Office of Research Integrity

PRINCIPAL INVESTIGATOR SELF-ASSESSMENT
Investigational Device, Non-Significant Risk

Principal Investigator: Click or tap here to enter text.

Protocol #:Click or tap here to enter text. **Study Title**: Click or tap here to enter text.

Device Name and Manufacturer: Click or tap here to enter text.

Purpose: This checklist is provided for your self-review to ensure that all the FDA Abbreviated Investigational Device Exemption (IDE) requirements for conducting a Nonsignificant Risk (NSR) Device study are met set forth in CFR 21 812.2(b).

If you have any questions or concerns regarding compliance with NSR Device regulations, see the ORI FDA-Regulated Research website or contact the ORI at **IRBSubmission@uky.edu** with your protocol number.

LABELING FOR INVESTIGATIONAL DEVICES DISTRIBUTED TO PARTICIPANTS (21 CFR 812.5)

1a. FDA requires device labels (or container labels for devices that cannot be labeled) to state: "CAUTION – Investigational Device, limited by Federal (or United States) law to investigational use". Is the device labeled as such?

☐YES ☐NO ☐N/A

1b. FDA requires labels to include the name and place of business of the manufacturer and quantity of contents, if appropriate. Does the label meet this requirement?

☐YES ☐NO ☐N/A

1c. FDA states labels cannot contain any statement that the device is safe or effective for the purpose it is being investigated. Does the label meet this requirement?

☐YES ☐NO ☐N/A

1.d. If applicable, the label should describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. Does the label meet this requirement?

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

MONITORING (21 CFR 812.46)

2a. FDA requires monitoring of non-significant risk device studies to ensure ongoing participant safety, data integrity, and compliance with the protocol. Do you have such a monitoring plan?

☐YES ☐NO If NO, consider implementing the following:

☐Verification that participants signed and dated currently approved consent form
☐Adherence to inclusion/exclusion criteria
☐Verification that protocol is being followed
☐Review of accuracy and completeness of data
☐Review of documentation, management and reporting of adverse events to the IRB
☐Other: Click or tap here to enter text.

COMMENT: Click or tap here to enter text.

TRAINING

3. Have all co-investigators and key study personnel been trained to the protocol and delegated tasks?

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

It is recommended that training logs or study team meeting minutes be on file to meet this requirement.

CASE REPORT FORMS/STUDY DOCUMENTATION (21 CFR 812.140(a)(3)(i))

4. Have you created study documentation, such as case report forms (CRFs), that accurately reflect the approved study and have a place for signature and date of the person(s) obtaining the information?

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

ACCOUNTABILITY AND STORAGE

5. In general, it is recommended to maintain records of the shipping, receipt, and dispensation of each device (quantity, date of receipt, name of person receiving). Are these records being maintained?

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

6. In general, it is recommended to provide secure storage for all devices in order to maintain proper control of the device(s). Is the device(s) stored in a secure location?

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

If you do not have a log or process for accountability, the Office of Research Integrity (ORI) has optional tools such as an Investigational Device Accountability Log [WORD] and Sample Investigational Device Accountability [WORD] Standard Operating Procedure.

FDA REPORTING REQUIREMENTS

7. FDA requires the maintenance of records concerning adverse device effects (whether anticipated or unanticipated) and complaints. Are these records maintained? (21 CFR 812.140(b)(5))

☐YES ☐NO

COMMENT: Click or tap here to enter text.

CLINICAL TRIAL INFORMATION

8. Is this study an applicable device clinical trial and, therefore, registered on ClinicalTrials.gov as required? If you are unsure, see ClinicalTrials.gov Checklist. For information and assistance see the Office of Sponsored Projects Administration (OSPA) Clinicaltrials.gov website

☐YES ☐NO ☐N/A

COMMENT: Click or tap here to enter text.

ADDITIONAL RESOURCES:

- FDA Guidance on Non-Significant Risk Devices
- FDA Sponsor and Sponsor-Investigator Responsibilities
- FDA Investigational Device Exemption FAQs
- ORI Guidance: FDA Regulated Research

Suggest retaining this self-assessment form with study regulatory documents for reference and/or presentation at quality improvement reviews or inspections.

J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\D167 NSR Device Self-Assessment.docx 2/27/25

This assessment has been adapted with permission using the University of Michigan Office of Research Compliance Review template for the development of this form.