IDE Application Process

A sponsor of a significant risk device study must submit a complete IDE application to the FDA, along with obtaining CPHS approval, before beginning clinical research.

IDE Application

Unlike an IND application, there are no pre-printed forms for an IDE application. Instead, there are required information elements that *must be submitted in the order specified below*:

1. Name and address of the sponsor.
2. Report of prior investigations, which must include reports of all prior clinical, preclinical, and laboratory testing of the device necessary to justify the proposed research. This report must include:
   - References for all publications, both supportive and adverse, that are relevant for the evaluation of safety and effectiveness of device;
   - Copies of all published and unpublished adverse effect information;
   - Copies of other significant information if requested by an IRB or the FDA;
   - Summary of all published and unpublished information (both supportive and adverse) that is relevant to the evaluation of safety and effectiveness of the device; and
   - If nonclinical laboratory data are provided, a statement that such studies were performed in compliance with Good Laboratory Practice (21 CFR 58). If such studies were not conducted in compliance with the GLP regulation, include a brief statement of the reason for noncompliance.
3. Investigational plan
   - Purpose (name and intended use of the device; objectives and duration of the clinical investigation);
   - Protocol (include analysis of scientific soundness);
   - Risk analysis (description and analysis of all increased risks to the research subjects and how these risks will be minimized; justification for the investigation; description of patient population including number, sex, age, condition);
   - Description of device (each important component, ingredient, property, and principle of operation and any anticipated modifications to the device during the clinical investigation);
   - Monitoring procedures; and
   - Additional records and supports, other than those already required by IDE application.
4. Description of the methods, facilities, and controls used for manufacture, processing, packaging, storage, and installation of the device.
5. Example of the agreement to be signed by the investigators and a list of names and addresses of all investigators (see 21 CFR 812.43).

6. Certification that all investigators have signed the agreement, that the list from #5 above includes all investigators participating in the study, and new investigators will sign the agreement before being added to the study.
7. List of names, addresses, and chairpersons of all IRBs that have or will be asked to review the investigation and approval letters (if available).
8. Name and address of any other institution where a part of the investigation may be conducted.
9. The amount, if any, charged for the device and an explanation of why this cost does not constitute commercialization.
10. Copies of all labeling for the device.
11. Copies of all informed consent forms and all related information materials to be provided to the subjects.
12. Any other information requested by the FDA. Previously submitted information may be referenced.

An Environmental Assessment is no longer required.

Suggested Content for the IND Application Cover Letter

It is recommended that the cover letter include *the following information in the order listed:*

1. Statement that the information provided is an original IDE application
2. Device information
   - Name of device
   - Intended use
3. Sponsor contact information
   - Name
   - Address
   - Contact person
   - Telephone number
   - Facsimile number
4. Manufacturer information
   - Name
   - Address
   - Contact person
   - Telephone number
   - Facsimile number
5. Applicant information: If the organization submitting the application is not the sponsor, provide full contact information.
6. Provide the following information, if available, for Pre-IDE submission(s) and Pre-IDE meeting(s).

- If Pre-IDE was submitted, state the Pre-IDE number and name of FDA reviewer.
- If Pre-IDE meeting occurred, provide name of FDA contact person and a copy of meeting minutes.

7. Waiver requests, if applicable.
8. References files.

Suggested format for IDE Submissions:

1. Use 8 ½" by 11" inch paper.
2. Use at least a 1 ½" wide left margin to allow for binding into jackets.
3. Use 3-hole punched paper to allow for binding into jackets.
4. If submission exceeds 2" in thickness, separate into volumes and identify volume numbers.
5. Clearly identify type of submission (i.e. initial application, annual report, etc). For submissions subsequent to initial application, identify the FDA assigned document number, the reason for the submission, and the type of submission.
6. All three copies of a submission must be identical.
7. Do not combine submissions for different devices.
8. Unless the IDE sponsor has delegated authority in writing for another person to submit information on the sponsor's behalf, only the IDE sponsor may amend, supplement, or submit reports for the IDE.
9. Sequentially number the pages, provide a detailed table of contents, and use tabs to identify each section.

Mail Address for IDE Applications and Subsequent Correspondence with the FDA:

Three signed copies of the "Application for Investigational Device Exemption" with cover letter must be submitted. The cover page must identify the submission as an application for an IDE and must be signed by the sponsor.

The initial application and all subsequent communications with the FDA must be mailed to:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850-3223

The subsequent IDE correspondence must be submitted in triplicate and reference the IDE number. The outside cover of each submission should identify the content ("IDE Application", "Waiver" etc).