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. XXXXXX 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 XXXX 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 XXXX device, for the treatment of XXXX will improve XXXX. Evidence of improved health outcomes will be substantiated through the following study Primary Objective(s). XXXXXX.

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 XXXX, 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 XXXX

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. XXXXXX. XXXXXX.

I have been involved in XXXX clinical trials, including principal investigator in xxx. My research training includes XXXXX. XXXXX. 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. XXXXXX

Non-clinical study activities will be managed by myself, and the research team in the XXXXX office space in the XXXXX. 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. XXXXXX.

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).

1. **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.
2. **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.
3. **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 (FWA­FWA00000820) 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 (FWA­FWA00002157) 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 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 enroll 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 NCTXXXXXXXXX.

Planned method and timing of the results of the primary outcomes data is XXXXXXXXX. 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 XXXX. 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 XXXXX. XXXXXXX.

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

Sincerely,

XXXXXXX XXXXX, MD

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With office at:

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XXXXXXX XXXXX, MD NPI XXXXXXXXXX