**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)

**Planned Emergency Research**

*Include this attachment to request a waiver of informed consent for research evaluating emergency treatments or interventions. Refer to SOP 11.7 Review of Planned Emergency 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

Study sponsor:

**[ ]** Name of company:

**[ ]** None -PI is sponsor-investigator

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| **Additional determinations for emergency research consent waiver***The IRB must find and document the following conditions, with the concurrence of a licensed physician member or consultant.* |

1. Necessity for emergency setting:

An emergency setting is necessary to conduct the research because:

1. The participants are in a life-threatening situation.
2. Available treatments are unproven or unsatisfactory.
3. The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

*Describe how the research would meet each requirement:*

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1. Consent not likely attainable.

Obtaining informed consent is not feasible because all the following are true:

1. The subjects will not be able to give their informed consent as a result of their medical condition;
2. The intervention involved in the research must be administered before consent from the subjects’ legally authorized representatives is feasible, AND
3. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

*Describe how the research would meet these requirements:*

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1. Prospect of direct benefit.

Participation in the research holds out the prospect of direct benefit to the subjects because all the following are true:

1. Subjects are facing a life-threatening situation that necessitates intervention;
2. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; AND
3. Risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

*Describe how the research would meet these requirements:*

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1. Research not practicable without waiver.

*Describe why the research could not practicably be carried out without the waiver of informed consent:*

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1. LAR contact within therapeutic window.

The proposed research protocol defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. *(Efforts made to contact representatives will be summarized and made available to the IRB at the time of continuing review.)*

*Describe how the research would meet this requirement:*

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1. Approval of consent process.

If obtaining informed consent is feasible, a process and informed consent documentis proposed for use with a participant or their legally authorized representative.

*Describe a consent process to be used where feasible; attach consent document.*

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| **Additional protections***The IRB must find and document that the research includes the following additional protections.* |

1. Community consultation.

Members of the communities in which the research will be conducted and from which the subjects will be drawn are consulted about the research (may include consultation carried out by the IRB, where appropriate).

*Describe how the research would meet this requirement:*

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1. Public disclosure.

Sufficient information is provided to the communities in which the research will be conducted and from which the subjects will be drawn. This includes prior notice of the plans for the research and its risks and expected benefits, as well as results after completion of the study.

*Describe how the research would meet this requirement:*

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1. Data monitoring.

An independent data monitoring committee is established to exercise oversight of the research.

*Describe how the research would meet this requirement:*

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1. Notification of family members.

When consent is not feasible from either the subject or their LAR, the investigator has a plan to attempt contact with family member(s) to ask whether or not they object to participation in the research.

*Describe how the research would meet this requirement:*

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1. Notification of participants.

The investigator has a plan to inform each subject, at the earliest opportunity, or their legally authorized representative or family member of:

* the subject’s inclusion in the research
* details of the research and other information contained in the informed consent document
* their choice to discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is already entitled.

*Describe how the research would meet this requirement:*

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**- - - - - - - - - -FOR IRB OFFICE USE ONLY - - - - - - - -**

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| **Waiver of informed consent is: [ ]  approved [ ]  not approved IRB meeting date : \_\_\_\_\_\_\_\_** |
| **IRB Signature: Date:** |
| **Comments:**  |