

**Research Committee**

**Amendment Submission**

All questions/blanks must be completed - Incomplete submissions will be returned. Whenever possible, use lay terms. **Note:** All paperwork submitted must be on 8 ½ x 11 paper and must be **single-sided** copies.

**SP Code:**       **Date:**

**Study Title:**

**Protocol #:**

**Principal Investigator:**       **Research Coordinator:**

**Routing Location:**       **Routing Location:**

**Phone:**       **Phone:**

1. **Use this form to request prior approval of the following changes in approved and funded research: (check all that apply)**

A change that is expected to affect the overall goal, specific aims, or objectives of the protocol;

A change that substantively alters the research methodology; and

A change in Principal Investigator or Co-Investigator status (please complete & include Appendix 1).

*Changes to the design or methodology of the study which do not significantly change the scope or planned outcomes of the investigation need not receive prior approval, but must be retrospectively reported to the Committee in summary fashion (along with justification for each change) at the time of continuing review.*

**2. Briefly describe the proposed modification(s):**

1. **Please revise all aspects of the protocol to reflect the proposed modification(s), highlighting additions and visibly striking out deletions (the track change feature in Microsoft Word is suggested). Include a revision date on the protocol and attach it to this submission form.**
2. **Explain why the proposed modification(s) is necessary for the successful completion of the project:**

1. **Does the proposed modification(s) affect the statistical significance or analysis plan of the study?**

No

Yes

* 1. If “Yes,” explain the impact of the proposed change(s) and include the signature of the biostatistician involved in the project at the bottom of this form.

1. **Are there any other revised or new study documents resulting from the proposed modification(s)? (e.g., data abstraction forms, measurement tools, etc.)**

No

Yes

* 1. If “Yes,” please briefly explain the document change(s) and attach new documents and /or red-lined versions of revised documents:

1. **Are the remaining funds adequate to complete the project with the proposed revision?**

No

Yes

* 1. If “No,” please briefly explain if adequate funds have been requested, or plans for obtaining adequate funds:

1. **Will this Amendment alter the timeline?**

No

Yes

* 1. If “Yes,” please complete the timeline form in Appendix 2.

1. **Indicate the Current Local Status** (Check all that apply):

Study is open to enrollment

Permanently closed to enrollment

Intervention with subjects ongoing

Data collection ongoing

Data analysis only

Other (Explain):

1. **Is this study active with the IRB?**

No

Yes

* 1. If “Yes,” please complete the IRB Amendment/Revision/Update (ARU) Submission form to report changes to the IRB.

**SIGNATURE**

*I have reviewed the information contained within this report.*

Signature of Principal Investigator Date

Printed Name of Principal Investigator Routing Location

Signature of Biostatistician (if Question #5 applies) Date

Printed Name of Biostatistician Routing Location

Printed Name of Person Completing Submission Routing Location

Signature of MCRF Lead Unit Center Administrator or Designee Date

**Submit completed paperwork to: Office of Research Integrity & Protections - 1R4.**

# Appendix 1

**Change of Investigator**

1. **Are you requesting a change of principal investigator?**

Yes

No (If “No,” skip to question #2)

* Please describe the new principal investigator’s qualifications to conduct this research:

* If the investigator is external, please provide a CV.

1. **Are you requesting the addition of a co-investigator?**

Yes

No

* Please describe the new co-investigator’s qualifications to conduct this research:

* If the investigator is external, please provide a CV.

1. **Are you requesting the removal of a co-investigator currently approved for this study?**

No

Yes (If ‘**Yes**,’ please list their name(s):

Today’s date:

**Appendix 2**

**Research Committee Project Timeline**

Please list and date all project activities (ie, completed activities and planned activities.)

**Example:**

1st Project Activity: Enrollment Actual Start Date of 1st Activity: 10-5-11 Est Overall Completion Date: 10-5-13

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Activities:*** | *Mo/Yr:*  ***10/11*** | *Mo/Yr:*  ***11/11*** | *Mo/Yr:* ***12/11*** | *Mo/Yr:* ***01/12*** | *Mo/Yr:* ***02/12*** | *Mo/Yr:* ***03/12*** | *Mo/Yr:*  ***04/12*** | *Mo/Yr:*  ***05/12*** | *Mo/Yr:*  ***06/12*** | *Mo/Yr:*  ***07/12*** | *Mo/Yr:*  ***08/12*** | *Mo/Yr:*  ***09/12*** |
| Enrollment | X | X | X |  |  |  |  |  |  |  |  |  |
| Data Collection |  |  |  | X | X | X |  |  |  |  |  |  |
| Data Analysis |  |  |  |  |  |  | X | X | X | X |  |  |
| Manuscript Prep |  |  |  |  |  |  |  |  |  |  | X | X |

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**1st Project Activity:**       **Actual Start Date of 1st Activity:**       **Est Overall Completion Date:**

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| ***Year 1 Activities:*** | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* |
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| ***Year 2 Activities:*** | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* |
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| ***Year 3 Activities:*** | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* | *Mo/Yr:* |
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