

Guidance for Abbreviated IDE Requirements

The Principal Investigator of a study that is requesting an abbreviated IDE for use of a non-significant risk device must attest to the following:

1. The device is not a banned device under 21 CFR 895
2. The device will be labeled in accordance with 21 CFR 812.5
3. The study will be monitored in accordance with 21 CFR 812.46
4. The PI will maintain records in accordance with 21 CFR 812.140(b) (4) and (5)
5. The PI will report as required by 21 CFR 812.150(b) (1) through (3) and (5) through (10)
6. The PI will ensure that participating investigators will ensure that participating investigators will obtain and document consent from each of their subjects
7. The PI will ensure that participating investigators will maintain the records required by 21 CFR 812.140(a)(3)(i)
8. The PI will ensure that participating investigators report as required by 21 CFR 812.150(a) (1), (2), (5), and (7)
9. The study will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices

Each of these requirements is addressed in the remainder of this document

1. The device is not a banned device under 21 CFR 895

21 CFR 895 Subpart B lists banned devices and should be consulted to verify that the device is not a banned device.

2. The device will be labeled in accordance with 21 CFR 812.5

21 CFR 812.5 Labeling of investigational devices

- (a) *Contents.* An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with 21 CFR 801.1*), the quantity of contents, if appropriate, and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use." The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
- (b) *Prohibitions.* The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated

*21 CFR 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

- (a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
- (b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The"

may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

- (c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, "Manufactured for ____", "Distributed by _____", or any other wording that expresses the facts.
- (d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice).
- (e) If a person manufactures, packs, or distributes a device at a place other than his or her principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading.

3. The study will be monitored in accordance with 21 CFR 812.46

21 CFR 812.46 Monitoring Investigations

- (a) *Securing compliance.* A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.
- (b) *Unanticipated adverse device effects.*
 - (1) A sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect.**
 - (2) A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect.
- (c) *Resumption of terminated studies.* If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and FDA approval. If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval and, if the investigation was terminated under paragraph (b)(2) of this section, FDA approval.

***Unanticipated adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

4. The PI will maintain records in accordance with 21 CFR 812.140(b) (4) and (5)

21 CFR 812.140 Records

- (b) *Sponsor records.* A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:
 - (4) For each investigation subject to abbreviated IDE requirements, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:
 - (i) The name and intended use of the device and the objectives of the investigation;
 - (ii) A brief explanation of why the device is not a significant risk device;
 - (iii) The name and address of each investigator;
 - (iv) The name and address of each IRB that has reviewed the investigation;
 - (v) A statement of the extent to which the good manufacturing practice regulation in [21 CFR 820](#) will be followed in manufacturing the device; and
 - (vi) Any other information required by FDA.
 - (5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints

- 5. The PI will report as required by 21 CFR 812.150(b) (1) through (3) and (5) through (10)

21 CFR 812.150 Reports

- (b) *Sponsor reports.* A sponsor shall prepare and submit the following complete, accurate, and timely reports:
 - (1) *Unanticipated adverse device effects.* A sponsor who conducts an evaluation of an unanticipated adverse device effect under 21 CFR 812.46(b)*** shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.
 - (2) *Withdrawal of IRB approval.* A sponsor shall notify FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.
 - (3) *Withdrawal of FDA approval.* A sponsor shall notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval.
 - (4) *N/A*
 - (5) *Progress reports.* At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, a sponsor shall also submit progress reports to FDA. A sponsor of a treatment IDE shall submit semi-annual progress reports to all reviewing IRB's and FDA in accordance with §812.36(f) and annual reports in accordance with this section.
 - (6) *Recall and device disposition.* A sponsor shall notify FDA and all reviewing IRB's of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made.
 - (7) *Final report.* In the case of a significant risk device, the sponsor shall notify FDA within 30 working days of the completion or termination of the investigation and shall submit a final report to FDA and all reviewing the IRB's and participating investigators within 6

months after completion or termination. In the case of a device that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion.

- (8) *Informed consent.* A sponsor shall submit to FDA a copy of any report by an investigator under 21 CFR 812.150(a)(5)**** of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use.
- (9) *Significant risk device determinations.* If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.
- (10) *Other.* A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

***21 CFR 812.46(b) – See 2. above

****21 CFR 812.150(a)(5) – See 6. below

6. The PI will ensure that participating investigators will obtain and document consent from each of their subjects. This is part of the PI's general oversight of all participating investigators.
7. The PI will ensure that participating investigators will maintain the records required by 21 CFR 812.140(a)(3)(i)

21 CFR 812.140 Records

- (a) *Investigator records.* A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:
 - (3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:
 - (i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

8. The PI will ensure that participating investigators report as required by 21 CFR 812.150(a) (1), (2), (5), and (7)

21 CFR 812.150 Reports

- (a) *Investigator reports.* An investigator shall prepare and submit the following complete, accurate, and timely reports:
 - (1) *Unanticipated adverse device effects.* An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

- (2) *Withdrawal of IRB approval.* An investigator shall report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
- (3) *N/A*
- (4) *N/A*
- (5) *Informed consent.* If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
- (6) *N/A*
- (7) *Other.* An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

9. The study will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices

21 CFR 812.7 Prohibition of promotion and other practices.

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

- (a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.
- (b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.
- (c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.
- (d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.