

Social and Behavioral Regulation: History, Flexibility, and Usability

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Troubling Cases of Social & Behavioral Research

- Wichita Study of jury deliberation (1954)
- Milgram's Study of obedience to authority (1963)
- Project Camelot Study of patterns of political change in South America (1960's)

Troubling Cases of Social & Behavioral Research (2)

- Rosenthal and Jacobson's *Pygmalion in the Classroom* Study of teacher expectations and students' intellectual development. (1960's)
- Humphreys' *Tearoom Trade* Study of impersonal sex in public places (1965-67)
- Zimbardo Study of behavior in a simulated prison (1971)
- Research involving undergraduate student research subject pools.

Legal and Regulatory History

- Surgeon General Lee circulates policy for Public Health Service Biomedical or Behavioral Research (1969)
- The Department of Health, Education and Welfare (HEW) circulates policy for review of biomedical and behavioral research (1971)
- The National Research Act authorizes HEW to create regulations requiring Institutional Review Board (IRB) review of biomedical and behavioral research (1974)

Legal and Regulatory History (2)

- HEW adopts 45 Code of Federal Regulations (CFR) Part 46 to protect human subjects in HEW funded research, except for research funded by the National Institute for Education and the Office of Education (1974)
- The Family Educational Rights and Privacy Act protects student education records (1974, as amended)
- HEW adopts 45 CFR 46 Subpart B to provide additional protections to fetuses and pregnant women (1975)

Legal and Regulatory History (3)

- HEW adopts 45 CFR 46 Subpart C to provide additional protections to prisoners (1978)
- HEW proposes to revise 45 CFR 46 to cover all research at all institutions receiving HEW funds, exempting some categories of research, and making certain categories of research eligible for expedited review (1979)

Legal and Regulatory History (4)

- The Department of Health and Human Services (HHS) revises 45 CFR 46 to cover HHS sponsored research, exempt five categories of research, and allow expedited review of 10 categories of research (1981)
- HHS adopts 45 CFR 46 Subpart D to provide additional protections to children involved as subjects in research (1983)

Legal and Regulatory History (5)

- 16 Federal Agencies jointly adopt regulations revising 45 CFR 46 Subpart A, extending the regulations protecting human subjects to cover all of these agencies' sponsored research (**The Common Rule**) (1991)
- The Protection of Pupil Rights Amendment (PPRA) is revised to apply to certain surveys of students funded by the Department of Education (ED) (1993)

Legal and Regulatory History (6)

- HHS and the Food and Drug Administration revise the categories of research eligible for expedited review (1998)
- PPRA is revised to apply to surveys, analyses and evaluations in all primary and secondary schools receiving federal funds. (2002)
- HHS issues final regulations protecting medical records under the Health Insurance Portability and Accounting Act (HIPAA) (2002)
- The Intelligence Reform and Terrorism Prevention Act requires the Department of Homeland Security to comply with 45 CFR 46 (2004)

The Pattern of Historical Change

- The Quantity of Social and Behavioral Research Covered by Federal Regulations Increases
- The Complexity of Federal Regulations covering Social and Behavioral Research Increases
- The Scope of the Kinds of Social and Behavioral Research Covered by Federal Regulations Varies

Historical Issues in the Regulation of Social & Behavioral Research

- Infringement on Academic Freedom
- Mismatch between regulations and research
- Applicability of regulations to research
- IRBs' lack of expertise
- Rigid interpretation of regulations
- Lack of Appeal Procedure

Current Issues

- IRB “Mission Creep”
- Review of Practitioner Research
- Quality Assurance/Improvement Activities
- Research about Specific Populations
- Evaluations of Subject Protection Systems
- Research about the Subject Protection System

‘Regulatory Flexibility’: Oxymoron or Under-Used Opportunity?

- Exempt Human Subjects Research
- Expedited Review
- Waiver/Alteration of Informed Consent and Documentation of Informed Consent

Human subjects research activities are exempt if the only involvement of the human subjects consists of one or more of the following:

- Research involving normal educational practices in established or commonly accepted educational settings
- Research involving educational tests or passive observation of public behavior if the data are anonymous or pose no risk to subjects' legal liability, financial standing, employability, or reputation.

Exempt Research Activities (cont.)

- Research involving surveys, interviews, or any observation of adults if the data are anonymous or pose no risk to subjects' legal liability, financial standing, employability, or reputation.
- Research involving existing data from nonpublic sources, if anonymously recorded.

Exempt Research Issues

- Does the Institution use the exemption categories?
- Who decides if an activity is exempt?
- How are the exemption categories interpreted?
- Do mistakes get made?
- What happens in exempt research?

Expedited Review -

- is applied by the Chair or IRB member(s) appointed by the Chair;
- uses the same review criteria as full board review for initial and continuing review;
- can approve or modify research activities, but not disapprove them; and,
- applies to minimal risk activities in the approved HHS/FDA list of categories .

Minimal Risk

- *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Social/Behavioral Research in the Expedited Review Categories:

- Data involving existing or future materials collected solely for nonresearch purposes
- Data from voice, video digital or image recordings made for research purposes
- Research on individual or group characteristics or behavior
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Expedited Review Issues

- Reviewer competence
- Judgment of “Minimal Risk”
- Interpretation of Expedited Review Categories

Waiver/Alteration of Conditions of Informed Consent (or Parental Permission/Assent)

- No more than minimal risk;
- Rights and welfare of subjects not adversely affected;
- The research could not practicably be carried out otherwise; and,
- Subjects will be provided with additional pertinent information as appropriate.

Waiver of Parental Permission is also allowed if (Subpart D):

- Parental permission is not a reasonable requirement to protect the subjects in the research (e.g., research on child abuse or neglect);
- an appropriate mechanism is substituted;
and,
- the waiver is consistent with Federal, State, and local law.

Waiver of Consent Issues

- Judgment of minimal risk
- What “rights” do subjects have?
- What does “practicably” mean?
- What happens in research where consent is waived?

Documentation of Informed Consent may be waived if:

- The only record linking the subject and the research is the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or,
- The research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

Issues of Documentation Waiver

- Judgment of minimal risk
- When is consent normally required?

Social/Behavioral Considerations in IRB Review of Social/Behavioral Research Activities

- What do IRB members have to know in order to approve?
- What are the IRB members' standards for approving research?
- What is the process of IRB review and decision-making?