**AUDIT REVIEW FOR TRIALS INVOLVING A NON-SIGNIFICANT RISK DEVICE (NSR)**

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| Principal Investigator: |  |
| Study Title: |  |
| Auditor(s): |  |

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| **Protocol Version Date:** |  | **IRB #:** |  |
| **Date of Review:** |  | **IDE #:** |  |

**Element A: Labeling. The device must be labeled in accordance with the labeling provisions of the IDE regulation in** [**§812.5**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.5) **and must bear the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use."**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Is the device labeled with the following information?:* The name and place of business of the manufacturer, packer, or distributor (in accordance with 801.1), and
* The quantity of contents, if appropriate.
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|  | Does the label include the following statement?: "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use." |  |  |  |
|  | Does the label describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions (if applicable)? |  |  |  |
|  | The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated. |  |  |  |

**Element b: IRB Approval. The sponsor and local investigator must obtain and maintain Investigational Review Board (IRB) approval throughout the investigation as a non-significant risk device study.**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Has IRB approval been obtained or is it in process? |  |  |  |
|  | Is the regulatory status of the device clear?* NSR determination by FDA (if applicable)
* NSR determination by IRB (if applicable)
* *When an investigator asserts that an investigational device is Non-Significant Risk (NSR) according to Federal regulations, the PI/sponsor must provide the IRB with a statement contending that the device, as it is to be used in the context of the named protocol, poses a non-significant risk of harm to the subjects. Documented justification of the rationale is required. Documentation could include:*
1. *An NSR determination made by the FDA;*
2. *Inclusion on an FDA list of NSR devices; or*

*A thorough risk analysis and a request for an IRB determination of NSR, etc.* |  |  |  |

**Element C: Informed Consent. The sponsor and local investigator must assure that investigators obtain and document informed consent from each subject according to** [**21 CFR 50**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50)**, Protection of Human Subjects, unless documentation is waived by an IRB in accordance with §56.109(c).**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Does the informed consent document for research subjects include all of the required elements?* This should be documented via IRB review and approval.
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|  | Are all NSR required procedures documented in the informed consent document? |  |  |  |

**Element D: Monitoring, Records, and Reports (§812.46, 812.140(b)(4 & 5), 812.150(b)(1-3, 5-10)). Sponsor and local investigator will comply with the FDA requirements for monitoring investigations, maintaining records and filing reports. All investigations must be properly monitored to protect the human subjects and assure compliance with approved protocols (§812.46). Guidance on monitoring investigations can be found in "**[**Guideline for the Monitoring of Clinical Investigations**](http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm135075.htm)**". Sponsors are required to maintain specific records and make certain reports as required by the IDE regulation.**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Is sponsor-investigator FDA correspondence on file (if applicable)? |  |  |  |
|  | Is the trial registered on <http://www.clinicaltrials.gov>? * Required if “device is intended for the treatment of a serious or life-threatening disease or condition and you are conducting clinical trials to test its effectiveness”.
* Contact: Compliance Office: 801-213-3601.
* The CT.gov disclosure must be in the Consent Document.
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|  | Has an FDA Form 3674, *Certification of Compliance with ClinicalTrials.gov Data Bank* been submitted to the FDA, and is a copy on file? |  |  |  |
|  | Has the CRCE (Clinical Research Compliance and Education) office reviewed and approved the MCA/NCD (Medicare Coverage Analysis/National Coverage Determination) pricing submission, if applicable? |  |  |  |
|  | Does the protocol include a description of plans for ongoing communication with the FDA and IRB, including annual reports, amendments, adverse events, etc.? |  |  |  |
|  | Does the PI have written verification of agreement to follow the protocol as written from each site participating (if applicable)? |  |  |  |
|  | Is there a Financial Disclosure Form in ERICA or a Form FDA 3455, *Disclosure: Financial Interests and Arrangements of Clinical Investigators*, on file for each investigator? |  |  |  |
|  | Is there a current CoI Disclosure for all essential study personnel on file in ERICA? |  |  |  |
|  | Are all versions of the protocol and consent completed and available for review? |  |  |  |
|  | Are the protocol, informed consent document, and relevant documents in compliance with the IRB and sponsor requirements? |  |  |  |
|  | If the study involves more than one investigator, has the name and address of the monitor been provided? |  |  |  |
|  | Are study personnel Curriculum Vitae (CV) and/or other relevant documents evidencing qualifications of primary investigator and co-investigator(s) (e.g. licenses) completed and on file for review? |  |  |  |
|  | Is the sponsor-investigator correspondence to the IRB on file? |  |  |  |
|  | Is the process to report protocol violations/deviations to the IRB included in the protocol? |  |  |  |
|  | Is the process for the notification of unexpected and serious adverse device effects to regulatory authority and the IRB clearly identified in the protocol?  |  |  |  |
|  | Is a Data, Safety, and Monitoring oversight committee (DSMC) identified and are the reporting instructions outlined in the protocol (if applicable)? |  |  |  |
|  | Is the process for reporting adverse events and adverse device effects consistent with the instructions from the FDA? |  |  |  |

**Element E: Prohibitions (**[**§812.7**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.7)**). Commercialization, promotion, test marketing, misrepresentation of an investigational device, and prolongation of the study are prohibited.**

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|  | Questions | Yes | No | Site Compliance Comments |
|  | Has the sponsor and investigator documented that they will abide by the following prohibitions?:*A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:** *Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.*
* *Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.*
* *Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.*
* *Represent that an investigational device is safe or effective for the purposes for which it is being investigated.*
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**Element F: Study Management**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Is there a subject screening log? |  |  |  |
|  | Is there a subject identification code list (enrollment or randomization log)? |  |  |  |
|  | Is there a monitoring visit log and a section for filing report forms? |  |  |  |
|  | Is there a study staff signature list on file? |  |  |  |
|  | Is the patient enrollment process identified in the protocol? |  |  |  |
|  | Is the process for recordkeeping outlined in the protocol? |  |  |  |
|  | Is there a staff training log? |  |  |  |
|  | Is there a delegation of tasks assignment sheet or log? |  |  |  |
|  | Is there a mechanism in place to record receipt, use and/or disposition of each device according to 21 CFR 812.140(a)? |  |  |  |

**Element G: Device Accountability**

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|  | Questions | Yes | N/A | Site Compliance Comments |
|  | Is there a mechanism in place to track device receipt, quantity, lot numbers, and return/disposal? |  |  |  |
|  | Device dispensing record:* Date investigational device was received
* Device numbers
* Labeling – “Investigational Device”
* Quantity
* ID of subject administered/implanted
* Disposition/record of return
* ID of person dispensing
* Return of device, count, reason for return
* Routine verification (Device custodian’s monthly/quarterly verification)
* Final product destruction/disposition
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