

*Application of the
Common Rule to Social
and Behavioral Science
Research*

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Application of the Common Rule

The effective and efficient application of the Common Rule to social & behavioral 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

IRB Expertise

IRB Expertise

45 CFR 46.107(a) "The IRB shall be **sufficiently qualified** through the experience and expertise of its members..."

- Scientific
- Regulatory/Ethical

IRB Expertise

- An IRB which reviews a protocol without sufficient scientific expertise to evaluate the research is not in compliance with the regulations.
 - Expertise necessary to independently identify risks
 - Expertise necessary to evaluate the potential benefits (direct, scientific, or social) of the research

IRB

Flexibility

Common Rule

The Common Rule provides sufficient flexibility for IRBs to effectively and efficiently review social & behavioral research

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

Definitions

- Research - a systematic investigation designed to develop or contribute to generalizable knowledge.
- Human Subject - a living individual about whom an investigator conducting research obtains
 - data through intervention or interaction with the individual, or
 - identifiable private information

46.102 (d) & (f)

Exempt Research

46.101(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy

Exempt Research

Research that is “exempt” includes:

- **Normal educational practices in established educational settings**
- **Educational tests, surveys, interviews, or observation of public behavior unless identified and sensitive**
- **Research using existing data, if publicly available or recorded without identifiers**
- **Research on elected or appointed public officials or candidates for public office**
- **Evaluation of public benefit service programs**
- **Taste and food quality evaluation and consumer acceptance studies**

Exempt Research

OHRP Guidance:

- Institutions should have a **clear policy in place on who shall determine** what research is exempt under 46.101(b).
- Those persons who have authority to make a determination of what research is exempt are expected to be **well-acquainted with interpretation of the regulations and the exemptions.**

Investigators should not have the authority to make an independent determination that research involving human subjects is exempt

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc95-02.htm>

Expedited Review

46.110

- An IRB may use expedited review for
 - Research on list of eligible categories
 - Minor changes in previously approved research
- Carried out by IRB chair or one or more experienced IRB members
- Reviewers can exercise all of the authorities of the IRB except disapproval
- All IRB members must be informed of research approved under expedited review

Expedited Review

- **Research activities that (1) present no more than minimal risk to human subjects, *AND* (2) involve only procedures listed in one or more of the following categories**

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/exprev.htm>

Expedited Review

Eligible research includes:

- **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**

Expedited Review

*Expedited Review is
not “review light”*

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.
- Written informed consent is not necessarily appropriate for all research, especially research in the social & behavioral sciences.

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.

***Risk in Social &
Behavioral Research***

Social & Psychological Risks

*Social &
Psychological risks
are real risks*

Social & Psychological Risks

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

Social & Psychological 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

- 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

Summary

- The Common Rule works for social & behavioral research
- IRBs must have expertise in social & behavioral research
- IRBs must understand and utilize flexibility in the regulations
- Researchers must understand the potential for risk in their research