Office of the Human Research Protection Program

Guidance: Planned Research in Emergency Settings with Waiver of Consent

(last updated June 9, 2016)

Introduction

This guidance provides investigators with information on when an investigator may conduct ***planned emergency research*** with a waiver of consent when more than minimal risk is involved. The approval criteria for this type of research are provided.

This ***exception to the consent requirement applies to a limited class of research activities*** involving individuals who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. The intent of these regulations is to allow research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent, while establishing additional protections to provide for safe and ethical studies.

IMPORTANT NOTES:

- For emergency use of a test article for treatment purposes see Guidance: Emergency Use of a Test Article.
- For the conduct of planned research with surrogate informed consent when potential research participants are unable to consent due to decisional impairment see Guidance: Use of Legally Authorized Representative (Surrogate Consent).
- For emergency medicine research supported by the DOD, an exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

Definitions

Legally Authorized Representative (LAR): an individual who is authorized under applicable law to grant permission on behalf of a prospective participant for their participation in research. Please refer to Guidance: Use of Legally Authorized Representative (Surrogate Consent) for information on identification and involvement of LARs in the consent process.

Family Member: Both FDA and DHHS define a "family member" 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.

Seven Requirements for IRB Approval

When triggered by selecting "Drugs/Biologics/Dietary Supplements" in response to Section 2.3/Item 1.0, webIRB Section 8.9 will guide UCLA researchers through the following considerations:

IMPORTANT NOTE: The text is hyperlinked to applicable sections of the regulations for reference.

- **Documentation in the Protocol:**
  The issues raised in the sections below will need to be documented in the appropriate sections of the application. The five points are summarized as follows:
  - The human research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions;
  - Obtaining informed consent is not feasible;
  - Participation in the research holds out the prospect of ***direct benefit*** to the subjects;
  - The study could not practicably be carried out without the waiver of informed consent; and
  - The study defines the length of the potential therapeutic window and the investigator has committed to attempting to contact a legally authorized representative to ask for consent for each subject within that window of time.
- **Community Consultation:**

  Consultation with appropriate community representatives will need to occur before the research begins.
- **Public Disclosure***:*

  Appropriate ***public disclosure*** will need to occur prior to the initiation of the study as well at the completion of the study.
- **Ongoing Attempts to Obtain Consent:**

  Consenting is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study also apply to subjects whose consent has been provided by a surrogate. In addition:
  - A subject who regains the cognitive ability to consent must be re-consented using standard consenting procedures.
  - In the event a surrogate provides consent for a subject, and a surrogate of higher priority subsequently notifies the investigator of his/her relationship to the subject, the investigator must

defer to the higher priority surrogate's decision regarding whether the subject will continue to participate or to withdraw from the study. This is accomplished by conducting the consent process with the surrogate of higher priority.

- In the event that the surrogate dies, the subject must be re-consented subsequent to any event that would otherwise trigger re-consenting the subject.

Thus, the following versions of consent forms will be needed:

- One for the surrogate

- One for the participant if he or she regains capacity to consent. This one should allow for
  - Person to continue in study
  - Person not to continue in study but to explain that data collected so far will be used for research purposes

In addition to the situations described above, if a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research should be provided to the subject's legally authorized representative or family member, when feasible.

- **Summaries of Attempts to Obtain Consent:**

  Investigators will need to document and ***summarize their attempts*** to contact family members to obtain their consent if obtaining informed consent is not feasible and a legally authorized representative is not reasonably available. This information will need to be submitted to the IRB at the time of continuing review

The following requirements would be addressed in other sections of webIRB:

- **A separate IND or IDE:**

  A separate IND or IDE will be needed for the study.

- **Independent Data Monitoring Committee:**

  An independent data monitoring committee will need to be established.

References and Regulations

- 21 CFR 50.24 Exception From Informed Consent Requirements for Emergency Research

- FDA Guidance: Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble - Information Sheet
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm126482.htm

- OPRR Reports: Informed Consent Requirements in Emergency Research, October 31, 1996.
  http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm

Change history:
6/9/2016: Replaced restatements of regulation with a link; added links to related guidance; specified related webIRB sections; corrected typos.