

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're meeting their regulatory obligations and institutional guidance. The form is in two parts. Part One is intended to be completed at the time of study initiation, after initial IRB approval and receipt of the device. Part Two should be completed at the time of the first scheduled continuing review (SCR).

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.

PART ONE

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 |
|-----|----|-----|
- 1b. FDA requires labels to include the name of the manufacturer. ([§812.5](#)) 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. ([§812.5](#)) Does the label meet this requirement?
- | | | |
|-----|----|-----|
| YES | NO | N/A |
|-----|----|-----|

Comment:

Monitoring

- 2a. 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:

- 2b. If Yes, which of the following FDA recommended components have you included as part of the plan?
- Verification 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 HRRP Operations Manual Part 8 VIII C](#))

YES NO If NO, please 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 the 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 comment 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 comment 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 comment 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](#).)
YES NO N/A

If YES, indicate NCT#:

Comment:

Additional Resources

[FDA Guidance on Responsibilities for Sponsors and Investigators of Nonsignificant Risk Devices](#)
[IRBMED UMIC: Significant and Nonsignificant Risk Devices in Human Subjects Research](#)

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

PART TWO

Monitoring (please note that documentation of monitoring is required and should be uploaded with your SCR)

1. Are there completed monitoring reports or other documentation that the monitoring plan is being followed?
YES NO If NO, please explain in the comment section below.

Comment:

Records and Storage

2. In general, it is recommended to maintain complete records of the disposition of each device (quantity, date of disposal/return, name of person disposing of the device). Are these records being maintained?
YES NO If NO please explain in the comment section below.

Comment:

Adverse Events and Recalls

- 3a. Were there any unexpected, serious adverse events related/possibly related to the study device? ([§812.150\(b\)\(1\)](#))
YES NO

- 3b. If Yes, were they submitted to both the FDA and IRB within 10 business days of notification of the event?
YES NO

Comment:

(For questions on how to submit adverse events to the FDA, contact the Division of Industry and Consumer Education (DICE) within FDA Medical Devices at [contact DICE at FDA](#)).

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