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| **INSTRUCTIONS**:   1. Before completing this form, please review the **Frequently Asked Questions** section outlined in **Appendix A**.      1. Submit your completed form along with any required supplemental documentation (as noted in this form) to [irb@une.edu](mailto:irb@une.edu) for review.   Contact the Office of Research Integrity at [irb@une.edu](mailto:irb@une.edu) for any questions you may have with regard to this form. |

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| Version Date: | Enter date when form is first completed or date when form is last updated |
| Principal Investigator: | Enter text |
| IRB #: | Enter ‘To Be Determined’ if IRB # not assigned yet |
| Study Title: | Enter text |

| 1. INVESTIGATIONAL DEVICE DETAILS |
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| 1. What is the name of the investigational device?   Enter text |
| 1. Does the investigational device have a model number? No  Yes *(provide details below)*   Enter text |
| 1. Who is the manufacturer of the investigational device?   Enter text |
| 1. Provide a description of the investigational device and how it will be used in the proposed study.   *Note: Attach a copy of any diagrams, photographs, and/or instructions for use for IRB review (as available).*  Enter text |
| 1. Is this investigational device study sponsored by an external entity or company?   No  Yes *(identify the Sponsor below; if applicable, attach a copy of the Sponsor’s protocol for IRB review)*  Enter text |
| 1. Identify your role in this investigational device study.   *Note: See Appendix A (FAQ #8) for definitions. Choose only one response below.*  Investigator only  Both sponsor and investigator (also known as the ‘Sponsor-Investigator’) |
| 1. Has the FDA formally determined this investigational device study to be non-significant risk?   No *(complete Section B below)*   Yes *(skip Section B below; attach a copy of the FDA device risk determination letter for IRB review)* |

| 1. INVESTIGATIONAL DEVICE RISK ASSESSMENT |
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| 1. Is the investigational device to be used in this study banned in the United States?  No  Yes *(explain below)*   Enter text |
| 1. What is the risk level of the investigational device?   Significant Risk  Non-Significant Risk  *Complete the table below to determine risk. All responses must be ‘False’ to be considered Non-Significant Risk.*  *Note: If your study involves a Significant Risk Device, refer to Appendix A (FAQ #6) for additional information.*   |  |  |  | | --- | --- | --- | | The Investigational Device… | | Response | | 1. Is intended as an implant¥ and presents a potential for serious risk to the health, safety, or welfare of a participant. | | False  True | | 1. Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant. | | False  True | | 1. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant. | | False  True | | 1. Otherwise presents a potential for serious risk to the health, safety, or welfare of a participant. | | False  True | | ¥ | An implant is a device that is placed into a surgically or naturally formed cavity of the human body and is intended to remain there for a period of 30 days or more. In order to protect public health, FDA may determine that devices placed in subjects for shorter periods are also implants. | | |

| 1. NON-SIGNIFICANT RISK INVESTIGATIONAL DEVICE INFORMATION |
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| 1. Provide a response to the questions outlined below.   *Note: If applicable, attach a copy of all FDA/Sponsor documents related to the device including Investigational Device Exemption (IDE) documentation and/or the Sponsor’s risk determination for IRB review.*   1. Provide a justification why the device does not pose a significant risk.   Enter text   1. Describe how the device is stored securely.   Enter text   1. Describe how the device is labeled.   *Note: The device must be labeled as an investigational device; see Appendix B for details.*  Enter text   1. Describe who has access to the device.   Enter text   1. Will participants be charged for the device?  No  Yes *(provide details below)*   Enter text   1. Describe how the device will be provided or delivered to participants.   Enter text |
| 1. Are you serving in the capacity as both the sponsor and the investigator for this investigational device study (also known as the ‘sponsor-investigator’)? No  Yes *(answer the questions below)* 2. Does the device require calibration prior to use?  No  Yes *(describe the calibration procedure below)*   Enter text   1. Detail the procedures to be followed should the device cause an injury to a research participant.   Enter text   1. Describe the monitoring activities that will be employed during the study to protect research participants and ensure compliance with the approved protocol. Also, who will be responsible for conducting the monitoring activities?   Enter text   1. Describe the extent to which the device will be manufactured in accordance with FDA good manufacturing practices ([21 CFR 820](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820)).   *Note: It is recommended that the sponsor-investigator reach out to the FDA for a consultation via* [*DICE@fda.hhs.gov*](mailto:DICE@fda.hhs.gov) *or 1-(800)-638-2041 to discuss this matter prior to submitting their application for IRB review.*  Enter text |

