INVESTIGATIONAL DEVICE EXEMPTION APPLICATION

Original IDE Submission

IDE Title (if title being used)

Sponsor-Investigator

Name of Sponsor Investigator, MD

X Professor, Department

Children’s Hospital of Philadelphia

Date of Submission

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*Created without page numbers to allow for integration of documents into this template for final IDE Assembly. Update before finalization of this document and terminal save prior to pdf conversion.*

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# Name and the address of the Sponsor-Investigator

*Sponsor-Investigator Name*, MD

The Children’s Hospital of Philadelphia

3401 Civic Center Blvd.

Philadelphia, PA, 19104

Telephone:

Fax

Email:

**Additional Authorized Contact**

*Additional Contact,* MD

The Children’s Hospital of Philadelphia

3401 Civic Center Blvd.

Philadelphia, PA, 19104

Telephone:

Email:

# Report of Prior Investigations

*In this section, sponsor should provide a complete report of prior investigations of the device.* ***Maintain all of the headings*** *in this document and if not applicable to your IDE, simply state this. Use of the headings ensures you fulfill all of the requirements and is easier for the reviewers to follow. The contents of the Report of Prior Investigations is described in detail in 21 CFR 812.27.*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27)

## General

*The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation. Consider starting with a tabular representation of these studies to provide a quick overview of the detailed content to follow.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Name  (Status) | Author  (Year) | Indication | # of Subjects  # of Animals | Design  Animal Model | Key Subject Criteria | Key Outcomes  AEs and SAEs |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |

## Specific Content

*a) A bibliography of all publications, whether adverse of supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.*

*b) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of safety or effectiveness of the device*.

*c) If information on nonclinical laboratory studies is provided a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice (GLP) regulation in 21 CRF part 58. If the study was not conducted in compliance with such regulations, a brief statement of the reason for the non compliance.*

### Laboratory Study Details

### Prior Preclinical Study Details

### Prior Clinical Study Details

### Justification and Evidence on Safety of Device and Study

### Rationale for Current Clinical Study

# Investigational Plan

*At the beginning of this section, sponsor can give a brief overview of the investigational plan, logic and need for this trial, is it a single-site study, what are the end points etc.. The specific details for what to include in the Investigational Plan is described in 21 CFR 812.25*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25)

## Purpose

*The name and intended use of the device and the objectives and duration of the investigations.*

### Trial Design

### Objectives

## Description of the Device(s)

*A description of each important component, ingredient, property and principle of operation of the device and of each anticipated change in the device during the course of investigation.*

A general description of the device is included in this section. Detailed information about the device is provided in IDE Section 4.

## Protocol

*A written protocol should describe the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound. Protocol should include objectives and the hypothesis of the trial. Also describe the type of trial (i.e., controlled/open, double-blind/single/blind, etc.). Describe in detail how the trial will be conducted and analytical methods that will be used to evaluate the study. If case report forms (CFR) will be used, please attach it to the protocol. Attach a copy of the protocol document in this section.*

## Risk Analysis

*A description and analysis of all increased risks to which subject will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population including the number, age, sex, and condition.*

### Risks and How they will be Minimized/Mitigated

### Justification for the Investigation

### Patient Population

*Include the proposed number of subjects, age, gender, condition, general eligibility.*

## Monitoring Procedures

*The sponsor’s written procedures for monitoring the investigation and the name and address of any monitor. Written monitoring procedures must be provided for all studies involving more than one investigator.*

*The following language can be used for studies conducted at a single site where only one investigator, the sponsor-investigator, is involved in the study:*

*"A risk-based monitoring plan will be developed and implemented for the proposed clinical study.*

*Based on the latest FDA guidance on IDE policies and procedures (January 20, 1998), the submission of written monitoring procedures is not required for a sponsor-investigator initiated study where only one investigator will be involved in the study. The sponsor-investigator, Dr. [insert name], will serve as the study monitor for the clinical study proposed under this IDE." Include information about any Safety Monitoring Committees or DSMB or Medical Monitor and if a contract research organization will be conducting monitoring with the name(s) and address of the CRO and Monitor.*

Clinical Study Monitoring for this single site Sponsor-Investigator IDE will be conducted on a routine basis by the Children’s Hospital of Philadelphia Office of Research Compliance monitoring team. The routine monitoring procedures established by the Office of Research Compliance will be utilized and reports from the monitoring visits will be issued to the Sponsor-Investigator. See specific details in Section X.x.x of the Protocol.

## Labeling

Details related to device labeling is included in this IDE Section 4.10

## Consent Materials

Copies of draft Informed Consent Materials are included in this IDE Section 12

## IRB Information

Detailed information about the Institutional Review Board is included in this IDE Section 7

## Draft Case Report Forms (CRF)

Examples of the draft Case Report Forms are attached in this section.

