Month xx, yyyy

U.S. Food and Drug Administration

Center for Devices and Radiological Health (CDRH)

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD. 20705-1266

*OR (choose one and delete the other)*

U. S. Food and Drug Administration

Center for Biologics Evaluation and Research (CBER)

Document Control Center

10903 New Hampshire Ave.

WO71, G112

Silver Spring, MD 20993-0002

CBERDCC\_eMailSub@fda.hhs.gov

**Subject: IDE Gxxxxx, Report R0xx – Current Investigator List**

To Whom it may Concern

In accordance with 21 CFR 812.150(b)(4), I am hereby submitting a report for the Current Investigator List for this IDE.

IDE and Sponsor Information

* IDE Number:
* Device name and indication(s) for use:
* Sponsor's name:

Children’s Hospital of Philadelphia

3401 Civic Center Blvd

Philadelphia, PA 19104

* Sponsor’s phone number:
* Sponsor’s fax number:
* Sponsor's email address:
* Additional authorized contact person:
* Additional contact email:

*Select the appropriate statement related to investigators and sites from below*

This is a single site, Sponsor-Investigator IDE being conducted only at Children’s Hospital of Philadelphia.

*OR*

The following is a listing of the study sites and corresponding investigators for this IND

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Address** | **Investigator** | **Email****(Phone)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Thank you for incorporating this information into this IDE file. If you have any questions, you may reach me at XXname@chop.eduXX or XXphoneXX.

Sincerely,

xxNAMExx

Sponsor-Investigator

Children’s Hospital of Philadelphia

Copy to: IND/IDE Support Program