MEDICAL COLLEGE OF WISCONSIN

OFFICE OF RESEARCH

Medical College of Wisconsin & Froedtert Health CMS Investigational Device Exemption (IDE) Submission Packet Instructions

The purpose of this CMS submission packet is to provide the user guidance in submitting a request for Medicare coverage of allowable routine care items, services, or medical devices. It is important to confirm relevance of the information within the templates to the IDE and accuracy of your submission. This submission addresses both facility and professional charges. It is the responsibility of the Holder of the IDE (Project PI) to complete this submission. The submission represents a collaborative effort between the research team and OCRICC.

Components of Original Submission:

A. Templates

1. Medical College of Wisconsin & Froedtert Health CMS Investigational Device Exemption Cover Document.
   - The purpose of this document is to provide CMS with a brief overview of providers, facility, the IDE device and requests for coverage.

2. CMS IDE Study Criteria Crosswalk Table.

   - The crosswalk table is a CMS recommended document providing the reviewer with the specific location of each *IDE Study Criteria* required for CMS evaluation of coverage of the qualifying costs related to the IDE study. In many instances, an individual criterion will be documented in multiple locations throughout the packet, choose those which best document the criteria.

3. Request letter describing how IDE study meets Medicare Coverage IDE Study Criteria.

   - The Request Letter summarizes how the IDE meets each Medicare Coverage IDE Study Criteria as a qualifying IDE study (for routine costs, services, and the device [Category B only]).

4. Investigator Agreement.

   - The Investigator Agreement, if not already included in the IDE submission provides documentation of study criteria element #6.

B. Documents provided by Investigator-Sponsor (PI)

5. Non-redacted copy of FDA approval letter of the IDE. The approved IDE code number and category designation must be on the letter.

6. IDE Clinical Investigation Plan (Protocol).

7. Institutional Review Board (IRB) approval letter.

8. NCT Number. Provide PDF copy of email from ClincalTrials.gov PRS indicating issue of NCT number and intention to post for public viewing.

9. Supporting Documents (additional documents as appropriate):
   - IRB **approved** informed consent
   - Executed Clinical Trial Agreement (contract)
   - Investigator Agreement
   - Copies of articles or referenced in this submission.

C. Instructions for Completion of Documents.

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

Definitions and field details for completion of the cover document.

Category A versus B IDE device

- **Category A device (experimental)**-a device where absolute risk of device is unknown, meaning the efficacy and safety issues have not been determined in the following conditions 1) the device is new, FDA is unsure whether the device is safe and effective for proposed intended or indications for use. No equivalent device has answered the questions of efficacy and safety and no De Novo request has been granted; 2) the indication or intended use of the proposed device is new for the proposed device or a similar device; or 3) the new technical characteristics compared to the legally marketed device does have changed, rendering available clinical and non-clinical data insufficient.

  CMS approval of a Category A (Experimental) IDE study will allow coverage of routine care items and services provided for the study, but not for the Category A device itself.

- **Category B device (non-experimental / investigational)**-a device where incremental risk is the element in question, meaning the efficacy and safety have been resolved for that device type from previous trials resulting in premarket approval or clearance for this type of device. The following conditions 1) no current PMA, 510(k), De Novo approval has been issued for proposed or similar device, however feasibility data from proposed or similar device has addressed initial questions of efficacy and safety for the FDA for proposed intended or indications for use; 2) this is a new indication or intended use of the proposed device, however satisfactory information exists as it is similar to previous indication or intended use for the proposed device or a similar device; 3) the new technical characteristics are similar when compared to a legally marketed device, rendering available clinical and non-clinical data sufficient.

Trade name field. Enter market name, then descriptor. Include IDE device (#1) and accessories required for device to function. These may include leads, battery packs, control units. Example-

> **Trade name/models (device):** The implantable portion of the Always Pacing System includes:
>
> 1. EVERREADY Implantable Pulse Generators (IPG)
> 2. SHINNY New Active Fixation and Passive Fixation Pace/ Sense Leads

Common name field. General description of the device and each accessory. Naming convention for primary device- General name, options or type, special feature or function. Naming convention for accessories-General name, general name of primary device accessory will support, use indication exceptions. Example-

> **Common name of the device:**
> - Pacemaker, single or dual chamber, rate-response (implantable)
> - Lead, pacemaker, other than transvenous VDD single pass

Classification-FDA device Classification (I, II, or III)- is 1.) dependent on both intended use (general purpose of the device or its function) and indications for use (describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended), and 2.) based on the level of risk posed to the individual receiving the device a/o user / handler of the device.

For purposes of this CMS submission process, the focus will be limited to Class III devices.

Class III: General Controls and Pre-market Approval required for use. Highest level of Regulatory Controls due to the nature of risk associated with use of the device. These devices most often support and sustain human life a/o can impose unreasonable risk on the research participant a/o user.

For proper FDA diagnostic device terminology access 21 CFR Chapter 1 Subchapter H Parts 862-898.

Classification Field. Provides reviewer diagnostic device terminology (proposed or similar device) and level of risk associated with use. Example-

> **Classification:**
>
> 1. "Implantable Pacemaker Pulse-Generator" (FDA Class III device)
> 2. "Permanent pacemaker electrode" (FDA Class III device)

CMS defines Routine Costs-"*of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:*

- *The investigational item or service, itself unless otherwise covered outside of the clinical trial;*

- *Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan);*
- *Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.*

Routine costs in clinical trials include:

- *Items or services that are typically provided absent a clinical trial (e.g., conventional care);*
- *Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and*
- *Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.*
- *This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare Administrative Contractor local policies."*

After July 9, 2007, "reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials". "For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care."

Routine costs language pulled directly from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1

2. CMS IDE Study Criteria Crosswalk Table

Include specific details relative to the location on each item on the Crosswalk Table down to the paragraph and sentence number in the boxes in the right column. Details may involve more than one document; all sources should provide the same level of detail.

3. Request letter describing how IDE study meets Medicare Coverage IDE Study Criteria

Help text is embedded within the body of the Sample Request Letter template.

4. Investigator Agreement

If an Investigator Agreement (equivalent to 1572 on drug side) was included in the IDE submission, include that as evidence to support federal regulation compliance. If not, consider this document for a component of CMS Study Criteria # 6.

5. Documents provided by Investigator-Sponsor (PI) (Section B) will need to be PDF versions of the items as listed.

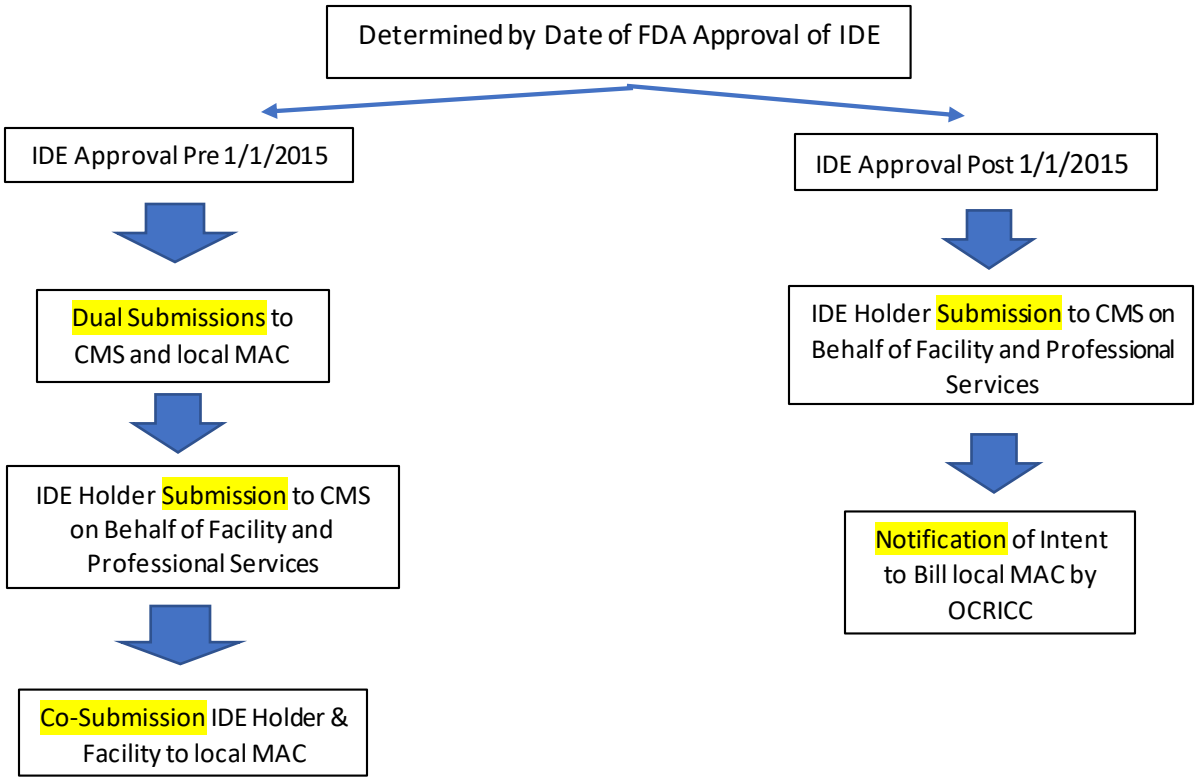
Changes Requiring CMS Re-Submission

1. Notify CMS of changes to IDE studies that require another FDA approval letter. Updated FDA approval letter and revised Clinical Investigational Plan with highlighted changes clinicalstudynotification@cms.hhs.gov.

2. When adding clinical study sites after CMS approval, the IDE Holder should update the ClinicalTrials.gov web entry

3. When study is complete inform CMS at clinicalstudynotification@cms.hhs.gov, update ClinicalTrials.gov web entry, and confirm OCRICC has notified the local MAC.

Process for Medicare Approval for Coverage of IDE Study Costs



Helpful Hints:

1. Electronic submissions are preferred.
2. Only one submission, electronic or mailed.
3. Review will be finished for each **complete** submission in approximately 30 days.
4. Disapprovals may be revised and re-submitted.
5. CMS Database should be checked to determine status, will need to know the Document ID as provided in response to your submission. https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx
6. Once your CMS approval is obtained share with facility (OCRICC).
7. Additional links of interest-

https://www.cms.gov/Medicare/Coverage/IDE
https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies

Electronic CMS Submission to
clinicalstudynotifcation@cms.hhs.gov
-OR-

Hard copy mailed to
Centers for Medicare and Medicaid Services
Center for Clinical Standards and Quality
Director, Coverage and Analysis Group
ATTN: Clinical Study Certification
Mail Stop: S3-02-01
7500 Security Blvd.
Baltimore, MD 21244