|  |
| --- |
| **Principal Investigator**: Click or tap here to enter text. |
| **HUM #**: 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 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)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.2). The purpose of this self-assessment is to help researchers assess whether they are meeting their regulatory obligations and institutional guidance. [Non-Significant Risk (NSR) Medical Devices: Monitoring Requirements](https://az.research.umich.edu/medschool/guidance/non-significant-risk-nsr-medical-devices-monitoring-requirements)

See ORCR’s [DropBox](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates) for templates to aid in study recordkeeping.

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** ([21 CFR 812.5](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5))

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?

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | [ ] N/A |

1b. FDA requires labels to include the name of the manufacturer. 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 |

COMMENT: Click or tap here to enter text.

**MONITORING** ([21 CFR 812.46](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=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? See [ORCR’s DropBox](https://www.dropbox.com/home/UMOR-ORCR%20Dropbox/ORCR%20Study%20Templates/Study%20level%20templates?preview=NSR+Monitoring+Plan+Template.docx) for the NSR Monitoring Plan Template.

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

COMMENT: Click or tap here to enter text.

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

[ ] 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.

**TRAINING**

1. 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](https://research-compliance.umich.edu/operations-manual-studies-regulated-fda-and-use-investigational-articles#oversight))

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

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)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140))

1. 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](https://research-compliance.umich.edu/operations-manual-studies-regulated-fda-and-use-investigational-articles#records))

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

COMMENT: Click or tap here to enter text.

**RECORDS AND STORAGE**

1. 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? ([U-M HRPP, Operations Manual Part 8 VIII F](https://research-compliance.umich.edu/sites/default/files/resource-download/om_pdf_final_04.13.2023_1.pdf#records))

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

COMMENT: Click or tap here to enter text.

1. 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: Click or tap here to enter text.

**FDA REPORTING REQUIREMENTS**

1. FDA requires the maintenance of records concerning adverse device effects (whether anticipated or unanticipated) and complaints. Are these records maintained? ([812.140(b)(5)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140))

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

COMMENT: Click or tap here to enter text.

**CLINICAL TRIAL INFORMATION**

1. Is this study an applicable device clinical trial (see [Identifying an “Applicable Clinical Trial](https://grants.nih.gov/clinicaltrials_fdaaa/docs/flow_chart-act_only.pdf)) and, therefore, registered on [ClinicalTrials.gov](https://clinicaltrials.gov/) as required? If you are unsure, see [ClinicalTrials.gov Checklist](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf).

|  |  |  |
| --- | --- | --- |
| [ ] YES | [ ] NO | If NO, Please explain in the comment section below. |
|  |  |  |

If YES, indicate NCT #: Click or tap here to enter text.

COMMENT: Click or tap here to enter text.

**ADDITIONAL RESOURCES:**

* [FDA Guidance on Responsibilities for Sponsors and Investigators of Non-Significant Risk Devices](https://www.fda.gov/media/75459/download)
* [MIAP Guidance: Abbreviated IDE Requirements](https://michr.umich.edu/resources/2022/5/12/abbreviated-ide-requirements)
* IRBMED Guidance: [Non-Significant Risk Devices: Monitoring Requirements](https://az.research.umich.edu/medschool/guidance/non-significant-risk-nsr-medical-devices-monitoring-requirements)
* [IRBMED UMIC: Significant & Non-Significant Devices in Human Subjects Research](https://www.dropbox.com/sh/q0228h2jasqnhys/AAAHpkKXvbsGztesvaJ_wLSKa/Significant%20and%20Nonsignificant%20Risk%20Device%20Studies?dl=0&subfolder_nav_tracking=1)
* HRPP Operations Manual: [Part 8: Studies Regulated by the FDA and Use of Investigational Articles](https://research-compliance.umich.edu/sites/default/files/resource-download/om_pdf_final_04.13.2023_1.pdf)

For questions related to this form contact ORCR at orcr-deptemail@umich.edu.

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |
| 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.)***