**INVESTIGATIONAL DEVICE EXEMPTION APPLICATION**

**[Title of IDE (if applicable)]**

**[Name of Sponsor-Investigator]**

**[Name, Department]**

**[Phone # XXX-XXX-XXXX]**

**[Mailing Address]**

**[Institution]**

**Signature of Sponsor-Investigator**



**Date of Submission: [XX Month 20XX]**

Table of Contents

[1. NAME AND THE ADDRESS OF THE SPONSOR 3](#_Toc453839134)

[2. REPORT OF PRIOR INVESTIGATORS 4](#_Toc453839135)

[2.1. General 4](#_Toc453839136)

[2.2. Specific Content 4](#_Toc453839137)

[3. INVESTIGATIONAL PLAN 5](#_Toc453839138)

[3.1. Purpose 5](#_Toc453839139)

[3.2. Protocol 5](#_Toc453839140)

[3.3. Risk Analysis 5](#_Toc453839141)

[3.4. Description of Device 5](#_Toc453839142)

[3.5. Monitoring Plan 5](#_Toc453839143)

[3.6. Additional Records and Reports 5](#_Toc453839144)

[4. MANUFACTURING INFORMATION 6](#_Toc453839145)

[5. EXAMPLE OF THE INVESTIGATOR’S AGREEMENT 7](#_Toc453839146)

[6. INVESTIGATOR CERTIFICATION 8](#_Toc453839147)

[7. IRB’S INFORMATION 9](#_Toc453839148)

[8. NAME AND ADDRESS OF THE INVESTIGATIONAL INSTITUTIONS 10](#_Toc453839149)

[9. FINANCIAL CLAIMS 11](#_Toc453839150)

[10. ENVIRONMENTAL ASSESSMENT 12](#_Toc453839151)

[11. LABELING 13](#_Toc453839152)

[12. INFORMED CONSENT 14](#_Toc453839153)

[13. ADDITIONAL INFORMATION 15](#_Toc453839154)

# NAME AND THE ADDRESS OF THE SPONSOR

# REPORT OF PRIOR INVESTIGATORS

## General

*Reports of prior investigations must include reports of all prior clinical, animal, and laboratory testing of the device. It should be comprehensive and adequate to justify the proposed investigation.*

## Specific Content

*Include:*

* *Bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety and effectiveness of the device*
* *Copies of all published and unpublished adverse information*
* *Copies of other significant publications if requested by an IRB or FDA*
* *A summary of all other unpublished information (whether adverse or supportive) that is relevant to an evaluation of the safety and effectiveness of the device*
* *If nonclinical laboratory data are provided, a statement that such studies have been conducted in compliance with the Good Laboratory Practice (GLP) regulations in 21 CFR Part 58. If the study was not conducted in compliance with the GLP regulations, include a brief statement of the reason for noncompliance*

# INVESTIGATIONAL PLAN

*The investigational plan shall include the following items in the following order.*

## Purpose

*The name and intended use of the device as well as the objectives and duration of the investigation*

## Protocol

*Written protocol describing the methodology to be used and an analysis of the protocol demonstrating its scientific soundness*

## Risk Analysis

*A description and analysis of all increased risks to the research subjects and how these risks will be minimized; a justification for the investigation; and a description of the patient population including the number, age, sex, and condition*

## Description of Device

*A description of each important component, ingredient property, and principle of operation of the device and any anticipated changes in the device during the investigation*

## Monitoring Plan

*The sponsor’s written procedures for monitoring the investigation and the name and address of each monitor*

## Additional Records and Reports

*A description of any records or reports of the investigation other than those required in Subpart G of the IDE regulations*

# MANUFACTURING INFORMATION

*A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and installation of the device.*

# EXAMPLE OF THE INVESTIGATOR’S AGREEMENT

*An examples of the agreement to be signed by the investigators and a list of the names and addresses of all the investigators. Information that must be included in the written agreement are found in § 812.43*

# INVESTIGATOR CERTIFICATION

*Certification that all the investigators have signed the agreement, that the list of investigators includes all investigators participating in the study, and that new investigators will sign the agreement before being added to the study*

# IRB’S INFORMATION

*A list of the names, addresses, and chairperson of all IRBs that have or will be asked to review the investigation and a certification of IRB action concerning the investigation*

# NAME AND ADDRESS OF THE INVESTIGATIONAL INSTITUTIONS

*The name and address of any institution (other than those above) where a part of the investigation may be conducted*

# FINANCIAL CLAIMS

*The amount, if any, charged for the device and an explanation of why sale does not constitute commercialization*

# ENVIRONMENTAL ASSESSMENT

*Please note that an environmental assessment as required under 21 CFR 25.40 or a claim for a 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*

# INFORMED CONSENT

*Copies of all informed consent forms and all related information materials to be provided to subjects as required by 21 CFR 50, Protection of Human Subjects*

# ADDITIONAL INFORMATION

*Any other relevant information that FDA requests for review of the IDE application. Information previously submitted to FDA in accordance with Part 812 may be incorporated by reference.*

**General Help:**

*Remember to delete all instructional text (italicized).*

*After filling in your information and reformatting, the page numbers will most likely change from the original Table of Contents. To reformat, go to the references tab in word and choose “update table” so page numbers will adjust based on the correct page numbers.*

*Sections on the cover page and in the headers on each page that are inside of brackets [], will be filled in with your information with the brackets deleted.*