| 1. **PRINCIPAL INVESTIGATOR CERTIFICATION** |
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| **As Principal Investigator of this research project, I acknowledge the following**:   * The information provided in this form is accurate.      * Abbreviated IDE requirements does not in any way exempt the Principal Investigator from complying with FDA regulations including requirements for informed consent and initial and continuing review conducted by the UNE IRB. * The Principal Investigator must monitor the research and report to the UNE IRB and FDA any noncompliance, adverse events, or unanticipated problems. * The Principal Investigator must maintain records and reporting according to the requirements set forth by  21 CFR 812.140 and 21 CFR 812.150 *(see* ***Appendix B & C*** *as applicable)*. * The Principal Investigator will not promote or test market an investigational device, until after FDA has approved the device for commercial distribution; charge participants for a device beyond recovering costs; unduly prolong the research; nor represent that the investigational device is safe or effective for the purposes for which it is being investigated.  |  |  |  | | --- | --- | --- | |  |  |  | | Signature of Principal Investigator |  | Date | |

**Appendix A**

| Frequently Asked Questions |
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| 1. What is an investigational device?   A device is considered investigational if either condition below applies:   * The device is NOT approved or cleared for marketing in the U.S., *or* * The device is approved or cleared for marketing but is being *clinically* evaluated for a new indication |
| 1. Who regulates research involving investigational devices?   The Food and Drug Administration (FDA) regulates research involving investigational devices, as well as all aspects of device manufacturing, marketing, and distribution.  The Investigational Device Exemptions (IDE) regulation ([21 CFR 812](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=812)) describes three types of device studies: significant risk, non-significant risk, and exempt projects. |
| 1. What is the difference between a significant risk and non-significant risk device study?   As defined in 21 CFR 812(m), a significant risk device means an investigational device that:   * Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; * Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; * Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or * Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.   *A non-significant device study is one that does not meet the definition for a significant risk device study (as noted above).* |
| 1. Who decides whether a device study is significant risk or non-significant risk?   Sponsors are responsible for making the initial risk determination and presenting it to the IRB. The FDA is also available to help the sponsor, investigator, or the IRB in making the risk determination.  Unless the FDA has already made a risk determination for the study, the IRB must review the sponsor’s significant risk or non-significant risk determination for every investigational device study reviewed and modify the determination if the IRB disagrees with the sponsor.  If the FDA has already made the significant risk or non-significant risk determination for the study, the agency’s determination is final. |
| 1. What is an IDE?   An Investigational Device Exemption (IDE) allows an investigational device to be used in a clinical study in order to collect safety and/or effectiveness data. All clinical evaluations of investigational devices [unless exempt per  [21 CFR 812.2(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.2)] must have an approved IDE before the study is initiated.  Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.  For significant risk device studies, the investigator or sponsor must obtain an Investigational Device Exemption (IDE) from the FDA.  If the IRB (or FDA) determines that a clinical investigation involves a non-significant risk device that is not exempt from the IDE regulations, an IDE application does NOT need to be submitted to and approved by the FDA. However, compliance with a subset of the full IDE requirements [[21 CFR 812.2(b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2)] is needed. This is known as an ‘Abbreviated IDE’.  An IRB’s non-significant risk device determination serves as the FDA’s surrogate review, approval, and continuing review of the non-significant risk device study. A non-significant risk device study may start at the institution as soon as the IRB reviews and approves the study and without prior approval by the FDA. |
| 1. Does the UNE IRB review both significant risk and non-significant risk device studies?   No. The UNE IRB only reviews non-significant risk device studies.  Significant risk device studies MUST be submitted to a qualified, accredited external IRB for review.  UNE-affiliated investigators involved in a significant risk device study must also submit a ‘Notification Form: Participation in a Research Study Approved or Exempted by an External IRB’ to [irb@une.edu](mailto:irb@une.edu) for review and acknowledgement. The Notification Form is available on the UNE IRB [website](https://www.une.edu/research/integrity/irb). |
| 1. What is the best course of action when it is unclear if the investigational device study meets the definition of a non-significant risk device?   When in doubt, it is highly recommended that the sponsor or sponsor-investigator reach out to the FDA for a consultation via [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov) or 1-(800)-638-2041 prior to submitting their application to the IRB for review.  Please note that the issuance of a formal study risk determination letter from the FDA may take up to 90 days. |
| 1. What is the definition of an investigator, sponsor, and sponsor-investigator?   Investigator: An investigator is an individual who actually conducts a clinical investigation (e.g., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject). In the event of an investigation being conducted by a team of individuals, ‘investigator’ refers to the responsible leader of that team.  Sponsor: A sponsor is a person or other entity that initiates but does not actually conduct the investigation. Typically, the sponsor is responsible for overall study preparation, planning, and control. An entity other than the individual (e.g., a corporation or an agency) which uses one or more of its employees to conduct an investigation that it has initiated is considered to be a sponsor, not a sponsor-investigator, and the employees are considered investigators. The sponsor of an IDE must be located in the United States.  Sponsor-Investigator: An individual who both initiates and actually conducts, alone or with others, a clinical investigation (e.g., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject). The term does not, for example, include a corporation or agency. *The obligations of a sponsor-investigator include those of a sponsor AND those of an investigator (see Appendix B & C).* |
| 1. What are the regulatory responsibilities of the sponsor and the investigator who are involved in a non‑significant risk device study?   Since there is no submission to the FDA for an abbreviated IDE, it is important to establish in writing who is the sponsor (e.g., the investigator, device manufacturer, etc.) before the study begins so that it is understood who is responsible for complying with the sponsor requirements.   * The regulatory responsibilities of the sponsor are outlined within Appendix B. * The regulatory responsibilities of the investigator are outlined within Appendix C.   *Note: If an individual assumes the role of both sponsor and investigator (‘sponsor-investigator’), they must comply with all regulatory responsibilities for both sponsor and investigator.* |

