**Inactive Status Request**

***Information Regarding Inactive Status***

IND sponsors are required to submit a brief progress report to FDA annually (within 60 days of the anniversary date that the IND went into effect).

If no subjects are entered into clinical studies for a period of 2 years or more under an IND, or if all investigations under an IND remain on clinical hold for one year or more, the IND may be placed on inactive status.

Note: INDs placed on Inactive Status **are not** permitted to be cross-referenced. Studies in Data Analysis **should not** be placed on Inactive Status.

If an IND is placed on inactive status, all investigators shall be so notified, and all stocks of the drug shall be returned or otherwise disposed.

*A sponsor is not required to submit annual reports to an IND on inactive status.*

A sponsor who intends to resume clinical investigation under an IND placed on inactive status shall submit a protocol amendment containing the proposed general investigational plan for the coming year and appropriate protocols. If the protocol amendment relies on information previously submitted, the plan shall reference such information. Clinical investigations under an IND on inactive status may only resume 30 days after FDA receives the protocol amendment, unless FDA notifies the sponsor that the investigations described in the amendment are subject to a clinical hold; or on earlier notification by FDA that the investigation may proceed.

An IND that remains on inactive status for five years or more may be terminated by FDA.

\*\*\*Please note that IIS team must be notified when a sponsor plans to place an IND on Inactive Status, so that appropriate paperwork is filed with FDA. \*\*\*

**To submit a request for inactive status, please include the following items listed below as a single PDF file to** **IIS@pitt.edu** **and we will submit via the FDA Electronic Submissions Gateway.**

1. An updated and signed Form FDA 1571; Field 11, Check “Other” and type Inactive Request
2. A cover letter requesting the IND to be placed on Inactive Status
3. A brief summary of the status of the study

*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

University of Pittsburgh

Hieber Building, Suite 303

3500 Fifth Avenue

Pittsburgh, PA 15213

Date:

Food and Drug Administration

(Specify applicable mailing address)

*Please refer to your letter from the FDA acknowledging the receipt of your IND application to identify the specific FDA contact person, and mailing address, to whom the Request for Inactive Status should be sent.*

**Re: Request for Inactive Status - IND #** *Specify IND number*

Dear: (*Specify FDA contact person*)

Enclosed please find a request to place IND *XX, XXX*, on Inactive Status. As of *[date]*, *[include a brief summary of the status of the study].* There are no plans to recruit or conduct clinical studies with the investigational drug during the upcoming year.

Thank you for incorporating this request for Inactive Status into the respective IND file.

Sincerely,

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Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor

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