**Institutional Review Board** …for the protection of human participants in research

North Dakota State University

Sponsored Programs Administration Date of Receipt

R1, Research & Technology Park

[www.ndsu.edu/irb](http://www.ndsu.edu/irb) 231-8908(ph) 231-8098(fax)

**Investigational Use of Medical Devices**

*Include this attachment for research involving investigational use of a medical device. Studies performed to determine safety and effectiveness of a device constitute ‘investigational use’, and include unapproved devices, as well as approved devices being evaluated for a new indication. Refer to SOP 11.6 Review of FDA-Regulated Research for more information.*

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| **Protocol Information** |

Title:

Principal investigator\*, Dept. affiliation:

Co-investigator\*, Dept. affiliation:

\*Attach current cv or other documentation of qualifications to conduct device research

Study sponsor:

Name of company:

None - PI is sponsor-investigator

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| **Device Information** |

1. Name of device and manufacturer/source:

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1. Is the device FDA approved for human use?

No

Yes: *Attach copy of approved device labeling or package insert.*

Will the device be used in accordance with the FDA approved indications?

Yes

No – describe how investigational use will differ from the approved use:

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1. Detailed description of device and proposed research use of device: *(may be provided as an attachment, including photos or diagrams)*

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1. Describe results of prior investigations, animal studies, or previous research with the device: *(may be provided as an attachment)*

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1. Describe plan for monitoring the clinical investigation to ensure the safety of subjects: *(may be provided as an attachment)*

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1. Is the research or clinical investigation required to be registered with ClinicalTrials.gov, or another registry?

No Yes

*Registration with ClinicalTrials. gov is the responsibility of the sponsor or sponsor-investigator, and applies to clinical trials, defined as: any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies do not require registration.*

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| **Risk Determination**  *Unless the FDA has already determined risk for the study, provide an initial assessment as significant (SR), or nonsignificant (NSR) risk. The FDA has ultimate authority regarding risk determination of an investigational device.* |

*NOTE: The determination of risk is based on: the type of device, proposed use of device, nature of harm that may result from use, and whether or not participants must undergo any additional procedures for the study.*

Regarding the proposed research use, this device:

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| Yes No | 1. is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject |
| Yes No | 1. is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject |
| Yes No | 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 subject, or |
| Yes No | 1. otherwise presents a potential for serious risk to the health, safety or welfare of a subject |

**Significant risk** **(SR)** **device**.

If *any* response to items 1 – 4 above is ‘Yes’, the device is classified as a significant risk (SR) device. *Examples of significant risk devices are found on the FDA website at:* [*http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf*](http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf)

**Non-significant risk** **(NSR)** **device**.

If *all* responses to 1 – 4 above are ‘No’, the device is classified as a non-significant risk (NSR) device. *Examples of non-significant risk devices are found on the FDA website at:* [*http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf*](http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf)

Provide a justification for the assessment of non-significant risk:

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| **Investigational Device Exemption (IDE) Requirements**  All r*esearch involving investigational use of a medical device requires an approved IDE, unless exempt from IDE regulations.* |

**SR device study:**

Unless exempt from IDE requirements, the sponsor or sponsor-investigator is responsible for submission of an IDE application to the FDA for approval prior to conducting research involving significant risk devices, following procedures outlined in [21 CFR 812.20](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.2). In addition to the abbreviated requirements cited below, the sponsor and investigator or sponsor/investigator are responsible for compliance with the full requirements as outlined in [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.2).

IDE# assigned by FDA:       - Provide documentation of FDA approval of the IDE

Holder of the IDE:  Sponsor  Sponsor-investigator

**NSR device study:**

An application to the FDA is not required prior to conducting research involving non-significant risk devices. Unless exempt from IDE requirements, the agency considers such devices to hold approved IDEs, provided that the device is not a banned device, IRB approval is obtained, and the sponsor, or sponsor-investigator complies with the FDA ‘abbreviated requirements’ as specified in [21 CFR Part 812.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.2):

* + labeling of the device for investigational use
  + IRB approval
  + informed consent ofsubjects
  + monitoring the investigation
  + recordkeeping and reports
  + prohibitions against promotion and marketing

**Exempt from IDE requirements:**

Research and clinical investigations involving any of the following investigational devices are exempt from IDE requirements: *(mark as applicable)*

a device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time

a device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

a diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:

(i) Is noninvasive,

(ii) Does not require an invasive sampling procedure that presents significant risk,

(iii) Does not by design or intention introduce energy into a subject, and

(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

a device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

a device intended solely for veterinary use.

a device shipped solely for research on or with laboratory animals and labeled in accordance with 812.5(c).

a custom device as defined in 812.3(b), unless the device is being used to determine safety and effectiveness for commercial distribution.

Provide justification for exemption from the IDE requirements:

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**\*\*NOTE\*\* Research and clinical investigations exempt from IDE requirements are not exempt from the requirement for informed consent and IRB review.**

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| ***In vitro* Diagnostic Devices  N/A**  Request for waiver of informed consent |

*In vitro* diagnostic (IVD) devices are used to collect, prepare or examine specimens (e.g., blood, serum, urine, spinal fluid, tissue specimens) after removal from the body.

Research utilizing human specimens for investigational IVD studies may qualify for a waiver of the requirement to obtain informed consent from the donors of the specimens, provided the study meets ALL the following criteria:

exempt from IDE requirements (see previous section)

specimens (and any associated clinical information) are provided to researchers without identifiers; supplier has policies to prevent release of personal information

only ‘leftover’ specimens are used (e.g., repositories, or remnants of specimens collected for routine clinical care that would have been discarded)

individuals caring for the patients are different from, and do not share information about the patient with those conducting the investigation

study has been reviewed by an IRB

IVD studies do *not* qualify for waiver of informed consent if:

specimens were collected specifically for the study (were not ‘left-over’ from routine clinical care or other research)

test results will be reported to the health care provider.

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| *The signature below certifies that, as principal investigator for this project, all information submitted pursuant to research subject to 45 CFR 46 and FDA regulations is truthful and accurate and no material fact has been omitted.*  Principal Investigator Date |

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| **Risk assessment:  Significant risk (SR)  Non-significant risk (NSR)  IDE exempt**  **IVD informed consent waiver:  approved  not approved IRB meeting date : \_\_\_\_\_\_\_\_** |
| **IRB Signature: Date:** |
| **Comments:** |