




IRB Flexibility



Jeffrey M. Cohen, Ph.D. CIP
President
HRP Associates, Inc.

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Overview

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

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



Definitions

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

Definitions

- Not all social/behavioral research meets the regulatory definition
 - Some oral history
 - Public use data files



Exemptions

Exempt Research

Research that is “exempt” includes:

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior unless identified and sensitive
3. Educational tests, surveys, interviews, or observation of public behavior on elected or appointed public officials or candidates for public office or if federal law requires confidentiality
4. Research using existing data, if publicly available or recorded without identifiers
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies



Expedited Review

Expedited Review

45 CFR 46.110

- 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

*Expedited Review is
not “review light”*

Expedited Review Categories

1. **Clinical Studies (No IDE/IND)**
 2. **Collection of Blood Samples**
 3. **Noninvasive Prospective Collection of Biological Specimens**
 4. **Noninvasive Data Collection Used in Clinical Practice**
 5. **Data, Documents, Records, Specimens Collected for Nonresearch Purposes**
 6. **Voice, Video, Digital, or Imaging Recordings for Research**
 7. **Individual / Group Characteristics or Behavior**
- Continuing Review**
8. **No new subjects**
 9. **Minimal risk approved under full review**



Consent Flexibility

Consent Flexibility

- 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 Flexibility

- 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

46.117(c)(2)

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.

Waiver of Documentation

46.117(c)(1)

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

Waiver of Consent

46.116(d)

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.

Summary

- The Common Rule provides sufficient flexibility for IRBs to effectively and efficiently review non-biomedical research
- IRBs should not be reluctant to use the flexibility in the regulations where appropriate