

**IND Amendment: New Investigator**

**FDA Regulations:**

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER D - DRUGS FOR HUMAN USE

PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION

Subpart B - Investigational New Drug Application (IND)

**Sec. 312.30 Protocol amendments.**

Once an IND is in effect, a sponsor shall amend it as needed to ensure that the clinical investigations are conducted according to protocols included in the application…

…

**(c) New investigator.** A sponsor shall submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol, except that a protocol amendment is not required when a licensed practitioner is added in the case of a treatment protocol under § 312.315 or § 312.320. Once the investigator is added to the study, the investigational drug may be shipped to the investigator and the investigator may begin participating in the study. The sponsor shall notify FDA of the new investigator within 30 days of the investigator being added.

**(d) Content and format.** A protocol amendment is required to be prominently identified as such (i.e. , "Protocol Amendment: New Protocol", "Protocol Amendment: Change in Protocol", or "Protocol Amendment: New Investigator"), and to contain the following:

(1) …(iii) In the case of a new investigator, the investigator's name, the qualifications to conduct the investigation, reference to the previously submitted protocol, and all additional information about the investigator's study as is required under § 312.23(a)(6)(iii)(b).

**Documents to accompany New Investigator IND Amendment:**

* Form FDA 1571
* Form FDA 3674
* Cover Letter
* Table of Contents
* Table of Investigators (**mark new in bold**) -- Example below
* Form(s) 1572 and CV(s) for new investigator(s)

**NOTE:**

* New Investigators must be submitted within 30 days.
* *Be sure fill in the blanks where noted in italics and delete any unused template information.*
* Submit paper documents in triplicate (the original and 2 photocopies with an electronic courtesy copy) by mail or submit electronically through the to the FDA CDER NextGen Portal.
* Submit all documents via the VCU FDA submission portal at **go.vcu.edu/submit/indide**.

**Revision History**

Version1: June 6, 2014

Version2: October 9, 2017

Version3: February 9, 2021



*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

XXXXX

Richmond, VA 23298

*Check your letter from the FDA regarding address and contact. Remove the addresses for the other FDA division*

*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

*Date:*

Re: **IND Protocol Amendment: New Investigator**

 **IND #** *Specify IND number*

To Whom It May Concern:

Per 21 CFR § 312.30 (c), enclosed please find new investigator information for *[insert protocol name(s) and IND number*].

**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*

**Table of Investigators *[EXAMPLE]***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Investigator Name** | **Site Name** | **Submission Date** | **Submission Number** | **Comments** |
| Elizabeth Ripley | VCU | 6/5/14 | 001 |  |
| John Clinical | VCU | 6/5/14 | 001 |  |
| **Sally Trial** | **VCU** | **7/5/14** | **004** | **New Sub Investigator** |
| **Beth Study** | **VCU** | **8/14/14** | **004** | **Change in Address** |
|  |  |  |  |  |

**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*

Thank you for incorporating this Protocol Amendment into the respective IND file. Please let me know if you have questions or concerns about the enclosed submission. I can be reached at *(insert contact information)*

Sincerely,

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

Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor

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

Phone # of Investigator-Sponsor Fax # of Investigator-Sponsor