**Medical College of Wisconsin & Froedtert Health CMS Investigational Device Exemption Cover Document**

**Facility (ies) Medicare Part A Contact:**

Roberta Navarro RN, BSN, Manager of

Froedtert Health Office of Clinical Research Innovative Care Compliance

9200 West Wisconsin Avenue

Milwaukee, WI 53226

Phone: 414-805-6530; Pager: 414-590-5747

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**Provider Medicare Part B Contact:**

Coordinator Name

Coordinator Title

8701 Watertown Plank Road

Milwaukee, WI 53226

Phone: 414-955-xxxx; Pager: 414-

Email of contact

**Name of Addressee (if different from contact):**

Name if applicable or remove section from request form

**Request on behalf of (may be both categories):**

[ ] Facility(ies) (Medicare Part A)

[ ] Individual practitioner(s) (Medicare Part B)

**Device IDE:**

**Project NCT Number:**

**IRB Protocol Number:**

**Study Name:**

**Device Description**

Trade name / models (device):

1.

2.

Common name of device:

1.

2.

Classifications:

1.

2.

**Site Specific Facility and Provider Details.**

Facility (ies) where service will be provided:

Froedtert Hospital

9200 West Wisconsin Ave

Milwaukee, Wisconsin 53226

Medical Provider Number: 520177

Participating Providers (includes all providers having potential to bill as part of project):

|  |  |  |
| --- | --- | --- |
| Provider (include APNP’s providing care) | Role | NPI |
|  | PI |  |
|  | Sub-I |  |
|  | Sub-I |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Project Details.**

**Number of enrollees for project:**  xxx participants are expected to sign informed consent and begin screening procedures, with xxx meeting all eligibility criteria to receive study device.

**Anticipated billing type (inpatient, outpatient, or both):**

Inpatient: IDE device will be implanted in the inpatient setting; inpatient recovery is expected for a period of xxx days.

Outpatient: Follow-up study visits occur on an outpatient basis.

**List of devices, supplies, drugs, or services for which the facility or provider will be reimbursed by the funding agent (manufacturer):**

MCW will be reimbursed by the funding agent for the following services that are part of the research only cost, additionally MCW reimburses Froedtert Hospital for research only technical components.

**Research Related Procedures, billable to funding source:** (This needs to be consistent with what is stated as being provided by the study in the informed consent as IRB approved)