

Institutional Review Board, Committees for the Protection of Human Subjects

# REviewer Checklist: § 50.24 Exception From Informed Consent Requirements For Emergency Research.

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| Protocol Information | |
| **Protocol Number and Title**: | |
| Requirements under 21 CFR 50.24 | |
| (a) The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that in- formed 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: | |
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| §50.24(a) | |
| Yes  No | 1) 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 effective- ness of particular interventions. |

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| Yes  No | (2) Obtaining informed consent is not feasible because:  (i) The subjects will not be able to give their informed consent as a result of their medical condition;  (ii) The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and  (iii) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation. |

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| Yes  No | (3) Participation in the research holds out the prospect of direct benefit to the subjects because:  (i) Subjects are facing a life-threatening situation that necessitates intervention;  (ii) Appropriate animal and other preclinical studies have been con- ducted, 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  (iii) 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. |

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| Yes  No | (4) The clinical investigation could not practicably be carried out without the waiver. |

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| Yes  No | (5) The proposed investigational plan 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. 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 | 6) The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with §50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject’s participation in the clinical investigation consistent with paragraph (a)(7)(v) of this section. |

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| Yes  No | (7) Additional protections of the rights and welfare of the subjects will be provided, including, at least:.  (i) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn; |

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| **Plan for Community Consultation** |

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| **Results of Community Consultation** |
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| **Public Disclosure Before the Study Begins** |

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| Yes  No | (ii) Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits; |

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| **Public Disclosure After the Study is Completed or Terminated** |

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| Yes  No | (iii) 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; |

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| Yes  No | (iv) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and |
| Yes  No | (v) If obtaining informed 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 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. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review. |

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| §50.24(b) |

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| b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible 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 clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the 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 member is told about the clinical investigation and the subject’s condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject’s legally authorized representative or family member, if feasible. |

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| Yes  No | Plan for informing subjects is appropriate |
| Yes  No | If the parent or LAR is not available there is a plan for informing a family member; |
| Yes  No | Parent, LAR or family is informed that they may discontinue the subject’s participation |
| Yes  No | Parent, LAR or family member cannot be informed of subject’s participation prior to subject’s death, information is provided after subject’s death. |
| Yes  No | Informed consent will be sought for subject’s continued participation. (This is not required by the regulations but may be included as part of the study plan.) |

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| §50.24(c) |

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| Yes  No | (c) The IRB determinations required by paragraph (a) of this section and the documentation required by paragraph (e) of this section are to be retained by the IRB for at least 3 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA in accordance with § 56.115(b) of this chapter. |

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| §50.24(d) |

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| Yes  No | (d) The sponsor has obtained a separate IND for the drug(s) under study from the FDA. |
| §50.24(e) | |
| Yes  No | (e) If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under paragraph (a) of this section or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. |

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| **Required and Recommended Stipulations** (if any) |
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| **Recommendations** | | |
| Approve plan as submitted  Approval with Modifications Required §  Deferral pending Required Modifications  Disapproval | **Revisions to be reviewed by:**  Review by Chair or Designee  Full Committee | |
| **IRB Reviewer Signature:** | | **Date:** |

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| **Additional IRB Responsibilities** | |
| Information to be provided to sponsor about Community Consultation | |
| Yes  No | Plans are in place to: promptly provide to the sponsor in writing a copy of the information that has been publicly disclosed about the initiation of the study under 21 CFR 50.24(a)(7)(ii) (Community Consultation): see 21 CFR 56.109(g) |

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| Information to be provided to sponsor about Public Disclosure |

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| Yes  No | Plans are in place for the IRB to promptly provide to the sponsor in writing a copy of the information that has been publicly disclosed following completion of the study (21 CFR 50.24(a)(7)(iii) (Public Disclosure); 21 CFR 56.109(g), 312.54(a) and 812.47(a)). |

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