **Legal Risk:** Legal risks include the exposure of activities of a research subject "that could reasonably place the subjects at risk of criminal or civil liability.
5. **Economic Risk:** Economic risks may exist if knowledge of one's participation in research, for example, could make it difficult for a research participant to retain a job or to find a job, or if insurance premiums increase or loss of insurance is a result of the disclosure of research data.

¹ Protecting Human Research Participants NIH Office of Extramural Research 2008
http://phrp.nihtraining.com/beneficence/03_beneficence.php