

Content and Format Requirements for an IDE

1. Name and Address of Sponsor;

2. Overall Clinical Plan: This should be about one page in length and included in the initial IDE application and updated as necessary. This should be brief and include a description of each clinical study for the device currently planned.

3. Complete Report of Prior Investigations: A report of prior investigations must include reports of all prior clinical, animal, and laboratory testing of the device. It should be comprehensive and adequate to justify the proposed investigation. Specific contents of the report must include:

- Bibliography of all publications (both adverse and supportive), that are relevant to an evaluation of the safety and effectiveness of the device;
- Copies of all published and unpublished adverse information;
- Copies of other significant publications if requested by an IRB or FDA;
- Summary of all other unpublished information (both adverse and supportive) that is relevant to an evaluation of the safety and effectiveness of the device; and
- If nonclinical laboratory data are provided, a statement that such studies have been conducted in compliance with the Good Laboratory Practice (GLP) regulation in 21 CFR Part 58. If the study was not conducted in compliance with the GLP regulation, include a brief statement of the reason for noncompliance.

4. Investigational plan: The investigational plan shall include the following items in the following order:

- Purpose: The name and intended use of the device and the objectives and duration of the investigation;
- Clinical Protocol: A written protocol describing the methodology to be used and an analysis of the protocol demonstrating its scientific soundness;
- Risk Analysis: a description and analysis of all increased risks to the research subjects and how these risks will be minimized; a justification for the investigation; and a description of the patient population including the number, age, sex, and condition;
- Description of this Device: a description of each important component, ingredient, property, and principle of operation of the device and any anticipated changes in the device during the investigation;

- Monitoring Procedures: the sponsor's written procedures for monitoring the investigation and the name and address of each monitor; see "Guideline for the Monitoring of Clinical Investigations" for a more detailed discussion;
 - Labeling: Copies of all labeling for the device;
 - a. **Content**: The Investigational Device or its immediate package shall bear a label with the following information:
 - i. Name and place of business of the manufacturer, packager, or distributor of the device;
 - ii. Quantity of contents, if appropriate;
 - iii. The statement, "CAUTION – Investigational device. Limited by Federal law to investigational use." ; and
 - iv. A description (on immediate label or other labeling of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
 - Consent Form: Copies of all forms and informational materials to be provided to subject to obtain consent;
 - IRB Information: A list of the names, addresses, and chairpersons of all IRBs that have or will be asked to review the investigation and a certification of IRB action concerning the investigation;
 - Other Institutions: The name and address of any institution where a part of the investigation may be conducted;
 - Additional Records and Reports: a description of any records or reports of the investigation other than those required in Subpart G of the IDE regulation
- 5. Methods, Facilities and Control Information**: A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and installation of the device; this should be provided in enough detail so that a person familiar with GMP standards can make a knowledgeable judgment about the quality control used in the manufacturing of the device
- 6. Certification of Investigators Agreement**: An example of the agreement to be entered into by all investigators and certification, this should include:
- All Investigators who participate in the investigation have signed an Investigators agreement;
 - List of Investigators participating in the clinical investigation of the device;
 - That no Investigators will be added to the clinical investigation of the device until they have signed an Investigators Agreement

Translational Research Program: www.childrenshospital.org/trp/regulatory

7. **Device Charges:** The amount, if any, charged for the device and an explanation of why sale does not constitute commercialization;
8. **A claim for categorical exclusion under 21 CFR 25.30 or 25.34 or an environmental assessment under 25.40**