
*Oversight of Social &
Behavioral Research*



Behavioral Research and the Belmont Report

- “It is important to distinguish between biomedical and behavioral research.”
- “The general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.”



Behavioral Research and 45 CFR 46

Section 102 (f): Definition of a “Human Subject”

The research “... obtains...(2) identifiable private information...(which) includes information about **behavior** that occurs in a context in which an individual can reasonably expect that no observation... is taking place.”

Social & Psychological Risk

*Social &
Psychological risks
are real risks*

IRB Responsibilities

- Identify Risks
- Determine that risks are minimized
- Determine that “risks to subjects are reasonable in relation to anticipated benefits”
- Determine that subjects are adequately informed about “any reasonably foreseeable risks or discomforts”

Identifying Risks

IRBs should not rely solely on investigators to identify risks

- No one can be objective about their own work
- People underestimate the risks involved in things they are very familiar with
- People overestimate the benefit of things that are important to them

Identifying Risks

- Social & Psychological Risks are TIME and SITUATION specific
- Social & Psychological risks are very subjective
- There is little or no empirical data on the likelihood of risk in behavioral or social research

Identifying Risks

- Examples
 - Emotional Distress
 - Psychological Trauma
 - Invasion of Privacy
 - Embarrassment
 - Loss of Social Status
 - Loss of Employment

Identifying Risks

- In some cases simply participating in the research can cause social or psychological harm
 - psychological reaction to situation
 - psychological reaction to questions

Identifying Risks

- Primary source of social risk results from a breach of confidentiality.
 - Confidentiality and anonymity are not the same
 - Names are not the only identifiers
 - Subjects' participation in the research may need to be kept confidential as well as their data

Minimizing Risk

Three ways to minimize risk

- Alternatives
 - other procedures that are less risky
- Precautions
 - procedures to decrease the likelihood that harms will occur
- Safeguards
 - procedures to deal with harms if they occur

Risk/Benefit

- Evaluation of Risk/Benefit ratio is subjective judgement
- IRB must decide whether the anticipated benefit justifies asking subjects to undertake the risks
- Should take into account different subject populations and individual differences among subjects

Informed Consent

- Consent process should empower subjects to make their own determination about risk
- Risks should be explained in terms that the subjects can relate to - everyday life experiences
- Consent process should not do more harm than the research

*Application of the
Common Rule to Non-
biomedical Research*

Common Rule

The Common Rule provides sufficient flexibility for IRBs to effectively and efficiently review non-biomedical research

- Exempt Research
- Expedited Review
- Waiver of Consent and/or Documentation of Consent

What Needs IRB Review?

- *Federally-funded Research (Agencies subscribing to the Common Rule)*
- *Institutional Assurance*
- *Meets Definition of “Research”*
- *Meets Definition of “Human Subject”*



Behavioral Research and 45 CFR 46

Section 102 (d): Definition of “Research”

“...a systematic investigation...designed to develop or contribute to generalizable knowledge.”

What “Contributes to Generalizable Knowledge”?

- Rule of Thumb:
 - Is it intended for publication?
 - Is it intended for presentation?
- Concern: Is this Interpretation Adequate?
 - For protection
 - For flexibility



Is the Concept “Generalizable Knowledge” Enough?

- Does it Adequately Distinguish What Needs Review?
- Does it Adequately Protect People from Risk of Harm?
- Is there a Better Approach that is More Consistent with the Belmont Principles?



Oral History and “Generalizable Knowledge”

- Oral History Interviews, in General, are not Designed to Contribute to “Generalizable Knowledge”
- Oral History Interviewing, in General, Does not Meet the Regulatory Definition of Research in 45 CFR 46

Exempt Research

Research that is “exempt” :

- **Research in established or commonly accepted educational settings, involving normal educational practices**
- **Educational tests, surveys, interviews, or observation of public behavior unless identified and sensitive**
- **Research using existing data, documents, records, pathological specimens, or diagnostic specimens, if publicly available or unidentifiable**

Expedited Review

Eligible research includes minimal risk +:

- **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes**
- **Collection of data from voice, video, digital, or image recordings made for research purposes**
- **Research on individual or group characteristics or behavior or research employing survey, interview, oral history, etc. methodologies**

Consent Waiver

- Written informed consent is not necessarily appropriate for all research, especially research in the social & behavioral sciences.
- IRBs have considerable flexibility and authority to modify or waive consent requirements and should not hesitate to do so when it is appropriate.

Consent Waiver

- Institutions are free to set their own consent requirements for exempt research
- All consent requirements must be met in expedited review
- IRBs have the authority to waive some or all of the requirements for consent and/or documentation of consent provided the research meets the criteria in the regulations.

Waiver of Documentation

- Investigators rarely object to obtaining informed consent from their subjects
- Investigators do object to obtaining signed consent forms where it is not appropriate.

Waiver of Documentation

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

- the research presents no more than minimal risk;
- and**
- the research involves procedures that do not require written consent when performed outside of a research setting.

45 CFR 46.117(c)(2)

Waiver of Documentation

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

- the principle risks are those associated with a breach of confidentiality concerning the subject’s participation in the research; **and**
- the consent document is the only record linking the subject with the research

45 CFR 46.117(c)(1)

Waiver of Consent

An IRB may approve a waiver or alteration of some or all of the consent requirements provided that:

- The research involves no more than minimal risk to subjects;**
- The waiver will not adversely affect the rights and welfare of subjects;**
- The research could not practicably be carried out without the waiver; and**
- Whenever, appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.**

Points to Remember

- **Whenever consent or documentation is waived, IRB must find and document that the research meets the criteria**
- **Deception research requires a waiver of consent with appropriate documentation**
- **"Passive consent" or "implied consent" is not consent and requires a waiver with appropriate documentation**
- **IRBs should not be afraid to exercise their waiver authority if the research meets the criteria and the finding is appropriately documented.**

Application of the Common Rule

The effective and efficient application of the Common Rule to non-biomedical research requires:

- An IRB that has sufficient expertise in social & behavioral research
- An IRB that understands and utilizes the flexibility in the Common Rule
- Investigators that understand the potential for social & psychological risk in their research