Request for an Amendment to a Previously Approved Study

Study Title: 

Principal Investigator: 

IRB Protocol Number: 

1) What type of amendment are you requesting? [Select one and see notes at end of this form.]
   - Addition/removal of study team member (co-investigator, coordinator, assistant, student)
   - Change of study principal investigator
   - Change to study protocol
   - Change to informed consent form or equivalent

2) In the space provided, please describe in detail the changes that you are requesting.

Name of PI: ___________________________ Signature: ___________________________ Date: __________

NOTES:
1 Submit a copy of the IRB application reflecting the changes to the study personnel in the appropriate sections. This type of amendment also requires the submission of a valid CITI training and a Financial Conflict of Interest Form for any new study personnel.
2 Submit a copy of the IRB application reflecting the changes to the study protocol in the appropriate sections. If the study protocol includes collection of new outcome measures, review your prior application “Use of Protected Health Information and HIPAA Requirements” to ensure that the requested changes comply with your original approval submission. If this is no longer the case, update this section of the IRB application and include a HIPAA Authorization form, if necessary.
3 Submit a copy of the new informed consent form or equivalent, parental permission with child assent, or IRB application reflecting the changes to the study protocol in the appropriate sections.