**Appendix B: Sponsor Checklist**

| Sponsor Responsibilities | Required Action(s) | Reviewed / Completed? |
| --- | --- | --- |
| Label the device in accordance with 21 CFR 812.5 | The labeling of an investigational device must not contain any false or misleading statements, nor imply that the device is safe or effective for the purposes being investigated.  An investigational device or its immediate package must bear a label with the following information:   * The name and place of business of the manufacturer, packer, or distributor. * The quantity of contents, if appropriate. * The statement: “CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.” * All relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. | Yes  No |
| Obtain and maintain IRB approval  21 CFR 812.2 (b)(1)(ii) | Present the reviewing IRB with a brief explanation of why the device is not a significant risk device. | Yes  No |
| Ensure investigators obtain consent  21 CFR 812 (b)(1)(iii) | Ensure that each investigator participating in an investigation of the device obtains informed consent under 21 CFR 50 for each subject under the investigator’s care and documents the consent, unless documentation is waived by an IRB under 21 CFR 56.109(c). | Yes  No |
| Comply with the requirements of 21 CFR 812.46 for monitoring investigations | A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator’s participation in the investigation.  A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject. | Yes  No |
| Maintains the records required under 21 CFR 812.140 (b)(4) & (5) | The following records must be maintained, consolidated into one location, and be available for FDA inspection and copying:   * The name and intended use of the device. * The objectives of the investigation. * A brief explanation of why the device is not a significant risk device. * The name and address of each investigator. * The name and address of each IRB. * A statement of the extent to which the good manufacturing practices (21 CFR 820) will be followed in manufacturing the device. Any other information required by the FDA. * Complaints and adverse device effects, whether anticipated or not. | Yes  No |
| Makes the reports required under 21 CFR 812.150 (b)(1) through (3) and (5) through (10) | Reports to be made:   * **Unanticipated Adverse Device Effects** – Report to FDA, investigators, and reviewing IRB’s within 10 working days after the sponsor first receives notice of the effect. * **Withdrawal of IRB Approval** – Report to FDA, investigators, and reviewing IRB’s within 5 working days after receipt of the withdrawal of approval. * **Withdrawal of FDA Approval** – Report to all investigators and reviewing IRB’s within 5 working days after receipt of notice of the withdrawal of approval. * **Annual Progress Reports** – Investigator to report to all reviewing IRBs. * **Recalls and Device Disposition** – Report to FDA, investigators, and all reviewing IRB’s within 30 working days after any request that an investigator return, repair, or otherwise dispose of any units of a device. * **Final Report** – Report to all investigators and reviewing IRB’s within 6 months after termination or completion of the study. * **Failure to obtain informed consent** – Report to FDA and IRB within 5 working days of receipt of notice. * **Significant Risk Device Determination** – If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB’s determination within 5 working days after the sponsor first learns of the IRB’s determination. * **Other Reports** – Upon request by the reviewing IRB or FDA. | Yes  No |
| Ensures participating investigators maintain records required by 21 CFR 812.140 (a)(3)(i) | Records of each subject’s case history and exposure to the device, including:   * Case report forms and supporting data. * Signed and dated consent forms. * Medical records, including progress notes of the physician, the individual’s hospital chart(s), and the nurses’ notes. * Documents demonstrating prospective informed consent and, for any use of a device without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. | Yes  No |
