Medicare Coverage Investigational Device Exemption (IDE) Study Criteria Checklist and Study Criteria Crosswalk Table

Parties interested in Medicare coverage of items and services in Category A or Category B IDE studies may wish to use this checklist and study criteria crosswalk table as they prepare their requests. Use of this checklist and crosswalk table is voluntary; however, when submitted with the request packet, it facilitates CMS' review.

☐ A. Request letter that describes the scope and nature of the IDE study, discussing how the IDE study meets each of the Medicare Coverage IDE Study Criteria.

☐ B. FDA approval letter of the IDE.

☐ C. IDE study protocol.

☐ D. Institutional Review Board (IRB) approval letter (interested parties need only submit one IRB approval letter with their request.)

☐ E. NCT number (e.g., NCT00000123)

☐ F. Supporting materials, as appropriate.

You may wish to use the following table to crosswalk the Medicare Coverage IDE Study criteria to where these criteria are located in your request materials (IDE study protocol, IRB approval letter(s), etc.).

Medicare Coverage IDE Study Criteria Element	**Criterion location – list document name, page, paragraph, and sentence(s)**
1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.	
2. 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.	
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.	
4. 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.	

Medicare Coverage IDE Study Criteria Element	Criterion location – list document name, page, paragraph, and sentence(s)
5. The study is sponsored by an organization or individual capable of successfully completing the study.	
6. 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.	
7. 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 studies is life threatening and the patient has no other viable treatment options.	
8. The study is registered with the National Institutes of Health National Library of Medicine's ClinicalTrials.gov.	
9. 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.	
10. 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.	