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| **Purpose:**  This appendix is designed to provide information to the IRB for human subjects research when requesting a Nonsignificant Risk (NSR) device determination for an Investigational Device (IDE). |

**Instructions:**

* Complete if:
  + You are using an investigational device which does not have an Investigational Device Exemption (IDE) number; **and**
  + You believe the use of investigational device in this study poses nonsignificant risk (NSR).
* Investigators must fill out a form for **each** device.
* Respond to every question on this application. Incomplete applications will be returned, and will result in a delay of your study being reviewed. If a question does not apply, answer N/A. Do not leave any question blank.
* This appendix is a part of the Research Plan and must be included with each Research Plan submission.
* Save this form to your computer before proceeding.

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| 1. General Information | | | | |
| **Principal Investigator:** | | **Version Date:** | | |
| **Faculty Advisor:** | | **Protocol Number:** | | |
| **Study Title:** | | | | |
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| **For funded research:**   * Submit one copy of the Research Plan/Project Description section of the grant application and any resubmissions. * Provide the following information: | | | | |
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| **Principal Investigator:** | | | |  |
| **Title of Grant Proposal if different from above:** | | | | |
| **Agency:** | **Grant #:** | | **EPCS #:** | |

| 1. Definitions |
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| * + Investigational Devices: |
| An ***investigational device*** is a medical device which is the subject of a human research study to evaluate its safety and/or effectiveness. Clinical studies of investigational devices must comply with FDA’s investigational device exemption (IDE) regulations. |
| * "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: |
| * recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or * intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." |
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| * + Significant Risk Study/Device: |
| A ***significant risk (SR) study*** is defined as “a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject ***AND*** |
| * is intended as an implant; ***OR*** * is used in supporting or sustaining human life; ***OR*** * is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; ***OR*** * otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.” [[21 CFR 812.3(m)](http://www.ecfr.gov/cgi-bin/text-idx?SID=c058c334180ffb48e12660b7a2c77ed8&mc=true&node=se21.8.812_13&rgn=div8)] |
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| * + Nonsignificant Risk Study/Device: |
| A study/device that does not meet the definition for a significant risk study/device is considered a ***nonsignificant risk (NSR)*** study/device. A NSR device does not pose significant risk to human subjects. |
| * It is the responsibility of the CPHS/IRB to classify a study as nonsignificant risk by evaluating the sponsor-generated device information provided by the investigator who is applying to the CPHS/IRB. * FDA approval is not required. Full CPHS/IRB review and approval is required. * Nonsignificant risk is not the same as a “minimal risk” classification used for Expedited Review. |

| 1. Device/Study Description |
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| * 1. Provide description of the methodology to be used and that may offer any analysis that the study is scientifically sound: |
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| * 1. Describe sample size, including a statistical justification: |
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| * 1. Describe study design – controlled/uncontrolled, prospective/retrospective, andomized/nonrandomized and justification for study design: |
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| * 1. Provide description of subject population (include age range): |
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| * 1. Describe the criteria and method for inclusion/exclusion: |
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| * 1. State overall study success criteria including justification (e.g., how will success of the device be measured and provide rationale): |
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| * 1. Duration of study: |
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| * 1. Duration and frequency of daily research activities if applicable: |
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| * 1. Number of study sites: |
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| * 1. Describe planned statistical analysis: |
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| * 1. Describe informed consent and information/training procedures: (NOTE: All device information/training documents must be attached.) |
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| * 1. Provide description of potential risk(s) (include any proposed warnings, precautions, contraindications, nature of harm that may result from use of the device, restrictions or training requirements, if known): |
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| * 1. Include Data Safety Monitoring Plan (if applicable): |
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| * 1. Provide description of potential benefit(s): |
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| 1. Risk | |
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| * 1. Sponsor/Investigator’s Assessment of Device/Study | |
| **Significant Risk (SR)** | |
| **Nonsignificant Risk (NSR)** | |
|  | * + 1. Explain why the use of the device in this study poses ***nonsignificant risk***, and attach any other supporting information (e.g., any reports of prior investigations). |
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|  | * + 1. Explain whether the FDA or any other IRB has determined the device to be significant or nonsignificant risk. |
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|  | * + 1. Include all of the following that are available: |
| * Detailed information from the sponsor, such as a description of the device and how it is used. * Diagrams and/or in situ photographs of the device. * Directions for use, typically provided by the sponsor or manufacturer. * Device labeling consistent with Federal Regulations [[21 CFR 812.5](http://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol8/CFR-2012-title21-vol8-sec812-5)]. * Relevant performance information on the device (may include: published or unpublished data, summary of bench and/or animal testing data, and/or summary of prior clinical experience). | |
| **Note:** If the CPHS/IRB determines that the proposed nonsignificant risk study is actually a significant risk study, the sponsor (researcher) must submit to the FDA a report of the CPHS/IRB findings within 5 working days after learning of the CPHS/IRB’s determination [[21 CFR 812.150(9)](http://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol8/CFR-2012-title21-vol8-sec812-150/content-detail.html)]. | |
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| * 1. Describe the device. Use as much space as needed: | |
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| * 1. Summarize any prior investigations conducted with the device: | |
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| * 1. State overall study success criteria including justification (e.g., how will success of the device be measured and provide rationale):: | |
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| 1. FDA Regulated Clinical Investigations | | |
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| * The FDA defines *Clinical investigation* as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58, regarding nonclinical laboratory studies. * The [FDA defines an Applicable Clinical Trial (ACT)](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered) as follows: (1) Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance. The FDA has further elaborated the definition of an ACT which can be found [here](https://grants.nih.gov/clinicaltrials_fdaaa/docs/flow_chart-act_only.pdf). | | |
| When employing an investigational device in research subject to FDA regulations, the following requirements apply:   * GCP training: Must be completed, logged and tracked for clinical investigators and staff who are involved in the design, conduct, oversight, or management of the clinical trial. Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines. * Registering & reporting of results at clinicaltrials.gov: All ACTs are expected to register and submit results information to Clinicaltrials.gov, as per the Food and Drug Administration Amendments Act of 2017 (FDAAA). * Consent Form Requirements: Informed consent documents for clinical trials are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.   NOTE: If the study also falls under the HHS 2018 Revised Common Rule, a copy of the consent form must be posted to clinicaltrials.gov within the timeframe outlined in the HHS regulations as noted above. | | |
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| * 1. Describe how the investigator is complying with the FDA requirements for a clinical investigation as outlined above: | | |
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| 1. Additional Consent Form Requirements |
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| * The consent form should include a brief lay description of the device and what it is designed to do. |
| * The consent form must include a clear statement that the device is investigational and has not been approved by the FDA for clinical use, or if applicable, that the device has been approved for use in a research. |
| * The consent form must include a list of various alternatives to participation in the study. This should name the standard therapies available with approved devices as well as other experimental treatments with investigational devices as applicable. |
| * The consent form needs to state whether or not the researcher is supplying the device at no charge. |
| * The consent form needs to state if the subject or their insurance carrier will be billed for the device (if applicable). |
| * The consent form needs to state that the costs may not be covered by insurance because the therapy is experimental. |
| * The consent form needs to describe the potential risks associated with using the device. |
| * The consent form needs to include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records. |