| Ensures participating investigators make reports required by 21 CFR 812.150 (a)(1), (2), (5), and (7) | Reports to be made by participating investigators include:   * **Unanticipated Adverse Device Effects**. Submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during the investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. * **Withdrawal of IRB Approval**. Report to the sponsor within 5 working days a withdrawal of approval by the reviewing IRB of the investigator’s part of an investigation. * **Failure to obtain informed consent**. Report to the sponsor and the reviewing IRB within 5 working days after the event. * **Other reports requested by a reviewing IRB or the FDA**. | Yes  No |
| Evaluate any unanticipated adverse device effects  21 CFR 812.46 (b) | A Sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect.  A sponsor who determines that an unanticipated adverse device effect present an unreasonable risk to subjects must terminate all investigations or parts of the investigations presenting that risk as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination, and no later than 15 working days after the sponsor first received notice of the effect.   * For a non-significant risk device investigation, a sponsor may not resume a terminated investigation without IRB approval. If the non-significant risk study was terminated for unanticipated adverse device effects, the sponsor must also obtain FDA approval. | Yes  No |
| Comply with the prohibitions in 21 CFR 812.7 against promotion and other practices | A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator cannot:   * 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 a higher price than that necessary to recover costs of manufacture, research, development, and handling. * Unduly prolong an investigation. If data developed by the investigation indicate that a class II device 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. | Yes  No |
| Register the study on ClinicalTrials.gov, if applicable | As applicable, register the study on [clinicaltrials.gov](https://clinicaltrials.gov/).  The HHS Final Rule and the NIH Policy describe which studies must be registered and results posted on ClinicalTrials.gov. Click [here](https://www.nejm.org/doi/full/10.1056/nejmsr1611785) for more information. | Yes  No |

**Appendix C: Investigator Checklist**

| Investigator Responsibilities | Required Action(s) | Reviewed / Completed? |
| --- | --- | --- |
| Ensure investigators obtain consent  21 CFR 812 (b)(1)(iii) | Ensure that each investigator participating in an investigation of the device obtains informed consent under 21 CFR 50 for each subject under the investigator’s care and documents the consent, unless documentation is waived by an IRB under 21 CFR 56.109(c). | Yes  No |
| Maintain subject records  21 CFR 812.140 (a)(3)(i) | Maintain the records of each subject’s case history and exposure to the device, including:   * Case report forms and supporting data. * Signed and dated consent forms. * Medical records, including progress notes of the physician, the individual’s hospital chart(s), and the nurses’ notes. * Documents demonstrating prospective informed consent and, for any use of a device without informed consent, any written concurrences of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. | Yes  No |
| Make required reports  21 CFR 812.150 (a)(1)(2)(5) and (7) | Reports to be made include:   * **Unanticipated Adverse Device Effects**. Submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during the investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. * **Withdrawal of IRB Approval**. Report to the sponsor within 5 working days a withdrawal of approval by the reviewing IRB of the investigator’s part of an investigation. * **Failure to obtain informed consent**. Report to the sponsor and the reviewing IRB within 5 working days after the event. * **Other reports requested by a reviewing IRB or the FDA**. | Yes  No |
| Financial disclosure, where applicable  21 CFR 812.110 (d) | If the data in a non-significant risk device study is submitted in a marketing application, 21 CFR 54 – Financial Disclosure applies. The clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the IDE applicant (or sponsor) to submit certification or disclosure of financial interests.   * The investigator must update the information if any relevant changes occur during the course of the investigation, and for one year following completion of the study. | Yes  No |