

Park University Institutional Review Board
8700 NW River Park Drive
Phone: 816-584-6502 e-mail: dkerkman@mail.park.edu.

Application for Review of Research Involving Human Subjects

OFFICE USE ONLY

- Exempt**
 Expedited
 Full Review

A. GENERAL INFORMATION

1. Principal Investigator(s): (Name, degree, title, dept, address, phone #, e-mail & fax)

2. Faculty Supervisor(s) (If PI is Student): (Name, campus address, phone #, e-mail & fax)

3. Title of Project: (Project title must match grant or contract title)

4. Level of Project:

Faculty Research

Student Research: *The signature of a faculty advisor is required when a PARK UNIVERSITY student is identified as the principal investigator of a research project. The faculty advisor's signature certifies that the research will be conducted in compliance with Federal and University policies.*

Dissertation

Thesis

Class Project

Other (Specify)

If thesis or dissertation research has this protocol been approved by the student's committee ? Yes No

A copy of the approval must be attached in order for the proposal to be considered.

5. Funding *

Is this a funded study? Yes () No () If yes, Please provide the following:

a. Type of funding:

- Contract/Grant
- Subcontract
- Gift
- Student Project
- Other

b. Source of funding:

- Federal Government
- Other Gov. (i.e., State, local)
- Foundation
- Other Private
- Campus/MU System Wide program
- Other

c. Name of Funding Agency:

d. Period of Funding:

e. Funding Status: NA Funded Funding Decision Pending

*A copy of the approved scope of work and contractual obligations, if any, are required for all sponsored research projects. (*a sponsored research project refers to projects that are receiving financial support*).

6. Location of Research

a. Is this a multi-center project in which PARK UNIVERSITY will function as the coordinating

center or lead institution? (*A multi-center study is one where different PIs at different institutions are conducting the same study or aspects of the same study*)

- No
- Yes

b. List all collaborating and performance sites

List all collaborating and performance sites	Provide letter of IRB approval	Provide letters of cooperation or support (as appropriate)
1. Is PARK UNIVERSITY a performance site? <input type="checkbox"/> Yes <input type="checkbox"/> No		
2. Is Truman Medical Center a performance site? <input type="checkbox"/> Yes <input type="checkbox"/> No		
3. Is Children's Mercy Hospitals & Clinics a performance site? <input type="checkbox"/> Yes <input type="checkbox"/> No		
4.	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A
5.	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A
6.	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A	<input type="checkbox"/> Attached <input type="checkbox"/> Will follow <input type="checkbox"/> N/A

7. Has this application been submitted to any other Institutional Review Board not listed above?

Yes No

If yes, provide name of committee, date, and decision. Attach a copy of the approval.

8. In carrying out this research project will you be collecting, reviewing or receiving "Protected Health Information"? (*Protected Health Information is individually identifiable health information transmitted or maintained in any form or medium, which is held by a "Covered Entity" or its business associate. A Covered Entity is a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a HIPAA transaction, such as billing.*)

Yes No

If you answered yes please provide as an attachment, information about the covered entity's policies and procedures regarding HIPAA compliance.

9. Expected Project Start Date: _____

10. Expected Project Completion Date: _____

B. SUMMARY OF PROPOSED RESEARCH

1. Project Summary

(Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.)

2. Purpose and/or Rationale for Proposed Research

(Describe the purpose and background rationale for the proposed project as well as the hypotheses/research questions to be examined.)

3. Methodology/Procedures

(Describe sequentially and in detail, all procedures in which the research participants will be involved, e.g., paper and pencil tasks, interviews, observations, surveys, questionnaires, reviewing private records/files, physical assessments, audiotaping and/or videotaping, time requirement including number of sessions, amount of time per session, and duration or period of time over which the research will take place, etc. For school-based research where class time is used, describe in detail the activities planned for nonparticipants and explain where both participants and non participants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent and assent forms.)

4. Measures

(List all questionnaires, surveys, interviews, psychological measures, or other measures, that participants will be asked to complete. submit labeled copies as an attachment to the application and indicate that the instrument is in the public domain or provide appropriate documentation of permission to use each scale.)

5. Location of Research

(List all locations where data collection will take place. Be as specific as possible. If you are collecting data in a location where it would be customary to ask permission to conduct the research project [e.g., schools, community centers, businesses, etc.], a letter stating the sites willingness to grant the researcher access is required. This letter must be submitted before IRB approval can be given. In addition provide a copy of IRB approval from those sites having Institutional Review Boards or another research review process.)

6. International Research

(For International research identify the country where the research will be conducted, and provide information about: whether there is an official or government agency in the country that needs to approve the research, the language of the research participants, the literacy level of the research participants, whether research participants face any special risks due to the political or social condition in the research setting and the qualifications of the researcher that allows them to estimate and minimize risks.)

7. Participants Involved in the Study

Participant Population *(Check all applicable boxes, if any)*

- | | |
|--|--|
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Minors (Under Age 18) <i>(Indicate Age Range)</i> _____ |
| <input type="checkbox"/> Institutionalized Residents | <input type="checkbox"/> Physically or Mentally Challenged |
| <input type="checkbox"/> Legally Incompetent | <input type="checkbox"/> Elementary School Students |
| <input type="checkbox"/> Illiterate Participants | <input type="checkbox"/> Secondary School Students |
| <input type="checkbox"/> Employees/Agency Staff | <input type="checkbox"/> Employees or Subordinates of Investigators |
| <input type="checkbox"/> Pregnant Women | <input type="checkbox"/> Public Officials or Candidates for Public Office |

(Describe in detail the sample to be recruited including number of participants, inclusion and exclusion criteria, gender, age range and any special characteristics.)

8. Recruitment Process

(Specifically describe the step-by-step procedures for finding and recruiting research participants or requesting pre-existing data or materials. Name any specific agencies or institutions that will provide access. Identify who will contact prospective participants. Describe solicitation through the use of advertising posters, flyers, announcements, newspaper, radio television or internet, face to face interactions such as direct mail or phone contact, class rooms, subject pools, health care registries, and institutional "gatekeepers" as applicable. Attach a copy of any recruitment materials including: poster(s) advertisement(s) or letter(s) or solicitation scripts to be used for recruitment.)

9. Compensation of Participants

Will participants receive compensation for participation? Yes No

(If yes, please provide details including the form of remuneration including dollar amount, course credit, lottery, gift certificate. Explain the remuneration plan, including whether and how pro-ration will be made for partial participation. For lotteries include the number of prizes, nature and value of each prize. Include information about compensation on the relevant consent and or assent forms. Please refer to “ The Consent Process” guidance for more information.)

C. POTENTIAL BENEFITS FROM THE STUDY

(Discuss any potential direct benefits to participants from their involvement in the project and/or the potential benefits to society that would justify involvement of participants in this study.)

D. POTENTIAL RISKS FROM THE STUDY

1. *(Discuss the known and anticipated risks, if any, of the proposed research. Specify the particular risks(s) associated with each procedure or test. Consider both physical and psychological/emotional risks.)*

2. *(Describe the procedures or safeguards in place to protect the physical and psychological health of the participants. [e.g., referral to psychological counseling resources])*

E. CONSENT

1. Consent Process:

(Describe when, where, from whom, by whom, and how often, voluntary informed consent will be obtained.)

2. Informed Consent:

(Describe the procedures used to obtain and document informed consent and attach a copy of the form you will use. Please see “The Consent Process” guidance for more information.)

3. Waiver / Alteration of Informed Consent

Are you requesting a waiver or alteration of Informed Consent? Yes No

(If you are requesting a waiver or alteration describe: (1) how the proposed research presents no more than minimal risk to participants,(2) why a waiver or alteration of informed consent will not adversely affect the rights and welfare of participants,(3) why it is impracticable to carry out the research without a waiver or alteration of informed consent. Also describe how pertinent information will be provided to participants, if appropriate, at a later date. Describe how you will otherwise fully inform participants, i.e., use of an information script, information letter, etc.)

For research involving minors, or others who are not competent to give legally valid consent, explain how the subject's understanding will be assessed and how often, include the questions that will be asked or actions that will be taken to assess understanding. Describe the process to be used to obtain permission of parent or guardian. Attach a copy of an information-permission letter to be used.

F. ASSENT

(For persons who are not legally competent to give consent but are reasonably competent to decide whether to participate or not, describe the procedure you would use to gain assent and attach the form. Children must assent (or, voluntarily agree) to participate and a parent must separately provide permission on behalf of his/her child. Two separate forms are required. Children under age 7 may assent either orally or passively, depending on their level of maturity.)

Please provide a numbered list of all consent/assent forms used for the study listing the title and purpose (i.e. , Child assent, staff consent, parent permission)

- 1.
- 2.
- 3.
- 4.

Will you be obtaining consent/assent from non-English speaking participants:

Yes No

Version Date: **(FILL IN DATE THAT DOCUMENT IS CREATED OR UPDATED)**

If yes describe the process that will be used to translate documents, the language and qualifications of the translator.

