**Tip Sheet**

**Responsibilities of a sponsor-investigator for a Non-Significant Risk Device**

**General Considerations:**
As the sponsor-investigator using a non-significant risk (NSR) device, you are not required to obtain an IDE from the FDA. However, NSR devices are subject to ‘abbreviated IDE requirements’.

As the sponsor of a non-significant risk (NSR) device, the FDA expects you to do the following:

**Labeling the NSR Device:**
Assure that the device is properly labeled:

**Contents:** An investigational device or its immediate package must be labeled with the following information:

- the name and place of business of the manufacturer, packer, or distributor
- 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.

**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.

Animal research: An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement: "CAUTION--Device for investigational use in laboratory animals or other tests that do not involve human subjects."

**IRB Oversight:**
Obtain IRB approval prior to initiating the study. You must secure from the IRB agreement that the device is a non-significant risk device.

Maintain IRB approval for as long as you are conducting the study/ies.

When managing a multi-site study, ensure that each investigator participating in an investigation of the device obtain informed consent and document that consent was received prior to initiating any study procedures.

**Record Keeping:**
Maintain the following records, consolidated in one location and available for FDA inspection and copying:

- The name and intended use of the device and the objectives of the investigation;
- A brief explanation of why the device is not a significant risk device;
- The name and address of each investigator: (when you are managing a multi-site study)
- The name and address of each IRB that has reviewed the investigation:
- A statement of the extent to which the good manufacturing practice regulation will be followed in manufacturing the device; and
- Any other information required by FDA.
- Records concerning adverse device effects (whether anticipated or unanticipated) and complaints

**Reports:**
Prepare and submit the following complete, accurate, and timely reports:

- **Unanticipated adverse device effects:** A sponsor who conducts an evaluation of an unanticipated adverse device effect 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.
- **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.
- **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.
- **Other:** A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

**Prohibitions:**
You may not promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

You may not 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.

You may not 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.

You may not represent that an investigational device is safe or effective for the purposes for which it is being investigated.