### Demographics – Eligibility

### Procedures

### Device Log

### AE Log

### SAE Log

### Deviation Log

### UADE Form

# Manufacturing Information

*If you are using a marketed device, then it is appropriate to refer to the product label and provide copy or a URL to the most current product label. If any modifications have been made, provide details on all changes.*

*If you have a Letter of Authorization (LoA) from another sponsor referencing their FDA submission (IND, NDA, BLA, IDE, DMF, etc), include the LoA in this section. The LoA serves the purpose to allow the FDA reviewer to review their submission on file in relation to your IDE application.*

*A description of the methods, facilities, and controls used for the manufacture, processing, storage, and, where appropriate, installation of the device, in sufficient details so that a person generally familiar with good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.*

## Manufacturer Information

|  |  |
| --- | --- |
| Device | Manufacturer’s Name and Address |
|  |  |
|  |  |

## Marketing and Regulatory Approval

*Describe the regulatory status and any marketing approval designations, PMA numbers, 510(k) approvals.*

## Device Model and Catalog Number

Table 4.4-1: Device Reference Numbers

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Manufacturer** | **FDA Approval Reference** | **Model Number** | **Catalog Number** | **Other Characteristics** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## Proposed Intended Use

## Proposed Indications for Use

## Detailed Device Designs, Manufacturing and Descriptions

### Manufacturing Methods

### Facilities

### Controls

### Manufacturing

### Processing

### Storage

## Device Principles of Operation

## Device Design Verification and Testing

## Device Labels

*Copies of all labeling for the device. (If you are using a marketed device, then it is appropriate to refer to the most current product labeling and provide a copy or a URL link to the most current labeling here.)*

*Labeling is defined as ‘all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.”*

*An investigational device or its immediate package must bear a label with the following information:*

* *the name and place of business of the manufacturer, packer, or distributor;*
* *the quantity of contents, if appropriate; and*
* *the statement, "CAUTION ­­ Investigational device. Limited by Federal (or United States) law to investigational use."*

*The label must also describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.*

*The labeling of an investigational device must not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated.*

## Right of Reference Letters

*If a Right of Reference Letter or Letter of Authorization has been obtained from the manufacturer of the device, state that here and describe what allowances for reference that letter supports.*

## Additional Device Information

The following additional information about the devices is attached in this Section.

### Right of Reference Letter for PMA Pxxxxxx from XXmanufacturerXX

### PMA – Approval Order

### PMA – Summary of Safety and Effectiveness

### PMA – Instructions for Use (IFU)

### Right of Reference Letter for 510(k) from XXmanufacturerXX

### Instructions for Use

# Example of the Investigators Agreement

A sample template of the Investigator Agreement that includes a list of investigator’s obligations under 21 CFR 812 is provided in this Section.

*An example of the agreement to be entered into by all investigators who will participate in the investigation to comply with investigator obligations stated under part 812, and a list of the names and addresses of all investigators who have signed the agreement.*

*The Investigator’s Agreement must include:*

1. *The investigators CV;*
2. *Where applicable, a statement of the investigator's relevant experience (including the dates, location, extent and type of experience*);
3. *If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination;*
4. *The investigator’s commitment to provide sufficient and accurate financial disclosure information and update information if any relevant changes occur during the investigation and for one year following the completion of the study; and*
5. *A statement of the investigator's commitment to:*

* *Conduct the investigation in accordance with the agreement, the investigational plan, Part 812 and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB and FDA;*
* *Supervise all testing of the device involving human subjects; and*
* *Ensure that the requirements for obtaining informed consent are met.*

## List of Names and Addresses of Investigators

The following individuals have signed this agreement

* XXsponsor-investigatorXX, MD – Sponsor-Investigator

The Children’s Hospital of Philadelphia

3401 Civic Center Blvd

Philadelphia, PA 19014

Phone:

Email:

* XXco-investigatorXX, MD – Co-Investigator

The Children’s Hospital of Philadelphia

3401 Civic Center Blvd

Philadelphia, PA 19014

Phone:

Email:

# Investigator certification

*A statement that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigator will be added to the investigation until they have signed the agreement.*

*The following statement can be used to satisfy this requirement:*

As required for an IDE study, we commit to obtain a signed investigator agreement from all current investigators who are participating in the investigation. Additionally, no future investigators will be added until they have signed the agreement.

# IRB Information

This is a Sponsor-Investigator IDE which will be conducted at a single site.

*A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by such IRB.*

*The information below is accurate and up to date as of 4/13/2023*

[*https://at.chop.edu/research/irb/quick-links/irb-contact-information*](https://at.chop.edu/research/irb/quick-links/irb-contact-information)

[*https://www.research.chop.edu/irb/irb-reviews#collapse-accordion-35449-1*](https://www.research.chop.edu/irb/irb-reviews#collapse-accordion-35449-1)

IRB information for this site, The Children’s Hospital of Philadelphia, is included below.

