



Protection of Human Subjects: Research Without Consent

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Consent for Resuscitation Research

- 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 Consent


- 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 Consent

- 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 Consent

Informed consent not feasible:

- Subjects incapable due to medical condition
 - Intervention necessary before authorized representative can be consulted
 - Subjects cannot be prospectively identified
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Waiver of Informed Consent / Exception from Informed Consen


Research study criteria:

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



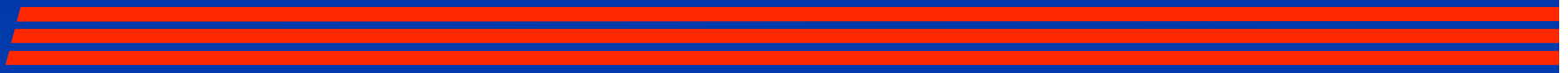
Waiver of Informed Consent / Exception from Informed Consent

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
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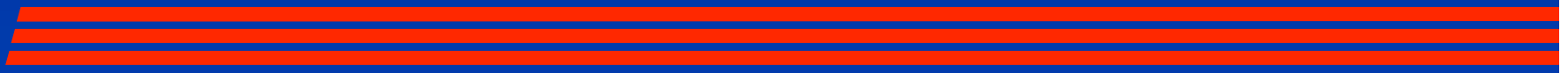
Waiver of Informed Consent / Exception from Informed Consent

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
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Waiver of Informed Consent / Exception from Informed Consent

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
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Waiver of Informed Consent / Exception from Informed Consent

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 Consent


- 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 Trials

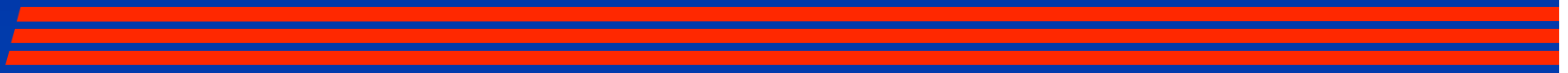
- Randomized, controlled trial of PAD
 - Cardiac arrest the prototypical “waiver” condition
 - Exception to informed consent granted by 24+ IRBs
 - Disparate interpretation of community consultation and pre-study notification
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“Research Without Consent: 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
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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” for purposes of adhering to the Emergency Research Consent Waiver regulations; and
 - 2) To determine the specific factors involved in judging research without consent to be acceptable/unacceptable by community members.
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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**
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