**IND Protocol Amendment**

Protocol Number

*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

University of California, Los Angeles

Address Here

*Address for Drug Products regulated by CDER:*

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:*

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:*

Food and Drug Administration

Center for Biologics Evaluation and Research

*Specify applicable CBER review division*

HFM-99, Room 200N

1401 Rockville Pike

Rockville, MD 20852-1448

Date:

Re: **IND Protocol Amendment:** *Specify type of amendment (i.e.* ***N*ew Protocol**; **Change in Protocol**; or **New Investigator**)

**IND #** *Specify IND number*

To Whom It May Concern:

Enclosed please find three copies (the original and 2 photocopies) of a completed FDA [Form 1571](http://www.fda.gov/opacom/morechoices/fdaforms/default.html) and my Protocol Amendment for IND Number \_\_\_\_\_\_\_\_\_\_\_.

Thank you for incorporating this Protocol Amendment into the respective IND file.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor

**IND Protocol Amendment: New Protocol**

**IND Number:** *Specify IND Number*

**Date:** *Specify date of submission*

**Significant Differences Between New and Previously Submitted Protocol(s)**

*Provide a brief description of the most clinically significant differences between the new protocol (which must be provided to the FDA as part of this submission) and previously submitted protocols*

*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) in the new 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.*

**IND Protocol Amendment: Change in Protocol**

**IND Number:** *Specify IND Number*

**Date:** *Specify date of submission*

**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 changes to the previously submitted protocol, including any specific questions you would like the FDA to address.*

**IND Protocol Amendment: New Investigator(s)**

**IND Number:** *Specify IND Number*

**Date:** *Specify date of submission*

**Investigator(s) Name(s) and Address(es)**

*Provide the name(s) and address(es) of new investigators added to carry out a previously submitted protocol, including the name of each sub-investigator (for example, research fellow, resident) working under the supervision of the new investigator(s)*

*Provide a reference (date and number) to the previous submission that contained the protocol for which new investigators have been added*

**Investigator’s Qualifications**

*Provide a statement describing the investigator’s qualifications to conduct work under the protocol*

**Name and Address of Research Facilities**

*Provide the name and address of the respective research facilities being used by the new investigator(s)*

**Name and Address of Institutional Review Board**

*Provide the name and address of the Institutional Review Board that is responsible for reviewing the protocol to be conducted at the new investigator’s site*