

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.5
Emergency Use and Informed Consent

Policy

The criteria allowing unplanned emergency use of a test article in a life threatening situation are listed in the checklist “Criteria Allowing Unplanned Emergency Use of a Test Article in a Life Threatening Situation.” Investigators who want to use a test article in an emergency basis in a life threatening situation are to follow this checklist. Whenever possible, investigators are to contact the IRB Chair in advance of the use.

For prior notifications, the IRB Chair uses the “Criteria Allowing Unplanned Emergency Use of a Test Article in a Life Threatening Situation” to determine whether the circumstances of the use meet regulatory criteria.

1. If the IRB Chair determines that circumstances of the use meet regulatory criteria, the IRB Chair informs the investigator and clears them to proceed without IRB review.
2. If the IRB Chair determines that circumstances of the use do not meet regulatory criteria, the IRB Chair informs the investigator and indicates that proceeding with the use without IRB approval will be serious non-compliance.

Investigators are to submit 5-day reports of emergency uses to the IRB.

The IRB Chair uses the “Criteria Allowing Unplanned Emergency Use of a Test Article in a Life Threatening Situation” to determine whether the circumstances of the use described in the 5-day report meet regulatory criteria.

1. If the IRB chair determines that circumstances of the use meet regulatory criteria, the IRB chair informs the investigator in writing.
2. If the IRB chair determines that circumstances of the use do not meet regulatory criteria, the IRB chair informs the investigator in writing that the use without IRB approval is serious non-compliance, and refers the matter to the convened IRB for review under the policy and procedure on “Non-compliance.”

Planned use of a test drug or device in an emergency setting will be permitted if the study procedures comply with applicable OHRP and FDA guidance on planned emergency research. The VA does not allow planned emergency research to be conducted in VA facilities. VASDHS investigators will comply with relevant VA policy on research in emergency settings.

Exception from Informed Consent

Even for emergency use, the investigator is required to obtain informed consent from the subject or the subject's legally authorized representative if possible. If informed consent can not be obtained, the investigator and a physician not otherwise participating in the human subjects research must adequately certify the following in writing prior to use of the test article:

1. The human subject was confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent could not be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
3. Time was not sufficient to obtain consent from the subject's legal representative.
4. There was no alternative method of approved or generally recognized therapy available that provided an equal or greater likelihood of saving the life of the subject.

If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain an independent physician's opinion prior to administering the test article, the determinations of the investigator must be reviewed in writing within 5 working days after the use of the test article by a physician not otherwise participating in the human subjects research. In this event, a copy of the independent review must be submitted to the IRB within 5 working days after the use of the test article.

The IRB will review the submitted documents and will indicate the regulatory basis for the emergency use and that its use was appropriate. Data obtained from such emergency use may not be published or otherwise used for research purposes. Submission of a research proposal by the investigator is required if future use of the test article is anticipated.

Exception from Informed Consent: Requirements for Planned Emergency Research

The IRB may approve proposals for emergency research without requiring that informed consent of all research subjects be obtained if it finds and documents (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) all of the following:

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.
2. Obtaining informed consent is not feasible because:
 - 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 identify prospectively the individuals likely to become eligible for participation in the human subjects research.

3. Participation in the research holds out the prospect of direct benefit to the subjects because:
 - 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 human subjects research could not practicably be carried out without the waiver.
5. The proposed investigational plan:
 - a. Defines the length of the potential therapeutic window based on scientific evidence, and,
 - b. The investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and;
 - c. If feasible, the investigator has committed to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent;
 - d. 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.
6. The IRB has reviewed and approved informed consent procedures and an informed consent document. 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.
7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the human subjects research will be conducted and from which the subjects will be drawn;
 - b. Public disclosure to the communities in which the human subjects research will be conducted and from which the subjects will be drawn, prior to initiation of the human subjects research, of plans for the investigation and its risks and expected benefits;
 - c. Public disclosure of sufficient information following completion of the human subjects research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
 - d. Establishment of an independent data monitoring committee to exercise oversight of the human subjects research; and
 - e. 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 human subjects 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.

The study plan must ensure that, 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, is informed of the subject's inclusion in the human subjects research, the details of the investigation and other information contained in the informed consent document.

The study plan must 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 human subjects research and the subject's condition improves, the subject is also to be informed as soon as feasible.

If a subject is entered into human subjects research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the human subjects research is to be provided to the subject's legally authorized representative or family member, if feasible.

If the study involves any FDA regulated product and involves an exception to informed consent, there must be a separate IND or IDE for the study.

If the IRB approves the exemption, its evaluation and the regulatory basis for approving the exemption will be documented. If the IRB determines that it cannot approve human subjects research because the investigation does not meet the criteria for exemption in part B of this section or because of other relevant ethical concerns, the IRB will document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the human subjects research.

Procedures

1. The IRB Chair will review Emergency Use documentation provided by the investigator in a timely manner and decide whether an emergency conference call of the IRB is indicated to discuss the matter.
2. The IRB Administrator will maintain telephone contact with investigator to quickly secure necessary documentation; schedule emergency use review meeting by conference call or in person in a timely manner; and provide investigator with relevant correspondence in a timely manner.

Applicable Regulations

[21 CFR 50.20](#)

[21 CFR 50.23\(a-d\)](#)

[21 CFR 50.24](#)

[21 CFR 56.104\(c\)](#)

[45 CFR 45.116](#)

[VHA Handbook 1200.05](#)