Amendment Modification of an Approved Protocol

This form may only be used if changes to the protocol are minimal and do not change the level of risk to participants. Major changes which would require a new application include (but are not limited to):

- Inclusion of a vulnerable population which had not previously been included
- Major change in methodology/design
- Change in procedure that increases the risk to participant
- Change in the direction of the study that will substantially change the purpose or goals of the study

For additional information and clarification about protocol revisions refer to the Investigator Handbook, Chapter 6

Principal Investigator: ___________________________ IRB Protocol #: ___________________________
Certification expiration date: ___________________________ (Click here to check expiration date)
Study title: ___________________________
Original Approval Date: ___________________________ Approval Type (see IRB approval letter):
Previous Amendment Approval Dates:

1. Revision Description: (check all that apply)
   - Revision to currently approved protocol (e.g., investigators, students, population, instruments, procedures)
   - Revision to currently approved consent
   - Other, e.g. advertisement, flyer/brochure

2. Risk (check one):
   - This revision does not increase risks to participants enrolled in the study
   - This revision does increase risks to participants enrolled in the study.

3. Provide a brief description and justification for the revision(s) and include information on any changes in risk to participants.

4. Attach revised copies of any documents affected by the change(s) (e.g., application, methods section of proposal, informed consent, instruments, etc.). Begin with current documents and identify changes using Track Changes or by highlighting revisions. Use all CAPS for revisions to the application form.

   List the revised documents submitted with this amendment:

Signature of PI: ___________________________ Date: ___________________________
(email accepted as PI signature)

For IRB Office Only: Date of IRB Review:
- Data base changes. Explain:
- Approved: This signifies notification of IRB Approval of the revision described above.
- Minor change
- Not Approved
- This amendment represents substantial change – new application required