AMENDMENT TO APPROVED STUDY

Purdue University - Institutional Review Board

v 20160525

INSTRUCTIONS

1. Use this form to request changes to an approved study.
2. Do not use this form to respond to IRB requests for Revisions.
3. Changes may not be implemented until the investigator receives final written IRB approval.

STUDY INFORMATION

Principal Investigator contact information:

Name	Email

Study Information:

IRB Study Number	Study Title

Indicate the type of change/addition and attach all applicable documents in COEUS:

- ☐ Adding Study Personnel
- ☐ Removing Study Personnel
- ☐ Recruitment Procedures
- ☐ Recruitment Materials
- ☐ Study Population
- ☐ Increasing Number of Subjects
- ☐ Study Procedures
- ☐ Study Instruments/Measures
- ☐ Funding
- ☐ Other – Please describe

1. **Briefly summarize the personnel change(s).** Who will be added to the study, and who will be removed from the study. For each individual added to the study, complete a Personnel Amendment Table and upload it as an attachment. Also add personnel in COEUS under Investigator/Study Personnel tab, and Access Permissions if the personnel need protocol viewing or aggregator status. If there are no personnel changes, write NA.

Briefly summarize the non-personnel change(s). For changes to study population, number of subjects, recruitment procedures or study procedures, please submit a copy of the revised study description (aka application narrative) updated to include the changes and using track changes or highlighting to indicate the changes. Do not cut and paste from the original protocol.

2. **Describe the rationale for the change(s).**

3. **How many subjects have been enrolled to date in this study?**

4. **In your opinion as principal investigator, how will these changes affect the overall risk or benefit to participants in the study?**

5. **Do the changes to the study prompt changes to any study materials?**

☐ NO
☐ YES, **attach copies of all the new materials or relevant revised materials** updated to include the changes and using track changes or highlighting to indicate the changes.

Check attachment type below:

☐ Study Description (aka application narrative)
☐ Recruitment Materials
☐ Study Instruments/Measures
☐ Consent/Assent Documents – submit both a tracked version and one without for approval stamping.
☐ Other – Describe:

PRINCIPAL INVESTIGATOR'S ASSURANCE

By submitting this Request, I give my assurance that the information supplied in this form and attachments are complete and correct. I have read the **Researcher Responsibilities** and will conduct this research in accordance with these requirements. I will close this study with the IRB as soon as the study is complete. If I leave Purdue before the three-year record keeping requirement has passed, my regulatory file for this study will be left with a records custodian whose identity will be made known to the IRB.

Submit this form and attachments to the Human Research Protection Program office electronically via CoeusLite.