OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

PRINCIPAL INVESTIGATOR SELF-ASSESSMENT

Investigational Device, Non-Significant Risk

Principal Investigator:

HUM #: **Study Title:**

Device Name and Manufacturer:

Purpose: This form is for researchers to use to conduct a self-assessment of their IRB approved Non-Significant Risk (NSR) Device study. NSR Device studies fall into the category of an abbreviated Investigational Device Exemption (IDE) set forth in CFR §812.2(b). The purpose of this self-assessment is to help researchers assess whether they are meeting their regulatory obligations and institutional guidance. The form is intended to be completed at the time of study initiation, after initial IRB approval and receipt of the device. Please complete and return this form to ORCR by .

If you have any questions or concerns regarding compliance with NSR Device regulations, contact the Office of Research Compliance Review at orcr-deptemail@umich.edu.

DEVICE LABELING

1a. FDA requires device labels (or container labels for devices that cannot be labeled) to state: "CAUTION – Investigational Device, limited by Federal law to investigational use". Is the device labeled as such? (§812.5)

○ YES ○ NO ○ N/A

1.b FDA requires labels to include the name of the manufacturer. (§812.5) Does the label meet this requirement?

○ YES ○ NO ○ N/A

1.c FDA states labels cannot contain any statement that the device is safe or effective for the purpose it is being investigated. (§812.5) Does the label meet this requirement>

○ YES ○ NO ○ N/A

COMMENT:

MONITORING

2.a FDA requires monitoring of non-significant risk device studies to ensure ongoing subject safety, data integrity, and compliance with the protocol. Do you have such a monitoring plan? (§812.43, §812.46)

○ YES ○ NO If NO, please explain in the comment section below.

COMMENT:

2.b If YES, which of the following FDA recommended components have you included as part of the plan?

☐ Verification that subject 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:

TRAINING

3. Have all co-investigators and key study personnel been trained to the protocol and delegated tasks?
(U-M HRPP, Operations Manual Part 8 VIII C)

◯ YES ◯ NO If NO, explain in the comment section below.

COMMENT:

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

CASE REPORT FORMS/STUDY DOCUMENTATION

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?
(U-M HRPP, Operations Manual Part 8 VIII F)

◯ YES ◯ NO If NO, please explain in the comments section below.

COMMENT:

RECORDS AND STORAGE

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

◯ YES ◯ NO If NO, please explain in the comments section below.

COMMENT:

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 If NO, please explain in the comments section below.

COMMENT:

CLINICAL TRIAL INFORMATION

7. Is this study an applicable device clinical trial (see link to definition) and, therefore, registered on ClinicalTrials.gov as required? If you are unsure, see CT.gov Checklist.

◯ YES ◯ NO N/A

If YES, indicate NCT #:

COMMENT:

ADDITIONAL RESOURCES:

FDA Guidance on Responsibilities for Sponsors and Investigators of Non-Significant Risk Devices

IRBMED UMIC: Significant & Non-Significant Devices in Human Subjects Research

For questions related to this form contact ORCR at orcr-deptemail@umich.edu or call 734-647-0489.

Principal Investigator Signature Date

(If this form is completed by someone other than the principal investigator, entering the PI's name verifies information contained above has been reviewed by the principal investigator.)