**FORM C – Use of Devices in Research**

**Project Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**SECTION A: Investigator Information:**

**1. Investigator experience with studies involving the use of devices, and in what capacity**

*(e.g. principal investigator, site investigator, collaborator, etc.)*

Click or tap here to enter text.

**2. Do any of the Investigators or research personnel have a financial interest in the device(s) being used in this research study?** *(e.g., royalty, patent or stock options, etc.)*

Click or tap here to enter text.

**SECTION B: Device Information**

1. **Name of the Device** *(Provide the full name, and if there is a marketed or brand name also include this information)*

Click or tap here to enter text.

1. **Type of Device (***Describe the device and its purpose for being used in the research)*

Click or tap here to enter text.

1. **Device Manufacturer Name and Contact Information**

Click or tap here to enter text.

1. **Device Sponsor** (*e.g. manufacturer, principal investigator, funding entity, etc.)*

Click or tap here to enter text.

1. **The Device Brochure is included with this application:**

Yes  No; *if no provide the reason why it is not included*: Click or tap here to enter text.

**SECTION C: FDA Status of the Device and Risk Assessment**

1. **The device being used in this study is:**

Marketed and FDA approved for this indication or use

Marketed but lacks FDA approval for this indication of use

Not marketed, not FDA approved

1. **A risk determination has been made for the device by:** *A copy of the determination must be attached*

FDA  Sponsor  Investigator  Other; describe: Click or tap here to enter text.

1. **The determination of the risk for the device is:**

**Significant Risk**

Under 21 CFR 812.3(m), a Significant Risk device means an investigational device that: Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Provide an explanation of why this is a Significant Risk Device:**

Click or tap here to enter text.

**Non-Significant Risk**

A Non-Significant Risk device study is one that does not meet the definition for an Significant Risk device study.

**Provide an explanation of this is a Non-Significant Risk Device:**

Click or tap here to enter text.

1. **List commonly reported adverse effects or problems with the Device**

Click or tap here to enter text.

**SECTION D – Use of the Device in the Research**

1. **Provide the method/route/mode of Device administration**

Click or tap here to enter text.

1. **The route of administration is consistent with the FDA approval**

N/A; no FDA approval  Yes  No; if no describe: Click or tap here to enter text.

1. **The Population in which the Device will be used:**

Adults Children Pregnant Women  Healthy persons

Persons with an illness or condition for which the device was designed or is being tested

Other: Click or tap here to enter text.

1. **Schedule and duration of device administration, including changes in frequency, or strength of the Device**

Click or tap here to enter text.

1. **Will participants be operating the device?**

**No  Yes***; if yes, describe the training that will be provided***:** Click or tap here to enter text.

1. **Describe any special instructions to use the device**

Click or tap here to enter text.

1. **Describe any certifications required to use the device**

Click or tap here to enter text.

1. **Describe any restrictions for using the device**

Click or tap here to enter text.

1. **Describe the procedures for monitoring device functionality and safety**

Click or tap here to enter text.

**SECTION E – Device Supply, Distribution and Storage**

1. **The device is available:**

By prescription only  Over the counter  Study Sponsor only

Other;Click or tap here to enter text.

1. **Location of device use:**

Click or tap here to enter text.

1. **Describe the plan for storage, security, and distribution of the device as well as accounting for its use and return:**

Click or tap here to enter text.

1. **Cost of Device to study participants**

No cost  Device will be charged to participant’s insurance company

Participant will pay for device; provide cost breakdown: Click or tap here to enter text.