| 1. Reporting Requirements |
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| * The investigator must make the following reports in a timely manner. |
| * Unanticipated Problems and Adverse Device Effects: The investigator must submit to the sponsor and RCS a report of any unanticipated problems and adverse device effects as soon as possible but no later than 1 working day after the investigator first learns of the event. |
| * Progress Reports: The investigator must submit progress reports to the sponsor/monitor, if applicable, and to RCS at regular intervals but no less than on a yearly basis. |
| * Deviations from the Investigational Plan: The investigator must notify the sponsor, if applicable, and RCS of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. The notice must be provided as soon as possible but no later than 1 working day after the emergency occurred. If it is not an emergency, prior approval from the sponsor is required for changes in or deviations from the investigational plan. If the change or deviation may affect the scientific soundness of the investigational plan or the rights, safety or welfare of the subject, the sponsor is required to obtain prior IRB approval and also to obtain FDA approval for a significant risk device investigation by submitting a supplemental application. |
| * Informed Consent: If an investigator uses a device without obtaining informed consent, the investigator must report the use to the sponsor, if applicable, and to the reviewing IRB within one working day after the use occurs. |
| * Final Report: The investigator must submit a final report to the sponsor, if applicable, and to the reviewing IRB within 3 months after termination or completion of the investigation. |
| * Other Reports: The investigator must provide accurate, complete, and current information about any aspect of the investigation upon request from the reviewing IRB or FDA. |

| 1. Control of Investigational Devices – Investigator Responsibilities |
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| * Investigators conducting studies in which an investigational device will be used must ensure adequate control of the device. Adequate control and handling of investigational devices include all of the following: |
| * The investigator must ensure that the investigational device is used only in accordance with the CPHS/IRB approved protocol, the signed agreement, the investigational plan and applicable FDA regulations. |
| * The investigator must administer the investigational device only to participants under the investigator’s direct personal supervision or under the supervision of a sub-investigator directly responsible to the investigator. |
| * The investigator must not supply the investigational device to any person not authorized to receive it. |
| * The investigation must maintain the following accurate, complete, and current records relating to the investigator’s participation in an investigation: |
| * The investigation must maintain accurate, complete, and current records relating to the investigator’s participation in an investigation. Records of receipt, use or disposition of a device that relate to the following must be kept: |
| * The type and quantity of the device, the dates of its receipt, and the batch number or code mark. |
| * The names of all persons who received, used, or disposed of each device. |
| * Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of. |
| * If the investigation is terminated, suspended, discontinued, or completed, the investigator must return any unused supplies of the investigational device to the study sponsor, or otherwise provide for disposition of the unused supplies as directed by the sponsor. |

| 1. Import/Export of Investigational Devices |
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| * Investigators should be aware that FDA does not recognize regulatory approvals from other countries; therefore, an imported medical device must meet all FDA requirements. |
| * The IDE sponsor/researcher must be located in the United States. |
| * Anyone who intends to import an investigational device takes on the responsibilities of a sponsor. |