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| Device Information Form  Use this form to give device specific information to supplement the Protocol. | C:\Users\cbcholka\AppData\Local\Microsoft\Windows\INetCache\Content.Word\UNM_OfficeInstitutionalReviewBoard_Horizontal_RGB.PNG  1805 Sigma Chi NE | Tel: (505) 277-2644  Website: irb.unm.edu | Email: [IRBMainCampus@unm.edu](mailto:IRBMainCampus@unm.edu) |

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| Project Identification | |
| Title of the project: |  |

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from [21 CFR 812](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812) are described in §812.2(c) of the IDE regulations. Significant Risk (SR) device projects are governed by the Investigational Device Exemptions (IDE) regulations (21 CFR Part 812). Non-Significant Risk (NSR) device projects have fewer regulatory controls than SR projects and are governed by the abbreviated requirements [21 CFR 8 l 2.2(b)]. The major differences are in the approval process and in the record keeping and reporting requirements. If a researcher proposes the initiation of a claimed NSR device project to the IRB, and if the IRB agrees that the device project is NSR and approves the project, the project may begin without submission of an IDE application to FDA.

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| Device Information | | | |
| Manufacturing name & model number: |  | | |
| Is the device FDA approved for the proposed use? | | No | Yes |
| If no, specify the IDE # (if applicable): | |  | |

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| IDE Exempt Investigations. In order to be exempt from IDE regulations, the project must meet one of the following criteria: | | | | | | | |
| 1. It is a legally marketed device used in accordance with its labeling. | | | | | | No | Yes |
| 1. It is a diagnostic device that complies with the labeling requirements at 21 CFR 809.10(c) and the testing: | | | | | | | |
|  | 1. Is noninvasive; | | | | | No | Yes |
|  | 1. Does not require an invasive sampling procedure that presents significant risk; | | | | | No | Yes |
|  | 1. Does not by design or intention introduce energy into a subject; | | | | | No | Yes |
|  | 1. Is not used for diagnostic procedures without confirmation by another medical established diagnostic produce or procedures; | | | | | No | Yes |
| 1. Is consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk. | | | | | | No | Yes |
| 1. Is with a device intended solely for veterinary use; | | | | | | No | Yes |
| 1. Is with a device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects." | | | | | | No | Yes |
| **IMPORTANT!** If your device meets one or more of the criteria above, the device is IDE Exempt and does not require a risk determination. Do not complete the next section, sign and submit the form. | | | | | | | |
| Device Risk Decision (Do not complete if IDE Exempt) | | | | | | | |
| Is the device is banned in the United States: | | | | No | Yes | | |
| What is the risk level of the device? | | Significant Risk | Non-Significant Risk | | | | |
| *(Use the following questions to determine risk; all answers must be “No” to be considered Non-Significant Risk)* | | | | | | | |
|  | 1. Is it intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant? | | | | | No | Yes |
|  | 2. Is it 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? | | | | | No | Yes |
|  | 3. Is the device 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? | | | | | No | Yes |
|  | 4. Does the device otherwise presents a potential for serious risk to the health, safety, or welfare of a participant? | | | | | No | Yes |
| **IMPORTANT!** If your device is a Significant Risk Device, please contact the OIRB prior to submission. | | | | | | | |

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| Non-Significant Risk Device Information | |
| Provide a justification why the device does not pose a significant risk: |  |
| Describe how the device is stored securely: |  |
| Describe how the device is labeled (note that the device must be labeled as an investigational device, see FDA guidance): |  |
| Describe who has access to the device: |  |
| **IMPORTANT!** If applicable, submit a copy of all FDA/sponsor documents related to this device including IDE documentation and/or risk determinations. | |

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| Certification | |
| \* Signature below certifies that the information provided on this form is accurate and that the above titled research is in full compliance with the regulations, laws, and institutional requirements/policies governing human subject research. Exempt and abbreviated IDE requirements do not in any way exempt you from complying with FDA requirements including the requirements for informed consent and initial and continuing review conducted by the UNM IRB. You must monitor the research and report to the UNM IRB and FDA noncompliance, adverse events, and unanticipated problems. If abbreviated IDE requirements apply, you will maintain records and reporting according to the requirements at 21 CFR 812.140 and 150 (see FDA guidance). You 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 an investigational device is safe or effective for the purposes for which it is being investigated. | |
| Principal Investigator | |
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| \* Signature | Date |