**IRB Chair:**

Barbara Engel, MD, PhD, CIP

(Chair, CPHS)

**Phone:** 267-426-6859

**Email:** [engelbc@chop.edu](mailto:engelbc@chop.edu)

**Vice-Chair:**

Susan Levy, MD, MPH, CIP

(Vice-Chair, CHPS)

**Phone:** 267-425-1109

**Email:** [levys@chop.edu](mailto:levys@chop.edu)

**Vice-Chair:**

Kevin Meyers, MBBCh

(Vice-Chair, CHPS)

**Phone:** 267-425-5304

**Email:** [meyersk@chop.edu](mailto:meyersk@chop.edu)

**Address:**

**The Children’s Hospital of Philadelphia (CHOP)**

The Committees for the Protection of Human Subjects

2716 South St., 4th Floor

Philadelphia, PA 19146

**CHOP Federalwide Assurance**:

CHOP holds a Federalwide Assurance (FWA00000459).

CHOP's FWA became effective on February 1, 2012 and will expire January 26, 2027. The CHOP IRBs comply with the registration requirements for both OHRP and the FDA. The [CHOP FWA](https://www.research.chop.edu/sites/default/files/web/sites/default/files/irb/IRB_fwa_expiration_26january2027.pdf) (FWA00000459) is on file with the Office of Human Research Protections (OHRP).

For those that are interested or need to view the registration, CHOP's IRB registration number is IORG0000195 and its FWA# is 00000459. Both can be located on [OHRP's website](https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fohrp.cit.nih.gov%2Fsearch%2Fsearch.aspx%3Fstyp%3Dbsc&data=05%7C01%7Cwentworthm%40chop.edu%7C799a763e8c0148f574ae08db3b80a193%7Ca611241607b041a59bb1d146b575c975%7C0%7C0%7C638169196130600049%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YFTxi1QgqVF%2Bs1WqxQ%2BxQrLesmUv5j7q0TdIO3yyxkA%3D&reserved=0).

* CHOP’s Human Research Protections Program has received full Accreditation from the Association for the Accreditation of Human Research Protections Programs (AAHRPP).

# Name and Address of the Investigational Institutions

*The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with section 7.*

The location which this single site Sponsor-Investigator IDE will be conducted at is:

The Children’s Hospital of Philadelphia

3401 Civic Center Blvd.

Philadelphia, PA 19104

United States of America

# Financial claims

*If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device. If the device will not be sold, this should be stated here.*

*If you do not plan to charge for the device, indicate so in this section.*

*If you will be charging for the device, indicate the amount to be charged and include an explanation of why the sale does not constitute commercialization of the device.*

We hold no financial claims for this device.

Although the device is currently marketed under a PMA (510(k), the device is purely investigation in the context of this IDE, so this does not constitute commercialization of the device.

We do plan (do NOT plan) to charge the subject or their insurance for the device and procedure.

# Environmental assessment

*Per the CDRH Web site,* [*https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application*](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application)*, an environmental assessment as required under 21 CFR 25.40 or a claim for categorical exclusion under 21 CFR 25.30 or 25.34 is no longer required.*

*Please maintain this header and include the following statement:*

Please note that an environmental assessment as required under 21 CFR 25.40 or a claim for categorical exclusion under 21 CFR 25.30 or 25.34 is no longer required [§25.34(g)].

# Labeling

*Copies of all labeling for the device. (If you are using a marketed device, then it is appropriate to refer to the most current product labeling and provide a copy or a URL link to the most current labeling here.)*

*Labeling is defined as ‘all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.”*

*An investigational device or its immediate package must bear a label with the following information:*

* *the name and place of business of the manufacturer, packer, or distributor;*
* *the quantity of contents, if appropriate; and*
* *the statement, "CAUTION ­­ Investigational device. Limited by Federal (or United States) law to investigational use."*

*The label must also describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.*

*The labeling of an investigational device must not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated.*

See Also Section 4.10 Device Labels

# Informed Consent

*Copies of all forms and informational materials to be provided to subjects to obtain informed consent.*

A copy of the Draft Informed Consent Form is attached in this Section.

# Additional Information

*Any other relevant information FDA requests for review of the application.*

*Information previously submitted (If a Q-Sub was submitted) include this information*

*This is a good place to list any references you are attaching to the application.*

## Previous FDA Communications/Interactions

## References

***References for this Template***

*NOTE: add Header with Sponsor-Investigator identifiers, date and Page Numbers after final combined assembly of the submission*

*Delete this section after completing the IDE Template for a Project.*

*IDE Regulations 21 CFR 812*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)

*812.20 – Application*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20)

*812.25 – Investigational Plan*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.25)

*812.27 – Report of Prior Investigation*

[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.27)

*FDA – CDRH Website for Investigational Device Exemptions*

[*https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide*](https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide)

*FDA – CDRH Website for Investigational Device Exemptions – Application*

[*https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application*](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application)

*Investigator Agreement Template (IND\_IDE-047, Version 10/26/2023)*

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*Certification of Financial Interests Template (IND\_IDE-050, Version 6/15/2023)*

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*Previous CHOP Template 2014*

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*University of Pennsylvania Template 2014*

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