MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH
UNIVERSITY OF MICHIGAN

Abbreviated IDE Requirements for Non-Significant Risk Devices (US)

Summarized in this document are the FDA regulations specific for conducting a clinical trial with a non-significant risk (NSR) device. If a reviewing IRB concurs with an assessment of NSR for your device and approves your study, under 21 CFR 812.2 you have an abbreviated IDE and you must follow the abbreviated IDE requirements described below.

Please contact the MICHR IND/IDE Investigator Assistance Program (MIAP) if you have any questions or need additional assistance. MICHRMIAP@med.umich.edu

Abbreviated IDE Applicability (21 CFR 812.2(b))

- Investigation of a device that is not significant risk
- IRB approval of the investigation after either:
    - presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and the IRB concurs with this assessment; or
    - presenting the reviewing IRB with an FDA determination that the device is non-significant risk as it is being used in the clinical protocol
- Obtain and document Informed consent from all subjects
- Follows all applicable regulations

The Sponsor 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 study will be monitored in accordance with 21 CFR 812.46**
3. **Maintain records in accordance with 21 CFR 812.140(b) (4) and (5)**
4. **Ensure that participating investigators will obtain and document consent from each of their subjects**
5. **Ensure that participating investigators will maintain the records required by 21 CFR 812.140(a)(3)(i)**
6. **Ensure that participating investigators report as required by 21 CFR 812.150(a) (1), (2), (5), and (7)**
7. **Report as required by 21 CFR 812.150(b) (1) through (3) and (5) through (10)**
8. **The device will be labeled in accordance with 21 CFR 812.5**
9. **The study will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices**

Additional information about complying with these regulations and a reporting timetable can be found below.

A Sponsor-investigator is defined as an individual who both initiates and conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

Banned Device [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.

Monitoring [21 CFR 812.46]

The Sponsor must have adequate oversight of the investigation, by ensuring the following:

- Ensure Investigators comply with the signed investigator agreement and the investigational plan.
- Secure 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 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.

- Ensure that participating investigators will obtain and document consent from each of their subjects.
- Ensure that participating investigators will maintain the records required below
- Document in the protocol, consent, or stand-alone document any expected adverse device effects (ADEs), including their frequency and severity
- Capture, document, and evaluate ADEs and immediately evaluate unanticipated adverse device effects** (UADEs) encountered during study conduct
    - A sponsor who determines that a UADE 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. To resume a terminated study, you must obtain FDA approval.

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

Sponsor Records [21 CFR 812.140(b) (4) and (5)]

The Sponsor Investigator shall maintain the following accurate, complete, and current records relating to the investigation in one location and they must be available for FDA inspection:

- The name and intended use of the device and the objectives of the investigation
- A rationale for why the device is not a significant risk device
- The name and address of each investigator
- The name and address of each IRB that has reviewed the investigation
- A statement of the extent to which the good manufacturing practice regulation in 21 CFR 820 will be followed in manufacturing the device. Note- the sponsor must follow the Design Control regulations found in 21 CFR 820.30, if applicable.
- Device accountability; i.e. records of shipment and disposition of the device
- Adverse Device Effects (ADEs), whether anticipated or unanticipated and complaints
- Any other information required by FDA

Investigator Records [21 CFR 812.140(a)(3)(i)]

A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:

- Records of each subject's case history and exposure to the device (including CRFs and supporting data including medical records and progress notes)
- Documents evidencing informed consent
- 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.
- Device Accountability; records of receipt and use of the device

Sponsor Reporting [21 CFR 812.150(b)(1)-(3) & (5)-(10)]

A sponsor shall prepare and submit the following complete, accurate, and timely reports:

- All UADEs shall be reported to the FDA and to all reviewing IRBs 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.
- Notify FDA and all reviewing IRBs and participating investigators of any withdrawal of IRB approval of an investigation or a part of an investigation within 5 working days after receipt of the withdrawal of approval.
- Notify all reviewing IRBs 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.
- At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRBs.

- Notify FDA and all reviewing IRBs 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.
- Submit a final report to all reviewing IRBs within 6 months after termination or completion
- 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.
- 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.
- Upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Investigator Reporting [21 CFR 812.150(a)(1), (2), (5), & (7)]

An investigator shall prepare and submit the following complete, accurate, and timely reports:

- Submit to the sponsor and to the reviewing IRB a report of any UADE 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.
- Report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
- 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.
- An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Labelling [21 CFR 812.5]

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
- The quantity of contents, if appropriate, and must have 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.
- The labeling of an investigational device shall not bear any statement that is false or misleading and shall not represent that the device is safe or effective for the purposes for which it is being investigated.

Protocol Information:

- The sponsor should provide detailed information on device labeling in the investigational protocol. This information may vary depending on the device and the nature of the study. Product labeling should be sufficient to ensure stability of the test article for the duration of the study (storage

requirements, calibration procedures), bear sufficient directions for proper administration, and detail procedures to follow in the event of patient injury

Prohibitions [21 CFR 812.7]

The following are prohibited under the regulations:

- Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.
- 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.
- Unduly prolong an investigation. If data developed by the investigation indicate 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.
- Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

Clinical Trials.gov (42 CFR 11)

Register, maintain, and provide results of your trial listing on Clinical Trials.gov. Small clinical trials to determine feasibility of a device product, or clinical trials to test prototype device products when a device product is being evaluated for the feasibility of the product or of a test prototype device and not health outcomes are excluded.

Additional considerations

An IDE application submission to the FDA could be required for all devices, including your NSR device when:

- Noncompliance with Abbreviated IDE regulations requires an application to be submitted
- Risk of device is higher than initially evaluated

Abbreviated IDE Reporting Timetable

Type of Report	Who Reports	Where to Report	Timeframe
IRB determines that a device the sponsor had proposed to be NSR, to be a significant risk device	Sponsor	Participating investigators, all reviewing IRBs and FDA	Within **5 working days** after the sponsor first learns of the IRB's determination
UADEs	Investigator	Local IRB and Sponsor	As soon as possible, but in no event later than **10 working days** after the investigator first learns of the effect
	Sponsor	Participating investigators, all reviewing IRBs and FDA	As soon as possible, but in no event later than **10 working days** after notification
Termination of the investigation due to UADE or an unreasonable risk to subjects	Sponsor	Participating Investigators, all reviewing IRBs and FDA	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
Withdrawal of IRB approval	Investigator	Sponsor	Within **5 working days**
	Sponsor	Participating Investigators, all reviewing IRBs and FDA	Within **5 working days** after receipt of the withdrawal of approval
Use of device without informed consent	Investigator	Sponsor and Local IRB	Within **5 working days** after the use occurs
	Sponsor	FDA	Within **5 working days** of receipt of notice of such use
Withdrawal of FDA approval of the investigation	Sponsor	Participating investigators and all reviewing IRBs	Within **5 working days** after receipt of notice of the withdrawal of approval
A request that an investigator return, repair, or otherwise dispose of any units of a device	Sponsor	Participating Investigators, FDA and all reviewing IRBs	Within **30 working days** after the request is made and shall state why the request was made
Final Report	Sponsor	All reviewing IRBs	Within **6 months** after termination or completion