



Icahn
School of
Medicine at
Mount
Sinai

Conduits
The Institutes for Translational Sciences

INVESTIGATIONAL DEVICE EXEMPTION APPLICATION

IDE **Title (if title being used)**

Name of Sponsor Investigator, MD
 Professor, Department
Icahn School of Medicine at Mount Sinai

Date of Submission

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1 NAME AND THE ADDRESS OF THE SPONSOR

2 REPORT OF PRIOR INVESTIGATIONS

In this section, sponsor should provide a complete report of prior investigations of the device.

2.1.1 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.

2.1.2 Specific Content

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that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.

b) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of safety or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 CFR part 58. If the study was not conducted in compliance with such regulations, a brief statement of the reason for the non compliance.

3 INVESTIGATIONAL PLAN

At the beginning of this section, sponsor can give a brief overview of the investigation plan, logic and need for this trial, is it a single-site study, what are the end points etc..

3.1.1 Purpose

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

3.1.2 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 details 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.

3.1.3 Risk Analysis

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

3.1.4 Description of Device

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

3.1.5 Monitoring Plan

The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.

4 MANUFACTURING INFORMATION

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.

5 EXAMPLE OF THE INVESTIGATORS AGREEMENT

An example of the agreement to be entered into by all investigators 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.

Investigators CV should be attached as a part of this section. When applicable a statement of the investigator's relevant experience (including the dates, location, extent and type of experience); If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination; and a statement of the investigator's commitment to:

1. 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;
2. supervise all testing of the device involving human subjects; and
3. ensure that the requirements for obtaining informed consent are met
4. 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.

6 INVESTIGATOR CERTIFICATION

A certification 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.

7 IRB'S INFORMATION

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.

8 NAME AND ADDRESS OF THE INVESTIGATIONAL INSTITUTIONS

The name and address of any institution at which a part of the investigation may be conducted.

9 FINANCIAL CLAIMS

State if device will be sold. If yes, please state the amount to be charged and an explanation of why sale does not constitute commercialization of the device.

10 ENVIRONMENTAL ASSESSMENT

Per Device Advice on the CDRH Web site, <http://www.fda.gov/cdrh/devadvice/ide/application.shtml>, 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.

11 LABELING

Copies of all labeling for the device.

The labeling should contain the statement "CAUTION-Investigational Device. Limited by Federal (or United States) Law to Investigational Use." [§ 812.5(a)].

12 INFORMED CONSENT

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

13 ADDITIONAL INFORMATION

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

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