P.I. Emergency Research Checklist – Research conducted under 21 CFR 50.24

Study Name:

Principal Investigator:

	Yes	No
The protocol is being performed under a separate investigational new drug application (IND) or investigational device exemption (IDE).		
The protocol clearly identifies that the research may include subjects who are unable to give informed consent.		
An independent data monitoring committee has been established to exercise oversight of the investigation. *(Note: The DSMB must be independent of the study team, appropriately comprised, and described to the IRB.)*		
The human subjects are in a life threatening situation.		
Available treatments are unproven or unsatisfactory.		
The collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.		
The clinical investigation could not practicably be conducted without a waiver.		
Obtaining informed consent is not feasible because:		
Subjects will not be able to give consent as a result of their medical condition;	☐	☐
The intervention must be administered before investigators can obtain consent from a legally authorized representative. (*Note – the protocol should address the possibility and probability of an emergency responder being able to identify, interact and obtain consent from the patient's legally authorized representative*);	☐	☐
There is no reasonable way to identify prospectively the individuals likely to become eligible for participation.	☐	☐
There is evidence 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 investigation 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.	☐	☐
The protocol defines the length of the potential therapeutic window based on scientific evidence.		
Informed consent procedures and an informed consent document will be used with subjects 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 subject within that window, and if feasible, asking the legally authorized representative for consent within that window; and	☐	☐
if a legally authorized representative is not reasonably available, attempting to contact, within the therapeutic window, the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation.	☐	☐

(Note: Investigators must outline steps that will be taken to obtain consent including proposed letters or phone scripts, and how this will be documented.)		
Procedures are in place to inform, at the earliest opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the investigation, the details of the investigation and other information contained in the informed consent document;		
Procedures are in place to inform, at the earliest opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.		
If a legally authorized representative or family members is informed about the investigation and the subject's condition improves, steps will be taken to inform the subject as soon as feasible.		
If a subject entered into the investigation dies before a legally authorized representative for family member can be contacted, information about the investigation will be provided to the legally authorized representative or family member, if feasible.		
Investigators must outline a proposed plan for steps 1, 2, & 3 below. A more detailed plan may be submitted as part of the initial review or subsequent to the initial review. The IRB application must indicate whether a more detailed plan will follow.		
1. Consultation with members of the communities in which the investigation will be conducted and from which the subjects will be drawn to assess, in a qualitative phase, their perceptions of the risks and benefits of the proposed study and, if necessary, to assess, in a quantitative phase, their tradeoffs among the risks and benefits, that is, the relative importance they place on each.		
2. Public disclosure prior to the initiation of the clinical investigation to inform leaders and members of the communities defined in (1) of plans for the investigation.		
3. Public disclosure after completion of the investigation to inform the public defined in (1) of the final demographics and results of the study.		