

	Institutional Review Board	
Effective: July 16, 2008	Revised: May 25, 2016	Revision: 2
Responsibility: OIRB		Page 1 of 4

Planned Emergency Research  
Exception from Informed Consent Requirements  
Policy and Procedure

**Table of Contents**

[Policy](#)

[Procedure](#)

[IRB Initial Review of Research Subject to FDA and DHHS Regulations](#)

[IRB Initial Review of Research Subject to DHHS Regulations only](#)

[Continuation Review](#)

[References](#)

I. Policy

- A. The IRB determines and documents whether the research is subject FDA regulations.
  - 1. If FDA regulated, the IRB reviews the study in accordance with [21 CFR 50.24](#) and [DHHS published waiver](#).
  - 2. If not FDA regulated, the IRB reviews the study in accordance with the [DHHS published waiver](#).
- B. The IRB documents and reports to OHRP planned emergency research not subject to FDA regulations that is approved under the requirements of the HHS Secretarial waiver under (45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings
- C. The IRB does not approve this waiver for research involving prisoners (subpart C of 45CFR46), research involving fetuses, pregnant women, and human in vitro fertilization (subpart B of 45CFR46), or any [VA research](#).

II. Procedure

- A. Initial review of research
  - 1. The convened IRB determines whether the research activity is subject to 21 CFR § 50. If the research is FDA regulated, the IRB follows the FDA regulatory criteria to allow an exception to the requirement to obtain consent (Sec. 50.24) and DHHS criteria as follows:
    - a) The IRB may approve the planned emergency research without requiring that informed 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 research) finds and documents each of the following: (Note: additional guidance related to the required determinations is provided in the [FDA Information Sheet on Exception from Consent in Emergency Research](#)) :
      - (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. (all three must be true)
      - (2) Obtaining informed consent is not feasible because (all three must be true):

- (a) The subjects will not be able to give their informed consent as a result of their medical condition;
  - (b) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
  - (c) There is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the clinical investigation.
- (3) Participation in the research holds out the prospect of direct benefit to the subjects because (all three must be true):
- (a) Subjects are facing a life-threatening situation that necessitates intervention;
  - (b) 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
  - (c) 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) The clinical investigation could not practicably be carried out without the waiver.
- (5) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has provided a plan to attempt to contact a legally authorized representative for each subject within that window of time and, if feasible, to ask the legally authorized representative contacted for consent within that window rather than proceeding without consent.
- (6) The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with FDA and HHS regulations. The procedures for obtaining informed consent 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:
- (a) Consent in an emergent setting may require a short form consent
  - (b) Procedure if subject regains competence within the therapeutic window
  - (c) Provisions for language barrier
- (7) The IRB application will provide details for implementing the following additional protections of the rights and welfare of the subjects, including, at least:
- (a) Community consultation:
    - (i) The PI's plan for consultation with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
    - (ii) The IRB will determine whether it is appropriate for the IRB to carry out community consultation in addition to that performed by the investigator.

- (b) The PI's plan for 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;
- (c) Community consultation and public disclosure should engage the affected communities in discussion about the proposed research, with the possibility of appropriate modification to the design and/or conduct of the study as a possible outcome. The plan for consultation and disclosure should consider the following:
  - (i) Use of radio/TV advertisements, talk shows, etc.
  - (ii) Press releases - newspaper, press interviews,
  - (iii) Community meetings/gatherings
  - (iv) Civic groups, churches, minorities organizations, public officials
  - (v) Target groups more likely to be involved
  - (vi) Include information related to procedures for opting out
- (d) The PI's 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;
- (e) The PI's plan to establish an independent data monitoring committee to exercise oversight of the clinical investigation;
- (f) The PI's plan to contact the subject's family member who is not a legally authorized representative to determine whether he or she objects to the subject's participation, if feasible. The plan is applicable in situations when obtaining informed consent from the subject is not feasible and a legally authorized representative is not reasonably available. The plan will be implemented within the therapeutic window defined in the proposal. (Family member is defined by DHHS rules as any one of the following legally competent persons: spouse; parents; children (including adopted children); brothers; sisters; and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.)
- (g) The PI's plan 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, :
  - (i) Of the **subject's inclusion in the clinical investigation**, the details of the investigation and other information contained in the informed consent document.
  - (ii) 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.
- (h) The plans provided in [II.A.1.a\)\(7\)\(f\)](#) above and [II.A.1.a\)\(7\)\(g\)](#) above will include:
  - (i) provisions for situations when 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, and

- (ii) 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.
    - (i) Evidence that the study will be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies the research may include subjects who are unable to consent. (The requirement for a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists). The initial IRB application for this research may not be submitted as an amendment under 21 CFR section 312.30 or 812.35.
  - b) The IRB determinations of this section are documented in the IRB record and 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 21 CFR 56.115(b).
  - c) If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided above 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 (see the [Reporting Policy and Procedure](#)). The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.
2. If the research is not FDA regulated, the IRB follows the DHHS regulatory criteria to waive the requirement to obtain consent using the criteria listed in [II.A.1.a\) above](#) with the following exceptions:
- a) The reference to applicable FDA regulations in section [II.A.1.a\)\(6\)](#) above,
  - b) The requirement for IND/IDE in section [II.A.1.a\)\(7\)\(i\)](#) above
  - c) The record retention schedule in section [II.A.1.b\)](#) above
  - d) The sponsor's responsibilities for notifying the FDA in section [II.A.1.c\)](#) above.
- B. Continuation Review. The investigator will summarize efforts made to contact legally authorized representatives and family members in the progress report
- C. After review, record keeping is in accordance with the [Recordkeeping Policy](#).
- D. Notifications are in accordance the [Reporting Policy and Procedure](#).

### III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))