Protection of Human Subjects: Research Without Consent

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Consent for Resuscitation Resear

- Informed consent required for ethical research
- Critically ill & injured patients unable to give consent; surrogates not available
- Before 1993:
  - Implied consent
  - Creative interpretation of regulations: minimal risk, physician surrogates
  - Deferred consent
- 1993: Moratorium on resuscitation research

Waiver of Informed Consent / Exception from Informed Consen

- September 1995: FDA Proposed Rule
- October 2, 1996 Federal Register
  - FDA Final Rule for "Exception to informed consent"
  - matching DHHS "waiver" criteria
- Effective November 1996

Waiver of Informed Consent / Exception from Informed Consen

- Potential participants must be in special circumstances
- Study must meet specific criteria
- Investigator must agree to specific conditions
- Additional special protections required:
  - Community consultation
  - Public disclosure

Waiver of Informed Consent / Exception from Informed Consen

Informed consent not feasible:

- Subjects incapable due to medical condition
- Intervention necessary before authorized representative can be consulted
- Subjects cannot be prospectively identified

Waiver of Informed Consent / Exception from Informed Consen

Research study criteria:

- Life-threatening condition
- Available treatments unproven/unsatisfactory
- Evidence needed to determine safety/efficacy

Waiver of Informed Consent / Exception from Informed Consen

Research benefits participants because:

- Life-threatening condition needing treatment
- Animal/preclinical studies indicate potential benefits of experimental therapy
- Risks reasonable compared to standard therapy and usual outcome

Waiver of Informed Consent / Exception from Informed Consen

Further Criteria:

- Investigation impracticable without waiver
- Investigator commits to attempt contact with authorized representative or family member within defined therapeutic window
- IRB approves informed consent procedures and documents

Waiver of Informed Consent / Exception from Informed Consen

Additional protections required:

- Consultation with community representatives
- Public disclosure to communities where investigation will be conducted prior to study
- Public disclosure of results after completion, including demographics of study population

Waiver of Informed Consent / Exception from Informed Consen

Additional protections required:

- Specific IDE or IND filing
- Independent data monitoring committee
- Individual notification of subjects or their representatives after enrollment
- Disclosure of any negative IRB decision to other/future IRB's

Waiver of Informed Consent / Exception from Informed Consen

- Study: life threatening condition
  potential benefit to participants
- Investigator: commitment to notify
- Additional protections:
  community consultation
  pre-study public notification
  post-study public notification

Public Access Defibrillation Tria

- Randomized, controlled trial of PAD
- Cardiac arrest the prototypical "waiver" condition
- Exception to informed consent granted by 24+ IRBs
- Disparate interpretation of community consultation and pre-study notification

"Research Without Consent: The Community Perspective"

- National Heart Lung & Blood Institute
  1 R01 HL73387-01 P.I.: Richardson, LD
- 59 residential buildings recruited by the New York City PAD Trial
- Community-based focus groups and structured interviews

RWC/TCP Specific Aims

1) To determine attitudes towards:

- the way "community" was defined and operationalized
- the processes of "community consultation" and "public disclosure" used by the NYC PAD Trial,
- the relevant and appropriate definition of "community" fo purposes of adhering to the Emergency Research Consen Waiver regulations; and

2)To determine the specific factors involved in judging research without consent to be acceptable unacceptable by community members.

AEM 2005 Consensus Conference

- Biros, MH "Research Without Consent: Current Status 2003"

  Ann Emerg Med 2003; 42:550-564
- **Research Without Consent:**

  The Final Rule Revisited

  May 21, 2005 in New York City
- Call for original research or concept papers: DEADLINE: March 31, 2005