

DHS-Public Health Division

EMERGENCY RESEARCH - EXCEPTION TO INFORMED CONSENT

The Public Health Division supports the concept of conducting emergency research in the pre-hospital setting in order to advance knowledge in treating critically ill or injured patients. A patient who is a potential subject for such research is typically experiencing a clinical condition that severely impairs his/her ability to provide informed consent. In addition, such emergency situations typically do not present opportunities to seek consent from a patient's legally authorized representative in a timely fashion.

To address this, the federal government has adopted stringent regulations to protect the rights and well-being of research subjects. The Public Health (PH IRB) will consider approving studies conducted in emergency settings only in accordance with 21 CFR 50.24 and 45 CFR 46, waiver of informed consent requirements for emergency research. Community consultation and notification will be required prior to final PH IRB approval.

NOTE: These studies take considerable time and effort from investigators, research staff and PH IRB members and final PH IRB approval may take several months.

The PH IRB will review these studies in phases.

Phase 1: Initial Review

First, the PH IRB will review the IRQ, protocol, relevant IND or IDE application, and other pertinent information to determine the research is ethically sound, reasonable and necessary.

If the study meets the above criteria, the PH IRB will find and document, with the concurrence of a board member who is a licensed physician and is not otherwise participating in the investigation, that the investigation meets the criteria set forth in 21 CFR 50.24. Investigators must address these federal requirements as part of the PH IRB application packet and document how they are addressed in the research protocol. A check list of these items has been developed for use by the principal investigator and will be provided to the primary and secondary PH IRB reviewers to submit as part of the PH IRB record for determining compliance with the regulations.

The PH IRB may determine that after initial review additional information is necessary before making a decision and may defer its decision until additional information is obtained.

Phase 2: Community Consultation and Notification

The PH IRB will review the community consultation and notification plan subsequent to initial review. The PH IRB will help define the process and content of the consultation and will negotiate modifications as appropriate relevant to the unique features of the study. The PH IRB will approve the process, determine if adequate consultation has occurred, request modifications as necessary based on feedback from the community, if appropriate, and approve proceeding with the study.

The following principals should guide the community consultation, and the detailed plan for each step must be approved by the PH IRB before being implemented.

- i. Consultation should be with a diverse group of community leaders and community members in sectors of the affected communities.
- ii. The following information should be provided to community representatives: (a) the nature and purpose of the study; (b) the specific patient population involved; (c) the meaning of informed consent, the reason informed consent cannot be obtained in this study, and the procedures that are being substituted for informed consent; (d) risks and probabilities; (e) benefits; (f) any opt-out provisions that will be available; and (g) contact information, for asking questions or providing additional information. (NOTE: Opt-out provisions are generally recommended.)
- iii. Questions should be asked of community representatives to which members of the public can reasonably expect to have answers or opinions after a reasonable opportunity to be informed about the study.
- iv. Conversations and questions should be probing – i.e. aimed at establishing that community representatives understand the proposed research and engendering a meaningful discussion of the associated risks and probabilities, and benefits.
- v. In most cases, the community consultation process should be based in qualitative methods. Where these methods reveal important differences in values or risk/benefit tradeoffs, the PH IRB may consider requiring researchers to conduct a quantitative assessment as a supplemental approach. If a quantitative assessment is required, questions should be informed by the qualitative work that has already been done. In addition, procedures for drawing samples should be thoughtfully designed to reflect appropriate inclusion of demographic diversity and specific populations relevant to the study. Standard quantitative approaches should be employed, i.e. unbiased sampling, pre-testing of surveys, appropriate statistical analyses, etc.

Phase 3: Review and evaluation of community consultation

The PH IRB's decision to grant or withhold consent on behalf of the community should be based on the list of risks and benefits perceived by various sectors of the community, any quantifications obtained on the perceived relative importance of the risks and benefits, information on the community's general level of support for the project, and the PH IRB's own understanding of the relevant medical facts. No arbitrary threshold of community support can relieve the PH IRB of this responsibility.

Phase 4: Final approval

Once the PH IRB has determined that the relevant criteria have been met, it may approve the study. Investigators will be informed of the approval by letter.

Applicable Regulations:

21 CFR 50.24

45 CFR 46, Emergency Research Consent Waiver