(Please note that the IRB requires a back translation be conducted as part of the translation process).

G. CONFIDENTIALITY

(Describe the procedures to be used to ensure confidentiality of participation and data obtained. Confidentiality is required unless subjects give express, written permission to have their identifiable information published, presented, or shared. Explain who will have access to raw data, whether raw data will be made available to anyone other than the Principal Investigator and immediate study personnel (e.g., school officials, medical personnel, federal agencies etc.) If yes, who, how and why? Describe the procedure for sharing data. Describe how the research participant will be informed that the data may be shared. Describe any circumstances under which you might be required to break confidentiality. Explain how you will inform potential subjects that confidentiality may be broken.)

1. Data Collection *(Explain how the data will be kept confidential. If anonymous data collection is proposed, provide details of how investigators WILL NOT HAVE THE ABILITY TO TRACE RESPONSES TO RESEARCH PARTICIPANTS IDENTITIES. For multiphase data collection or if multiple contacts will be made with research participants, specifically explain the tracking and coding systems that will be used. Address the confidentiality of data collected via e-mail, databases, Web interfaces, computer servers and other networked information, as applicable.)*

Check if any of the following will be used in Data Collection: Audio tapes Video tapes
 Still photos Other imaging

(If any of these data collection methods are used describe how/where tapes will be stored, who will have access to them, and at what point and how they will be destroyed)

2. Data Storage/Disposition

(Indicate where and how you will store the data and how long you plan to retain it. Describe how you will ultimately dispose of data including notes, drafts, lists of subjects, disks, etc.)

H. DECEPTION (if applicable):

Will participants be deceived or be incompletely informed regarding any aspect of this study?

Yes No

Version Date: **(FILL IN DATE THAT DOCUMENT IS CREATED OR UPDATED)**

(If your response is “yes” describe the type of deception you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script you will use with research participants explaining when and how it will be used.)

I. INVESTIGATOR TRAINING

(Investigators and all other key personnel involved in this project must complete the NIH Computer Based Training Course entitled Human Participants Protections Education for Research Teams (<http://www.Park University.edu/research/protections/IRB/education2.html>) and print out a certificate. A copy of the certificate of completion should be provided to the IRB office with the completed application and renewed every 2 years.

Additional Research Staff (attach sheet if necessary)

NAME	Research Role (PI, Co-PI, Student Investigator, Faculty Advisor, Collaborator, Data Manager, Research Assistant, etc.)	Dept/Affiliation	Training Completion Date

J. FINANCIAL DISCLOSURE:

(Could the results of the study provide a potential financial gain to you, a member of your family, or any of the co-investigators that may give the appearance of a potential conflict of interest?

No_____ Yes_____ *(If yes, and the financial interest exceeds \$10, 000, a financial disclosure statement is required with the application. This form can be downloaded from the research website at <http://www.Park University.edu/research/disclosure.pdf>)*

Principal Investigator Statement of Assurance

The proposed investigation involves the use of human subjects. I am submitting the form with a description of my project prepared in accordance with Park University policies for the protection of human subjects participating in research. I certify that the information provided in this application, and in all attachments, is complete and correct. As Principal Investigator/ Faculty Advisor, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and the strict adherence to any stipulations imposed by the IRB. I am aware of the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes.
2. If any problems involving human subjects occur, I will immediately notify the chair of the IRB.
3. I will cooperate with the IRB requests to report on the status of the study
4. I will conduct this study only during the period approved by the IRB Administrator.
5. I will prepare and submit a continuing review request and supply all supporting documents to the IRB before the approval period has expired if it is necessary to continue the research project beyond the time period approved the IRB.
6. I will prepare and submit a final report upon completion of this research project.
7. I will maintain records of this research according to IRB guidelines.
8. I will obtain legally effective informed consent from each participant or their legal representative, unless waived by the IRB, using only the currently IRB approved stamped consent form .
9. I will complete and stay current with all training requirements.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. I will not begin work on this project until I receive written notification of final IRB approval.

Signature of Principal Investigator

Date

Signature of Faculty Advisor (if any)

Date

As an advisor of student research, in the event that your student investigator is unreachable or fails to comply with the IRB's request to complete renewal/progress report documents, your signature confirms that you will act as the liaison between the IRB and the student investigator, including responding to the IRB's request to complete the required progress report form.

Your signature further assures that you agree to oversee the conduct of this research and compliance with all of the policies stated above.