MEDICAL COLLEGE OF WISCONSIN

OFFICE OF RESEARCH

8/18/2020

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

RE: Request Letter for Medicare Coverage of a Category A or B IDE study

Dear Clinical Study Certification Reviewer,

I am the principal investigator for the "full title", an FDA approved Investigational Device Exemption (IDE) clinical study. The IDE number is xxxx. I hold this IDE. XXXXXXX is the manufacturer of the device covered under this IDE, and is [however, is not] providing support to conduct this clinical study. This is a prospective, single-site interventional study which will be conducted by Medical College of Wisconsin providers and study staff, with procedure completion and study follow-up at the following Froedtert Health facilities- Froedtert Hospital.

The purpose of this request letter is to describe the nature and scope of this study, as well how it meets each of the Medicare Coverage IDE Study Criteria.

This study will be completed with a principal purpose of determining whether utilization of the (indicate device), for the treatment of (patient population) will improve (indicate outcome attempting to change). Evidence of improved health outcomes will be substantiated through the following study Primary Objective(s). (List Primary Objective(s)).

We anticipate that Medicare beneficiaries will be included in the XXX participants enrolled for this IDE clinical study.

Rationale justifying this study includes…

As evidenced by (current poor outcomes), current medical knowledge and treatment options regarding care of this patient population has failed. This study is uniquely positioned to generate new information and assist with establishing improved treatment options. We will (what are you doing & how is it different)

Study design is……

Justification of sample size is……

Analysis of primary objectives will be completed using …….

As the sponsor-investigator of the clinical IDE study, I am a XXXXXXXX physician with expertise in XXXXXXXX. Describe experience in treatment of patient population. Additional supportive information.

Commented [MS2]: Select if this is a category A or B device.

Commented [MS3]: Insert full title, as is consistent on IDE approval & CT.gov registration document.

Commented [MS4]: Indicate IDE number

Commented [MS5]: Name of device manufacturer.

Commented [MS6]: Choose correct response regarding manufacture support.

Commented [MS7]: Correctly describe this project.

Commented [MS8]: *The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.*

Commented [MS9]: *The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.*
Study rationale. In short what clinical issue needs to be addressed and why? This section should include potential benefits as identified in Clinical Investigational plan.

Commented [MS10]: *The study results are not anticipated to unjustifiably duplicate existing knowledge.*

Commented [MS11]: *The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.*

Commented [MS12]: *The study is sponsored by an organization or individual capable of successfully completing the study.*

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I have been involved in XXXX clinical trials, including principal investigator in xxx. My research training includes XXXXX. Additional supportive information. I have the required capacity and experience to properly conduct this IDE study.

Additionally, I will provide oversight of all clinical study activities completed by the seasoned research team convened to conduct of this study. Describe the team and their expertise.

Non-clinical study activities will be managed by myself, and the research team in the (specify team specialty) office space in the (identify building). All necessary technology, resources, and physical space is available, and meets all federal, state, and local requirements governing human research study activities.

The resources and facilities of Froedtert Hospital, and clinics is well suited for the clinical procedures for this study and the care of this patient population. Describe what makes these locations suitable.

Evidence of compliance with all applicable Federal Regulations concerning the protection of human subjects includes:

1. **21 CFR part 50.** Assurance informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Subjects CRF Part 50, the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

   IRB approved consent document includes all required and appropriate additional elements. Procedures relative to these regulations include presentation of an IRB approved informed consent document to interested participants for study consideration, obtaining participant volunteered signature on the consent document once appropriate, followed by initiation of study procedures. Further details are included in the study Clinical Investigational Plan (Protocol).
2. **21 CFR part 56**. Assurance this IDE study is reviewed and approved by the MCW IRB prior to initiation of study related procedures. All documents required to complete the initial review were provided to the IRB. Annual reviews, safety reports or deviations and amendments will be submitted in accordance to all local, state, and federal regulations. Further details specific to these intentions are provided in the study Clinical Investigational Plan (Protocol). The IRB approval letter is included in the submission package.
3. **21 CFR part 812.** Assurance conduct of this IDE study will be in accordance of 21 CFR part 812, as detailed in the project Clinical Investigational Plan approved by the FDA on XXXXX. The Clinical Investigational Plan and the Investigator Agreement are offered in confirmation of this intent.
4. **45 CFR part 46.** All criteria related to IRB membership, review and approval, as well consent requirements and documentation have been met. This project does not [does] involve a federal funding mechanism. Please see the following MCW and facility FWA details,
   - The Medical College of Wisconsin (MCW) has an approved Federal Wide Assurance (FWA-FWA00000820) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). The MCW IRB Organization number is IORG0000056.
   - Froedtert Hospital (FH) of Milwaukee, WI has an approved Federal Wide Assurance (FWA-FWA00002157) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, FMLH cedes responsibility for IRB review to the six MCW IRB Committees.
   - The following MCW Institutional Review Boards (MCW IRBs) are registered with OHRP and are designated in the MCW FWA to conduct reviews of research involving human

