**The purpose of this form is to determine whether an Exception from Informed Consent (EFIC) wavier can be granted for planned emergency research** [**(21 CFR 50.24)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=50.24)**.**

* **Planned Emergency Research:** A systematic investigation of a condition experienced by individuals in a setting where the emergency circumstances require prompt action and generally provide insufficient time and opportunity to locate and obtain consent from each subject's legally authorized representative (LAR). Planned emergency research involves the prospective identification and enrollment of participants into a study.

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| **Basic Information** |
| **Title of Study:** |       |
| **Short Title:** |       |
| **Principal Investigator Name:** |       |
| **Section 1: Status of Subjects (21 CFR 50.24 (a)(1))** |
| Explain how human subjects are in a life-threatening situation:       |
| Explain how available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized investigations, is necessary to determine the safety and effectiveness of particular interventions:      |
| **Section 2: Obtaining Consent is Not Feasible (21 CFR 50.24(a)(2))** |
| Explain why the subject will not be able to give their informed consent as a result of their medical condition:      |
| Explain why the intervention under investigation must be administered before consent is obtained from the subjects’ legally authorized representatives (LAR):      |
| Describe why there is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the clinical investigation:      |
| **Section 3: Prospect of Direct Benefit (21 CFR 50.24(a)(3))** |
| Describe how participation in the study holds out the prospect of direct benefit to the subjects because they are facing a life-threatening situation that necessitates intervention:      |
| Describe the appropriate animal and other preclinical studies that have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual participants:      |
| Describe how the 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, and what is known about the risks and benefits of the proposed intervention or activity:      |
| **Section 4: Waiver of Consent ((21 CFR 50.24(a)(4))** |
| Explain why the investigation could not be carried out without the waiver:      |
| **Section 5: Contact of Legally Authorized Representatives (LAR) (21 CFR 50.24(a)(5))** |
| Describe the length of the potential therapeutic window based on scientific evidence proposed in theinvestigational plan:      |
| Explain that the investigator has committed to attempting to contact a legally authorized representative (LAR) for each subject within the potential therapeutic window of time. If feasible, the investigator has committed to asking the LAR contacted for consent within that window rather than proceeding without consent:       |
| Describe how the investigator will summarize efforts made to contact the LAR and make this information available to the IRB at the time of renewal:      |
| **Section 6: Informed Consent Procedures (21 CFR 50.24(a)(6))** |
| Describe how and when you will consent subjects/LAR during the study:      |
| **Section 7: Additional Protections of Subjects (21 CFR 50.24(a)(7))** |
| Describe the plan for a consultation (including consultation by the IRB) with appropriate representatives of the communities in which the investigation will be conducted and from which the participants will be drawn:       |
| Describe the plan for public disclosure to the communities, in which the investigation will be conducted and from which participants will be drawn, informing them of the investigation and its risks and expected benefits, for the communities in which subjects will be drawn, prior to the initiation of the clinical investigation:      |
| Describe the 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:      |
| Describe the independent data monitoring committee that will exercise oversight over the clinical investigation:      |
| If obtaining consent is not feasible and a LAR is not reasonably available, describe the process, if feasible, that the investigator will take in order to contact a family member who is not a LAR within the therapeutic window and asking whether the family member objects to the subject’s participation in the clinical investigation:      |
| Describe how the investigator will summarize efforts made to contact the LAR and make this information available to the IRB at the time of renewal:      |
| **Section 8: Post Enrollment Notification (21 CFR 50.24(b))** |
| Describe how the investigator will ensure that each subject, LAR, or family member will be notified of the subject's enrollment in the study, the details of the study, and other information in the informed consent:      |
| Describe how the investigator will inform each subject, LAR, or family member that he or she may discontinue the subject's enrollment at any time without penalty or loss of benefits to which the participant is otherwise entitled:       |
| If a LAR or family member is told about the study and the subject's condition improves, describe the process to ensure the subject is informed as soon as feasible:      |
| If a subject is enrolled with waived consent and dies before a LAR or family member can be contacted, describe how information about the study will be provided to the LAR or family member, if feasible:      |
| **Section 9: Record Keeping (21 CFR 50.24(c))** |
| Explain how records will be kept and made accessible for inspection and copying by the FDA:       |
| **Section 10: IND or IDE *(if applicable)* (21 CFR 50.24(d))** |
| Has a separate investigational new drug (IND) or investigational device exemption (IDE) been obtained for the study that clearly identifies the protocol as having subjects who are unable to consent:      |