**FORM 5.2D: CHECKLIST - EMERGENCY RESEARCH CONDUCTED UNDER EXEMPTION FROM INFORMED CONSENT REQUIREMENTS**

CHECKLIST-EMERGENCY RESEARCH CONDUCTED UNDER EXEMPTION FROM INFORMED CONSENT REQUIREMENTS

STUDY: IDI REC TRACKING #

|  | **Yes** | **No** |
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| The protocol is under a separate investigational new drug application (IND) or investigational device exemption (IDE). |  |  |
| The protocol clearly identifies that the research may include participants who are unable to give informed consent. |  |  |
| The human participants are in a life-threatening situation that requires intervention, and |  |  |
| Available treatments are unproven or unsatisfactory, and |  |  |
| The collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions, and |  |  |
| The clinical investigation could not practicably be carried out without the waiver of informed consent: |  |  |
| The intervention under investigation must be administered before consent from the participants' legally authorized representatives is feasible; and |  |  |
| There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation. |  |  |
| There is evidence that participation in the research holds out the prospect of direct benefit to the participants: |  |  |
| 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 participants; and |  |  |
| Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard  therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity. |  |  |
| The protocol defines the length of the potential therapeutic window based on scientific evidence. |  |  |
| The IDI REC has reviewed and approved informed consent procedures and an informed consent document to be used with participants or their legally authorized representatives in situations where  use of such procedures and documents is feasible. |  |  |
| **The protocol includes documentation that the Investigator will make every reasonable effort to obtain informed consent within the therapeutic window by:** |  |  |
| Attempting to contact a legally authorized representative for each participant and obtain consent within the therapeutic window. |  |  |
| If a legally authorized representative is not reasonably available, 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. |  |  |
| Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. |  |  |
| That he or she may discontinue the participant's participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. |  |  |
| 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. |  |  |
| Procedures and information to be used when providing an opportunity for a family member to object to a participant's participation in the clinical investigation consistent with regulations and guidelines are acceptable. |  |  |
| **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.** |  |  |
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| **Community disclosure and consultation will be carried out.** |  |  |
| Consultation (including, where appropriate, consultation carried out by the IDI REC) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn will be carried out. |  |  |
| 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. |  |  |
| 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. |  |  |
| An independent data monitoring committee to exercise oversight of the clinical investigation will be established. |  |  |

Primary Reviewer Date