June 6, 2014

**IND Amendment**

**Change in Protocol**

This Submission Should Include

Cover Letter

Form 1571

Form 3674

Table of Contents

Revised Protocol

Redline Protocol

Investigator Brochure if changed or new one

Consent

Should be paginated

If adding new investigators also include information from that template also and those documents.

Note if the IND is already in effect (ie it has either received approval or has waited the 30 days) amendment to protocol submissions do not require a waiting period. You can submit to both IRB and FDA at the same time. If you are waiting for an FDA opinion regarding the protocol then you should wait 30 days before asking about the review and not start the study until these questions are answered and FDA agrees with starting.

Submit to CRCO via REDCap Survey



*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

XXXXX

Richmond, VA 23298

*Check your letter from the FDA regarding address and contact.*

*Address for Drug Products regulated by CDER (incorporate if applicable):*

*Food and Drug Administration*

*Center for Drug Evaluation and Research*

*Specify applicable CDER review division*

*Central Document Room*

*5901-B Ammendale Road*

*Beltsville, MD 20705-1266*

*Address for Biological Products regulated by CDER (incorporate if applicable):*

*Food and Drug Administration*

*Center for Drug Evaluation and Research*

*Specify applicable CDER review division*

*Therapeutic Biological Products Document Room*

*5901-B Ammendale Road*

*Beltsville, MD 20705-1266*

*Address for Biological Products regulated by CBER (incorporate if applicable):*

*Food and Drug Administration*

*Center for Biologics Evaluation and Research*

*Document Control Center*

*10903 New Hampshire Avenue*

*Building 71, Room G112*

*Silver Spring, MD 20993-0002*

Date:

Re: **IND Protocol Amendment: Change in Protocol**

**IND #** *Specify IND number*

To Whom It May Concern:

Per 21 CFR § 312.30 (b), enclosed please find a protocol amendment for study (enter protocol number and name). Enclosed is a red-lined version of the amended protocol showing all changes from the (original, previous amended) protocol.

*If appropriate Include a summary of any agency communications that led to the change in protocol.*

**Description of Changes in Previously Submitted Protocol**

*Phase 1 protocol: provide a brief description of any changes in a previously submitted phase 1 protocol that significantly affects the safety of subjects*

*Phase 2 or 3 protocol: provide a brief description of any changes in a previously submitted phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study*

*Provide a reference (date and number) to the previous submission that contained the protocol that is being revised*

*Provide a reference, if necessary, to specific technical information in the IND or in a concurrently submitted Information Amendment to the IND that the investigator-sponsor relies on to support any clinically significant change(s) to the previously submitted protocol. If the reference is made to supporting information already in the IND, the investigator-sponsor shall identify by name, reference number, volume, and page number the location of the information*

**Request for Comments** *(Include this section, as applicable)*

*If desired, state your request for the FDA’s comments on the new protocol submission, including any specific questions you would like the FDA to address.*

Please let me know if you have questions or concerns about the enclosed submission. I can be reached at (insert contact information)

Sincerely,

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Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor