

Applying Flexibility in the Regulations

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Topics to be covered

- Disclosure of test results.
- Cooperation between institutions.
 - Single IRBs for multi-site studies.
- Definition of ‘research.’
- Definition of ‘human subject.’
- Ethical requirements when research is deemed ‘exempt.’

Disclosure of Test Results

- Epidemiology: Results affect community.
 - Pollutants or contamination in water, earth or air. (eg) Bacteria, radon, pesticides, etc.
 - Engage community in planning including mode of disclosure of results.
- Clinical testing: Results affect individual or family.
 - Non-validated tests; criteria for disclosure:
 - Accuracy (sensitivity and specificity).
 - Magnitude of the threat.
 - Availability of therapeutic or preventive response.

Single IRB of Record for multi-site studies (ANPRM)¹

- Precedents: Oncology, Veterans Administration.
 - Designed for multicentered randomized clinical trials
- Participation by institutions voluntary.
 - Acceptance got off to slow start.
 - Concern about liability.
 - Concern about responsibility of ‘home institution.’ OHRP actions.

Single IRB of Record for multi-site studies (ANPRM)²

- Concern: ‘Commercial IRBs’ take over.
- Advantages:
 - Reduced bureaucracy.
 - Reduced expense.
 - Consumer satisfaction.
- I favor a trial of voluntary single IRBs following the oncology model.
 - Perhaps mandatory for federally sponsored RCTs.
 - Local ‘fine tuning.’
 - Ensure strong local HRPP programs.

Definition of 'Research'¹

- Controversial since the Belmont Report.
 - Responsive to Congressional mandate to define the boundaries between 'research' and 'practice.'
 - Much research has no corresponding practice.
- Gerrymandering to escape regulatory control perceived as burdensome.
 - Public health.
 - Quality improvement.
 - Health policy research.
 - Social and behavioral research.

Definition of 'Research'²

- Resolution: Stop trying to redefine research.
- Focus instead on the methodologies one wishes to regulate.
- Projects underway:
 - PRIM&R
 - Johns Hopkins

Definition of 'Human Subject'¹

- Definition first appeared in 45 CFR 46, 1981.
 - Not recommended by National Commission.
- “...living individual about whom an investigator ...conducting research obtains... identifiable private information.”
- Controversy in 1999 (VCU study), survey instrument asked questions about parents (sensitive matters).
 - Parents were, by definition, research subjects.
 - Customary medical practice: Family history creates record of highly sensitive matters.

Definition of 'Human Subject'²

- Resolution: As with 'research' the definition is not the problem.
- The resolution of this issue lies in revising (or negotiating the interpretation of) regulatory justifications for “waivers and alterations” of the elements of informed consent.

Exemption from Coverage by Regulations¹

- Commonly misinterpreted as removing the requirement for informed consent and other ethical standards such as IRB review.
- Response: Create competent committee with IRB-like responsibilities.
- Model described in Hastings Center Report on QI.
 - Integration of the ethical oversight of QI into the system of accountability for the conduct of clinical care.

Exemption from Coverage by Regulations²

- Consider public health agencies' 'outbreak investigations.'
 - Must react very rapidly (within ~24^o).
 - Review for informed consent, risk/benefit, selection of subjects, etc.
 - Must be expert in (or have prompt access to experts in) the scientific considerations.
 - May have to consider retroactive review.
 - May have to endorse categories of investigations.

THANK YOU!