Medical Research in Times of Bioterrorism - OHRP's Perspective

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Michael A. Carome, M.D.
Associate Director for Regulatory Affairs
Office for Human Research Protections

Medical Research and Bioterrorism: OHRP's Perspective - Presentation Overview

- Applicability of HHS regulations for the protection of human subjects - planning ahead
- Comments on specific provisions of 45 CFR part 46
- Secretarial waiver of HHS regulatory requirements
- Classified research

Applicability of HHS Regulations for the Protection of Human Subjects - Planning Ahead for Bioterrorism

Title 45
Code of Federal Regulations
Part 46

Protection of Human Subjects
(Last revised November 13, 2001)

Ethical Framework for the Conduct of Human Subject Research
The Belmont Report

- Respect for Persons
- Beneficience
- Justice

Fundamental Provisions of 45 CFR Part 46

- IRB review
- Legally effective informed consent
- Assurance of Compliance

Applicability of 45 CFR Part 46 to Human Subjects Research Related to Bioterrorism

The regulations apply to all nonexempt research involving human subjects conducted, supported or otherwise subject to regulation by HHS.
45 CFR 46.101(a).

Human Subjects Research Related to Bioterrorism – Planning Ahead

- Human subjects research in the setting of a bioterrorism event may need to be initiated within a short time frame.
- Sponsors, research institutions, and investigators should anticipate need for human subject research related to potential bioterrorism events and seek IRB review and approval before such events occur.
- "Rapid response" IRBs can be established to review research on an urgent basis.

Human Subjects Research and Bioterrorism
Comments on Specific Provisions of 45 CFR Part 46

IRB Membership Requirements

45 CFR 46.107(a)

- Each IRB shall have at least 5 members, with varying backgrounds to promote complete and adequate review
- Shall be sufficiently qualified through the experience and expertise of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- Shall possess the professional competence necessary to review specific research activities.

Criteria for IRB Approval of Research

Vulnerable Subjects - 45 CFR 46.111(b)

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Legally Effective Informed Consent

45 CFR 46.116

- Except as provided elsewhere in the regulations, no investigator may involve a human being in research unless the investigator has obtained the legally effective informed consent of the subject.
- An investigator shall seek consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Secretarial Waiver of HHS Regulatory Requirements

Secretarial Waiver of HHS Regulatory Requirements – 45 CFR 46.101(i)

- **Unless otherwise required by law, the Department of Agency head (Secretary of HHS) may waive the applicability of some or all of the provisions of 45 CFR part 46 to specific research activities or classes of research activities otherwise covered by the regulations.**
- **Except when otherwise required by by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to OHRP and shall also publish them in the *Federal Register* or in such manner as as provided in Department or Agency procedures.**

Classified research

Classified research (1)

- In response to report issued by the Advisory Committee on Human Radiation Experiments, President Clinton issued a March 27, 1997 memorandum, entitled "Strengthened Protections for Human Subjects of Classified Research," to Common Rule agencies and departments.
- The President instructed that no agency shall conduct or support classified human subjects research without having proposed and promulgated the Common rule, including changes set forth in the memorandum.

Classified research (2)

President's 1997 memo regarding classified research:

- **Prohibited waiver of informed consent**
- **Required researchers to disclose that project is classified**
- **For all but minimal risk studies, required researchers to inform subjects of sponsoring agency**
- **IRBs for secret projects must include a non-governmental member and have appeals process**
- **Requires agencies to disclose annually the number of secret human research projects undertaken by the agency**

Human Subjects Research and Bioterrorism - Conclusions

- The regulations apply to nonexempt HHS conducted or supported research related to bioterrorism.
- Important considerations need to be given to IRB membership, potential vulnerability of potential subjects to be recruited into such research, and to the informed consent process.
- Department and Agencies heads can waive the human subject protection regulatory requirements.
- Status of classified human subjects research????