

Guidelines for Completing a New Study Application Park University Institutional Review Board

(Please DO NOT Include the Instructions Pages with Your Submission)

All research activities involving the use of human subjects must be reviewed and approved by a PARK UNIVERSITY Institutional Review Board (IRB). Investigators may not solicit subject participation or begin data collection until they have received approval from the appropriate Institutional Review Board.

1. Please read through the entire application before beginning.
2. Make sure that you are completing the most updated version of this form.
3. Complete all sections of the form.
4. Handwritten forms will not be accepted. All submissions must be legible and suitable for photocopying. Do not staple documents; use paper clips instead. Electronic submissions are preferred.
5. Double click on check boxes to check them.
6. Fill out and attach the appropriate appendices required by responses in the application.
7. Attach and label all supporting documentation: consent form(s), survey instruments, interview questions, solicitation letters, flyers, advertisements, etc.
8. Fill in the Version Date on the header on each page. This date should be updated each time a new version of the application is submitted to the IRB.

CHECKLIST FOR SUBMISSION

- The original signed IRB APPLICATION form.
- Telephone scripts, e-mails, letters, verbal statements, or advertisements used to recruit participants.
- Informed Consent document(s) including parental/guardian permission and assent documents. The informed consent form must be written in the second person using lay language and include the “Basic Elements of Informed Consent” as well as required text in the “In Case Of Injury” portion of the consent form. (*see Consent Form Template for the required text*). A one-inch or larger margin on all sides of each page must be used in order for the IRB to stamp each page of the document with approval and expiration dates. (*see guidelines on informed consent for more information on this topic*).
- Questionnaires, surveys, interview questions or testing instruments (if any) to be used in this project as well as source of permission for their use.

- Written letters of approval from each performance site including cooperating schools, hospitals, organizations, clubs, or similar type of groups. Letters must be on letterhead and from an individual authorized to approve such activities.
- Debriefing materials if the study includes deception.
- For funded or potentially funded projects include one complete copy of the approved scope of work and contractual obligations, if any. Clearly highlight any pages referencing human participants.
- All research staff involved in research activities are responsible for completing the required training as explained under question “I. Investigator Training” on the Application Form.
- A Curriculum Vita, Resume and or Biosketch for the PI and Faculty Advisor, if the PI is a student, must be on file with the IRB office.
- Financial Disclosure Statement if question “J. Financial Disclosure” was answered affirmatively in the Application Form.
- HIPAA Policies and Procedures that you are following from any Covered Entity from which you are collecting Protected Health Information.

ADDITIONAL INSTRUCTIONS/INFORMATION

Protocol Number: A protocol number will be assigned by the IRB as soon as your application is logged into the system. Please be sure to use that number on all communications with the IRB about your protocol.

Principal Investigator (PI): If more than one investigator is involved in the project, list as the PI, the investigator who will be the primary point of contact between the IRB and the research team.

Principal Investigator E-mail: E-mail is the primary means of communication with the PI. Be sure to check your university e-mail account regularly after submitting an application. After your application has been logged into the IRB database you will get a notice telling you that the application has been received and giving you a protocol number. If you do not receive such an email shortly after submitting your protocol please check with the IRB office.

Mailing Address: If the PI does not have a campus mailing address, provide a US mail address. Notification of IRB approval will be sent via campus or US mail to the PI ONLY, unless you are a student and then your faculty advisor will be copied.

Student Researchers: Students conducting required research such as thesis and dissertation must provide written documentation from their faculty advisor or supervisory committee indicating that the research has been approved. In addition, the student's faculty advisor must sign the Statement of Assurance page on the IRB application. Students conducting other research projects such as class or independent research projects must also have a faculty member/advisor sign the Statement of Assurance in the IRB application.

SUBMIT ONE COPY OF A COMPLETE APPLICATION PACKET TO THE ADDRESS BELOW

Dennis D. Kerkman, Chairperson
Institutional Review Board
Park University
8700 N. W. River Park Dr.
Parkville, MO 64152
816-584-6502
816-741-4911 Fax
dennis.kerkman@park.edu

You can email a copy of the application and attachments as long as you comply with Park University's electronic signature policy.