**Modification/Amendment/Continuation to Approved Research Activities**

**Involving Human Subjects**

**Date:**

**Protocol IRB #:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI Address:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PI telephone and email:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Faculty advisor name and email if applicable**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Approved Protocol:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name and Date of Human Subjects Protection Certification for each investigator:**

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**Indicate request by circling the correct statement below:**

1. **Update personnel only**
2. **Request for Continuation, no modifications involved**
3. **Request for Modification/amendment to previously approved protocol**

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1. ***If this is a request to update personnel only, then list any new personnel here and attach certification in human subjects protection training to this form***
2. ***If this is a request for continuation only, no modifications to the study documents and/or procedures, then provide the following information***
   1. ***Current status of study: \_\_study not begun \_\_enrolling subjects \_\_\_enrollment has ended***
   2. ***Number of subjects currently involved in study:***
   3. ***Total number of subjects expected:***
   4. ***Expected end date for subject enrollment:***
   5. ***Report any study related incidents here:***
3. ***If this is a request for amendments/modifications, then provide the following:***
   1. ***Reason(s) for the proposed change(s)***
   2. ***Current status of study: \_\_study not begun \_\_enrolling subjects \_\_\_enrollment has ended***
   3. ***Number of subjects currently involved in study:***
   4. ***Total number of subjects expected:***
   5. ***Expected end date for subject enrollment:***
   6. ***Report any study related incidents here:***
   7. ***Describe any impact of the proposed change(s) on the risk to subjects***
   8. ***If your proposed change(s) requires a change(s) in recruitment, describe here***
   9. ***If your change(s) requires modifications to the solicitation script, include copy of revised solicitation script***
   10. ***If your change(s) requires modifications to the informed consent, include revised informed consent***
   11. ***If your change(s) requires the use of additional measures (or changes to existing measures, include the new measures or revisions.***

Please check all that apply:

\_\_\_\_ I have attached an Informed Consent/Parental Permission Form(s), Assent Script, Project Summary or Measures that will be used in addition to the current one(s).

\_\_\_\_ I have attached an Informed Consent/Parental Permission Form(s), Assent Script, and Project Summary or Measures that will replace the current one(s).

\_\_\_\_ The proposed modification does not call for changes in the Informed Consent/Parental Permission Form(s), Assent Script, Project Summary or Measures.

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Signature of Principal Investigator

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E-mail Address Campus Telephone Number

Name of Faculty Sponsor, if applicable Signature of Faculty Sponsor, if applicable