Commented [MS13]: *The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.*

Commented [MS14]: Date of FDA Project Approval.

Commented [MS15]: Projects involving a federal funding mechanism may be subject to additional sections of part 46. Review if this is the case.

Commented [MS16]: Include data relevant to facility. Information related to MCW affiliates included in the HRPP Open Letter to Sponsors included in the submission package.

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subjects for the Medical College of Wisconsin, Froedtert Hospital, and the other institutions that cede IRB review:

- IRB00001395-Committee #1
- IRB00001396-Committee #2
- IRB00001564-Committee #3
- IRB00000078-Committee #4
- IRB00006380-Committee #5
- IRB00011716-Committee #6

This project does not represent a phase I study designed to exclusively test toxicity or disease pathophysiology in healthy individuals. This IDE study will only include enrollment of and is being explored to treat individuals with a clinical diagnosis of XXXXXX.

The study is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov. The posting number is NCTXXXXXXXXXX.

Planned method and timing of the results of the primary outcomes data is XXXXXXXXXX. This will include release of negative outcomes if any, once that data has been verified. Disclosure of this data sharing plan is found on ClinicalTrials.gov (Individual Participant Data (IPD) Sharing Statement, within the informed consent document, and in the Clinical Investigational Plan.

All participants with a clinical diagnosis of XXXXX, meeting the study eligibility criteria are suitable candidates for use of the XXXXXX device under this IDE indication. All individuals, regardless of age, receiving the XXXXXX device under this IDE indication are proposed to benefit by (decreasing what risk or scenario). Medicare beneficiaries are not specifically targeted. The age range of the clinical patient population is XX-XX, with approximately XX% of an age greater than 65 years. Estimates of XX% of patients with this clinical diagnosis are anticipated to have disability coverage.

We hypothesize that (how the study results are or are not expected to be generalizable to the Medicare beneficiary population). Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

Attached are supporting statements and information believed to fulfill Medicare's IDE Study Criteria for Medicare Coverage of a Category A or B IDE study. I welcome any additional clarifications, questions or requests to facilitate your review.

Thank you for your consideration of this request. I look forward to hearing from you.

Sincerely,

XXXXXXX XXXXX, MD
Medical College of Wisconsin
8707 Watertown Plank Road
Milwaukee, Wisconsin 53226
Email address

With office at:
Division or Department

Commented [MS17]: Input clinical diagnosis for which IDE is indicated.

Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

Commented [MS18]: *The study is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov.*

Commented [MS19]: Planned data release language needs to be consistent with the Individual Participant Data (IPD) Sharing Statement on the project CT.gov posting and what is included in the informed consent. Confirm language is included in the project Clinical Investigational Plan (protocol).
The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

Commented [MS20]: *The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.*

Commented [MS21]: IDE application should have data to support the values in this paragraph. If not include & list the articles in the submission package, as well add a reference at the bottom of this letter.

Commented [MS22]: Study team to determine response.

Commented [MS23]: This may include a statement indicating disease prevalence & need for treatment increases with age, disability, concomitant medical conditions.

Commented [MS24]: Select if this is a category A or B device.

Commented [MS25]: As per MD license & NPI documents

XXXXXXXXXX (Indicate Actual Office Address)
Milwaukee, Wisconsin 53226
XXXXXXXX XXXXX, MD NPI XXXXXXXXXX

Commented [MS26]: As per MD license & NPI documents