Research Projects Involving Planned Emergency Research

To Approve an Exception to Acute Care Informed Consent for Planned Emergency Research, the Institutional Review Board (IRB)[1] must find and document FDA 21 Part 50.24, DHHS 45 CFR Part 46.101(i)[2]:

1. Administration involves life threatening situation; Available treatment unproven or unsatisfactory; Collecting of evidence necessary to determine safety and effectiveness

2. Obtaining consent NOT feasible because:
   a. Subject's medical condition
   b. Intervention must be administered before feasible to consent legally authorized representatives
   c. No reasonable way to identify prospective subjects

3. Research of potential direct benefit to subjects:
   a. Life threatening situation necessitates intervention
   b. Animal and preclinical studies support potential direct benefit of intervention for individuals
   c. Risks reasonable in relationship to
      1. What is known about medical condition
      2. Risks and benefits of standard therapy
      3. Risks and benefits of proposed intervention

4. Investigation could NOT practicably be carried out without waiver

5. Investigator has:
   a. Defined length of potential therapeutic window
   b. Is committed to attempting to contact and obtain consent from legally authorized representative within window
   c. Will summarize efforts to contact authorized representative at the time of continuing review
   d. Is committed to contact within window subject's family member[3] and ask if he/she objects (if obtaining consent from subject or legally authorized representative is not feasible)
   e. Will summarize efforts to contact family member at the time of IRB continuing review

6. IRB has:
   a. Approved informed consent procedures and documents to be used with subject/legally authorized representative
   b. Approved procedures and information to be used when providing family members opportunity to object

7. Consultation with representatives of communities from which subjects will be drawn and in which research will be conducted

8. Public disclosure in communities prior to initiation including:
   a. Plans for study
   b. Risks and benefits

9. Public disclosure to community at completion of study including:
   a. Demographics of population
   b. Results of study

10. Establishment of an independent data and safety monitoring committee

11. Procedures are in place to inform at earliest opportunity each subject (if competent), legally authorized representative, and/or family member of:
   a. Subject's inclusion in study
   b. Details of study and other information in informed consent document
   c. Opportunity to discontinue subject's participation without penalty or loss of benefit to which subject is entitled

12. Additional reporting and recordkeeping, FDA drug and device application requirements must be met [These are outlined in attached document]

Footnotes

ℵ IRB review must include concurrence of a licensed physician who is a member or a consultant to IRB and who is not otherwise participating in the clinical investigation.

ℶ For Department of Health and Human Services (DHHS) regulated studies, waiver not applicable to research involving prisoners, fetuses, pregnant women, human in vitro, and fertilization.

ℜ "Family member" is defined 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.

Additional Planned Emergency Research Informed Consent Exception
Reporting Recordkeeping Requirements
FDA 21 CFR Part 50.24; DHHS 45 CFR Part 46.101(i)

1. For Food and Drug Administration (FDA) regulated investigations, a separate Investigational New Drug application (IND) or Investigational Device Exemption (IDE) is required
   a. Separate IND/IDE identifies protocol as including subjects unable to give consent
   b. Submission of separate IND/IDE required even if IND/IDE for same drug/device exists
   c. Applications may not be submitted to FDA as amendments
2. If research is NOT subject to FDA 21 CFR Part 50, but DOES fall in purview of DHHS 45 CFR Part 46, the IRB must report to the Office for Human Research Protections (OHRP) that approved acute care informed consent waiver has occurred. [Note: The conditions for approval of DHHS are identical to those outlined in FDA 50.24]
3. If the IRB does NOT approve request for waiver:
   a. IRB must document findings including reasons for disapproval and promptly provide to:
      1. clinical investigator
      2. sponsor
   b. Sponsor must promptly report disapproval to:
      1. FDA
      2. Other clinical investigators in this or substantially

equivalent clinical investigations

3. Other IRBs reviewing this or substantially equivalent investigations

4. If waiver is approved:
   a. IRB must provide sponsor with copy of information that has been publicly disclosed prior to initiation and at completion of study [Investigator must provide IRB with information]
   b. Sponsors must provide copies to FDA

5. IRB, Investigator, and Sponsor records must be:
   a. retained for three years after completion of clinical investigation
   b. accessible for inspection and copying by FDA

For detailed information on FDA's policies pertaining to Exceptions to Informed Consent in Planned Emergency Research, see the following document:
"Food and Drug Administration (FDA) Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors on Exception from Informed Consent Requirements for Emergency Research", April 1, 2013
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf