

5.6 Exceptions from Informed Consent Requirements for Emergency Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for IRB review and approval of an exception from informed consent requirements for emergency research.

2.0 Policy

- **2.1.** It is the policy of the Organization that an exception from informed consent requirements for emergency research must be in full compliance with the requirements of 21 CFR 50.24 for FDA-regulated research.
 - **2.2.** It is the policy of the Organization that the informed consent requirements of 45 CFR 46.116 and 45 CFR 46.408 may be waived for emergency research not subject to 21 CFR 50, provided the IRB has approved both the research and a waiver of informed consent and has found and documented that conditions for emergency research contained in the Secretarial waiver document have been met [61 FR 51531, 1996].
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3.0 Definition

- **3.1. *Emergency Research*** means a planned clinical investigation that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory
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4.0 Requirements

- **4.1.** For research which is subject to the FDA regulations at 21 CFR 50.24, the IRB may approve the investigation without requiring that informed consent for all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is an IRB member or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents that each of the conditions under Section 4.3 below have been satisfied.
- **4.2.** For research not subject to FDA regulations, the IRB may approve the research without requiring that informed consent for 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 research) finds and documents 1) that the research is not subject to regulations codified by the FDA at 21 CFR Part 50, and (2) that the conditions under Section 4.3 below have been satisfied. In addition, this documentation must be submitted to OHRP.
- **4.3.** Conditions for granting an exception from informed consent for emergency research are as follows:
 - **4.3.1.** 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 effectiveness of particular interventions.
 - **4.3.2.** Obtaining informed consent is not feasible because:
 - **4.3.2.1.** The subjects will not be able to give their informed consent as a result of their medical condition, and
 - **4.3.2.2.** The intervention under investigation must be administered before informed consent from the subjects' legally authorized representatives is feasible, and
 - **4.3.2.3.** There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation or research.
 - **4.3.3.** Participation in the research holds out the prospect of direct benefit to the subjects because:
 - **4.3.3.1.** Subjects are facing a life-threatening situation that necessitates intervention, and
 - **4.3.3.2.** Appropriate animal and other pre-clinical 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
 - **4.3.3.3.** 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.
 - **4.3.4.** The clinical investigation could not practicably be carried out without the waiver.
 - **4.3.5.** The protocol defines the length of the potential therapeutic window based on

- 4.3.6. The PI will attempt to contact a LAR for each subject within the therapeutic window and, if feasible, ask the LAR for informed consent within that window rather than proceeding without informed consent.
- 4.3.7. The PI will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review.
- 4.3.8. The IRB has reviewed and approved informed consent procedures and an ICF consistent with 21 CFR 50.25/45 CFR 46.116 and 46.117. These procedures and the ICF are to be used with subjects or their LAR in situations where use of such procedures and documents is feasible.
- 4.3.9. 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.
- 4.3.10. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - 4.3.10.1. 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.
 - 4.3.10.2. 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.
 - 4.3.10.3. 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.
 - 4.3.10.4. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
 - 4.3.10.5. If obtaining informed consent is not feasible and a LAR is not reasonably available, the PI has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the clinical investigation.
 - 4.3.10.6. The PI will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
- 4.4. 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 LAR 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 ICF.
 - 4.4.1. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a LAR 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.
 - 4.4.2. If a LAR 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.
 - 4.4.3. If a subject is entered into a clinical investigation with waived informed consent and the subject dies before a LAR or family member can be contacted, information about the clinical investigation is to be provided to the subject's LAR or family member, if feasible.
- 4.5. Protocols subject to FDA regulations and involving an exception to the informed consent requirement must be performed under an FDA approved separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to informed consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.
- 4.6. If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception, or because of other relevant ethical concerns, the IRB will document its findings and provide these findings promptly in writing to the PI and to the sponsor of the clinical investigation.
- 4.7. The IRB determinations are to be retained by the IRB for at least 7 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA.

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