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| **IRB-HSR#/ UVA Study Tracking #       PI:**  **Reviewer:       Meeting Date:** |

The IRB-HSR is responsible for the review, approval, and continuing review of the clinical investigation and may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following as per 21CFR50.24(a):

**All of the following criteria must be answered “Yes” of “N/A” in order for the planned emergency research to be approved.**

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| **Yes  No** | **Life Threatening Situation:**  The IRB must find that the human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and 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. |
| **Yes  No** | **Informed Consent is Not Feasible:**  The IRB must find that obtaining informed consent is not feasible because:   * the subjects will not be able to give their informed consent as a result of their medical condition; * the intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible; and * there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research. |
| **Yes  No** | **Prospect of direct benefit:**  The IRB must find that participation in the research holds out the prospect of direct benefit to the subjects because:   * subjects are facing a life-threatening situation that necessitates intervention; * 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 * 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. |

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| **Yes  No** | **Research Impracticable in Absence of Waiver of Informed Consent:**  The IRB must find that the research could not practicably be carried out without the waiver of informed consent. |
| **Yes  No** | **Therapeutic Window:**  The IRB must find that the proposed investigational plan defines the length of the potential therapeutic window based on available scientific evidence and the investigator has committed to attempting to contact a legally authorized representative for each participant within that window of time and, if feasible, asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. ***The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.*** |

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| **Yes  No** | **Informed Consent Process and Documents:** The IRB must find that the investigator has provided an informed consent document and describes an informed consent process that meets the requirements of 21 CFR 50.25 (for FDA regulated research) or 45 CFR 46.116-117 (for non-FDA regulated research). This process will be used to obtain and document informed consent from the participant or a legally authorized representative.  The consent process includes the following:   * The investigator has summarized efforts that will be made to contact and obtain consent from legally authorized representatives as soon as possible upon identification of an eligible participant and make this information available to the IRB at the time of continuing review. * If obtaining consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the participant’s ***family member*** who is not a legally authorized representative, and asking whether he or she objects to the participant’s participation in the clinical investigation. ***The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.*** * If a legally authorized representative or family member is told about the clinical investigation and the ***participant’s condition improves***, the participant is also to be informed as soon as feasible. * If a participant is entered into a clinical investigation with waived consent and the ***participant dies*** before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the participant’s legally authorized representative or family member, if feasible. |

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| **Yes  No** | **Community Consultation and Public Disclosure:** The IRB must find that the investigator has provided an appropriate plan for consultation with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn. The IRB will determine whether it is appropriate for the IRB to carry out community consultation in addition to that performed by the investigator.   * **Prior to initiation of the clinical investigation**: The IRB must find that the investigator has provided an appropriate plan for public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, *prior to initiation of the clinical investigation*, of plans for the investigation and its risks and expected benefits. * ***Completion* *of the clinical investigation*:** The IRB must find that the investigator has provided an appropriate plan for public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. |
| **Yes  No** | **Independent Data Monitoring Committee:** The IRB must find that an independent data monitoring committee has been established to exercise oversight of the clinical investigation. |
| **Yes  No**  **N/A** | **Separate IND/IDE:**  The IRB must find that an IND or IDE has been obtained from the FDA specifically for the planned emergency research.   * *N/A if the study is not FDA regulated.* |
| **Yes  No** | **Vulnerable Populations:**  The IRB must confirm that the protocol does not allow the enrollment of prisoners or women known to be pregnant. |
| **Yes  No** | **Impact of Study Intervention on Pregnant Women or Fetus**  The IRB must find that the protocol has an appropriate plan for emergency testing prior to enrollment (if feasible and appropriate) or follow – up to ensure the safety of the pregnant woman or fetus after incidental enrollment. Any study procedures performed after pregnancy is identified must meet the criteria found under:  [Vulnerable Populations Checklist-Pregnant Women, Fetuses, Neonates](http://www.virginia.edu/vpr/irb/HSR_docs/Checklists/vulnerable_pop_pregnant_fetus_checklist.doc) |

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**Name (Scientific Reviewer) Date**