Consider this report: ☐ Final Report ☐ Request for Amendment ☐ Request for Continuing Review (Check all that apply)

Faculty Supervisor (s) (If PI is Student): (Name, campus address, phone #, email & fax)

Date Study Began: If Completed, Date:
2. Current Status of the Research: (check only one of a-f below):
   a. □ Still in Proposal Stage (no research participants enrolled, no research initiated)
   b. □ On-going

   Are research participants still being enrolled in the study? □ Yes □ No
   Have all enrolled research participants completed study participation? □ Yes □ No
   No
   Is the research active only for long-term follow-up of enrolled participants? □ Yes □ No
   No
   c. □ Data analysis only

   Please Note if you do not plan to collect additional data and the data that you are
   analyzing has no links to identifiable information (identifiable information includes
   videotapes, photographs, code lists, etc.) you may submit this form as a Final Report.
   □ Data has link to identifiers □ Data has no link to identifiers

   d. □ Completed Date of Completion:
   e. □ Withdrawn Date of Withdrawal:
   f. □ Other (explain)

3. If you are requesting a continuing review describe the research activities of the
   preceding year.

4. If you are requesting a continuing review explain why you are requesting time to
   complete this research project.

5. Has the study been modified from the original protocol? □ Yes □ No (If Yes, list in
detail all the changes/amendments approved since the initial protocol was submitted.)
6. Has approval for this study expired  □ Yes  □ No  (If Yes, answer the questions below.)

   a. Why did approval lapse?

   b. What will you do differently in the future to prevent this from happening again?

   c. Were any additional research participants enrolled or data collected after the expiration date?  □ Yes  □ No  (If Yes, describe all activities that continued including number or participants involved and any adverse event or incidents that occurred after expiration of approval.)

   NOTE: If renewal of the study does not occur before the expiration date of study approval ALL enrollment of participants and DATA COLLECTION must stop at the expiration date. Procedures and treatment needed for the safety of participants should continue but data collected during this time period CANNOT be used for research purposes.

7. Amendments

Are you requesting a further modification with this submission? ( ) Yes ( ) No (If yes describe the changes/amendments you wish to make. If applicable, provide a copy of all updated research procedures and any revised document such as application, surveys, questionnaires, consent and assent forms, etc. In addition to submitting the revised version include a copy showing changes by underlining and bolding the additional text and striking out deletions.)

Describe the effects of the requested amendment on risks, benefits and consent procedures.

8. Is the Principal Investigator/Project Director (and Co-Principal Investigator or Project Director, if Applicable) same as the Original PI/Project Director? ( ) Yes ( ) No  If No, List the changes:

9. Participant Information

Number of participants entered into the project:

   since last progress report
   since initial approval
9. cont.

Number of participants who have completed participation:
   since last progress report
   since initial approval

Number of solicited individuals who declined to participate in this project:
   since last progress report
   since initial approval

Number of participants who withdrew from the project (provide reason, if known):
   since last progress report
   since initial approval

10. Adverse Events

Were there any adverse events or unanticipated problems involving research participants?
   Yes ( ) No ( ) If yes, Explain:

Were there any complaints from participants about any aspect of the research?
   Yes ( ) No ( ) If yes, Explain:

11. Is this a funded study? Yes ( ) No ( ) If yes, Please provide the following:
   a. Type of funding:
      □ Contract/Grant
      □ Subcontract
      □ Gift
      □ Student Project
      □ Other
11 cont.

b. **Source of funding**
   - Federal Government
   - Other Gov. (i.e., State, local)
   - Foundation
   - Other Private
   - Campus program
   - Other

c. **Name of Funding Agency:**

d. **Period of Funding:**

e. **Have there been any changes to the funding for this study since the last approval?**
   - Yes
   - No

   If yes, please identify new funding and any that has been terminated. Note: you must attach a copy of the new scope of work and contractual obligations if any.

12. **Provide a brief summary of the results:** (use additional pages if necessary).

13. **Informed Consent:**

   a. **Does this study use a consent form?**
      - Yes
      - No

      (If Yes, attach a copy of the “stamped” IRB approved consent form used during the previous year as well as a clean copy if there are no modifications. If there are modifications follow the instructions under # 7 “Amendments”.)

   b. **Is this study closed to recruitment and therefore does not require a newly stamped consent form?**
      - Yes
      - No

      (If No, provide a copy of the consent document you plan to use during the extension if you plan to recruit participants, collect human subject data and/or will have access to identifiable information during the renewal period.)

14. **Other Enclosures:**

   - If study was reviewed by another Institutional Review Board submit an updated approval letter.
15. **Authorized Personnel:** Please update the list of authorized personnel on this project; deleting those who have left and adding the names of new persons working on the project.

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<tr>
<th>NAME</th>
<th>Research Role (PI, Co-PI, Student Investigator, Faculty Advisor, Collaborator, Data Manager, Research Assistant, etc.)</th>
<th>Dept/Affiliation</th>
<th>Completion Date Of Required Protection of Human Subjects Training</th>
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16. **Does any member of the research team have a financial interest in the research or its products or in the study sponsor?** ( ) Yes ( ) No. *If yes, is there a financial interest disclosure form on file with the IRB? If not and the investigators’ potential gain exceeds $10,000 a financial disclosure statement is required.*
17. Investigator’s Assurance:

The information given in response to the questions above is complete and accurate. I assure the Park University Institutional Review Board that this human subjects research has been conducted in accordance with the previously approved protocol and conditions. I certify that I and all key research personnel have completed the required initial and/or continuing protection of human subjects training program.

__________________________
Signature of Principal Investigator     Date

18. Faculty Advisor’s Assurance:

My signature assures that I agree to continue overseeing the conduct of this research and I will require the student investigator to report any changes in the project, adverse events, or incidents to the SSIRB, which may affect the conduct of this research.

__________________________
Signature of Faculty Advisor  (if PI is a student)     Date

Send form and relevant materials to:

Dennis D. Kerkman, IRB Chairperson  
Park University  
8700 NW River Park Drive  
Parkville, MO 64151  
(816) 584-6502  
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 procedures.