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I. PURPOSE

The purpose of this standard operating procedure is to outline the requirements that investigators must meet, and IRBs must verify, in order to establish additional protections for human subjects who participate in emergency research where the informed consent requirement is waived.

II. POLICY STATEMENT

The IRB may approve an exception to the informed consent requirement for research involving human subjects if the study involves the use of an intervention (drug, biologic or device regulated by the FDA) to treat a life-threatening condition for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent.

III. SCOPE

These policies and procedures apply to all prospectively planned research conducted in emergency settings where waivers of informed consent are requested.

IV. DEFINITIONS

Life-threatening: Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and disease or conditions with potentially fatal outcomes, where the end point of the clinical trial analysis is survival.

Severely debilitating: Diseases or conditions that cause major irreversible morbidity.


V. PROCEDURES

A. Emergency Use Without Informed Consent


There are some classes of prospectively planned research that involve emergency medical interventions in which informed consent cannot be obtained. These types of research are distinct from the emergency use situations described in **SOP 802**, and are usually not eligible for emergency use exemptions.

B. For Research Subject to FDA Regulation

1. The IRB may review and approve the clinical investigation without requiring that the informed consent of all research subjects be obtained only if the IRB (with the concurrence of a licensed physician who is a member of or a consultant to the IRB and who is otherwise not participating in the clinical investigation) finds and documents the requirements of 21 CFR 50.24 have been met including:

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- (a) The human subject(s) are in a life-threatening situation, and;
- (b) Available treatments are unproven or unsatisfactory, and;
- (c) The collection of valid scientific evidence is necessary to determine the safety and efficacy of the intervention, and;
- (d) Obtaining informed consent is not feasible because:
 - (1) The subjects will not be able to give their informed consent as a result of their medical condition;
 - (2) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
 - (3) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation, and;
- (e) Participation in the research holds out the prospect of direct benefit to the subjects because:
 - (1) Subjects are facing a life-threatening situation that necessitates intervention;
 - (2) 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
 - (3) Risks associated with the research 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, and;
- (f) The clinical investigation could not practicably be carried out without the IRB approval of a waiver of informed consent, and;
- (g) The protocol 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

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investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review, and;

(h) That there is an informed consent process and an informed consent document meeting all the requirements of informed consent as described in **SOPs 701 and 702** that the investigator will use if it is feasible to get consent from the participant or the participant's authorized representative within the therapeutic window, and;

(i) Additional protections of the rights and welfare of subjects will be provided, including, at least:

- (1) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn
- (2) Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits;
- (3) Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
- (4) Establishment of an independent data monitoring committee to exercise oversight of the research; and
- (5) 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 research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

2. The investigator or sponsor will carry out the clinical investigation under a separate FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE), the application for which has clearly

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identified the protocols that would include subjects who are unable to consent, and

3. If the IRB finds that the clinical investigation is not approvable under the provisions of §50.24 due to a relevant ethical concern, it will document its findings and will promptly provide them in writing to the investigator and/or the study sponsor.

C. For research not subject to FDA regulations

The Secretary of DHHS issued a notice in the Federal Register (Vol. 61, pp. 51531-51533, 1996) that waived the general requirements for waiver under §46.101(i). Consistent with this waiver, the IRB may waive the requirement for informed consent for emergency research provided:


1. The IRB reviews and approves both the activity and a waiver of informed consent and must (i) find and document that the research is not subject to 21 CFR 50 regulations, and (ii) find, document, and report to the OHRP that the conditions listed under B.1 above have been met relative to the research.
2. Because of special regulatory limitations relating to research involving fetuses, pregnant women, and human in vitro fertilization (Subpart B of 45 CFR 46), and research involving prisoners (Subpart C of 45 CFR Part 46), this waiver is inapplicable to these categories of research.

VI. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	21 CFR 50.24
45 CFR 46. Waiver of Informed Consent in Certain Emergency Research. FR 61: 5131-5135, 1996	Subpart B of 45 CFR 46
Subpart C of 45 CFR Part 46	Federal Register (Vol. 61, pp. 51531-51533, 1996)

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 701: Required Consent Documentation	SOP 802: Emergency Use of Unapproved Drugs, Biologics, or Devices
SOP 702: Assent and Parental Permission	

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for educating investigators on their roles and responsibilities with regards to research conducted in emergency settings.
Chair, CPHS	Responsible for periodically reviewing and modifying (as appropriate) the requirements investigators must meet to maintain compliance

IX. ATTACHMENTS:

X. REVISION:

- 6-10-2010 Revised to correct minor grammatical issues for consistency across SOPs.
- 9-25-2018 Revised to update definitions, update regulations and SOPs referenced and minor edits

XI. APPROVAL:

 Director, Human Subject Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date