

Human Subjects Protection

Interpretation of the Common Rule for
the Protection of Human Subjects by the
National Science Foundation

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What is the relationship between the Common Rule and the Federal Regulation for the Protection of Human Subjects?

- The “Common Rule” is the term used by seventeen federal agencies who have adopted the same regulations. Each agency’s regulations are printed in the Code of Federal Regulations (CFR) with different preface numbers but the same section (§) numbers (e.g., **45 CFR 690 = NSF; 45 CFR 46 = NIH**).
- **The text of the regulation in each case is identical.**

Subparts of the Regulations

- Subpart A: The Common Rule
- Subpart B: Research on Pregnant Women, Fetuses and Neonates
- Subpart C: Research on Prisoners
- Subpart D: Research on Children

NSF has not adopted Subparts B, C and D.

→ Institutions with HHS assurances do not **NECESSARILY** have to apply the subparts to NSF-supported research.

Principles of a Human Subjects Protection System 1

Assumption: Funding agencies, institutions, researchers, and staffs, should foster an “Ethical climate of research”. **No one should be hurt because they were involved in research.** This means:

1. **The risk of harm must be minimized,** and
2. Participants exercise **informed consent** to understand and accept the risks involved in the research.

Principles of a Human Subjects Research System 2

- **Assumption:** Research is a national good, which improves human life.
- **Conclusion:** Research should not be impeded without good reason.
- **Conclusion:** The weight of bureaucratic oversight should be related to the level of risk of harm

Principles of a Human Subjects Research System 3

- **Assumption:** Doing research with human subjects is a privilege, not a right.
- **Assumption:** Institutional identity legitimizes the research of university-based researchers.
- **Conclusion:** Institutions have the right to evaluate the research of members to ensure that policies are followed. Researchers should not declare themselves exempt.

Principles of a Human Subjects Research System 4

- **Assumption:** The human research protection system of researchers, funders, institutional administrators, students and staff, should foster an **Ethical Climate of Research.**
- **Conclusion:** IRBs should engage in continual and proactive education.
- **Conclusion:** Researchers should serve on IRBs.

IRB Review Should Balance Risks to Participants and Degree of Oversight

- Minimal risk research does not need the same level of oversight as high risk research.
- Scarce resources should be devoted to overseeing higher-risk research, not wasted in the oversight of lower-risk research.
- The benefits of research to society should not be impeded without a clear and reasonable expectation of risk reduction.

Where can I get authoritative advice on the interpretation of the Common Rule?

→ Under the Common Rule, the agency funding the research is the most knowledgeable source of interpretation of the regulations.

But my institution's Assurance is from ORHP, doesn't that mean that I must talk to that agency when I have a question about the regulations?

→ Not necessarily, under the Common Rule the agency funding your research has the authority to interpret the regulations for these projects.

Exempt, Expedited, and Excluded Research

Researchers do not have sole authority to declare their own research **exempt**. Normally the IRB will declare this status, which means free from **continued** review by the IRB.

HSRS is preparing a list of **expedited** research categories appropriate for social and behavioral science research.

Excluded research is not subject to IRB oversight.

Is **Oral History** excluded from IRB oversight?

- OHRP recently declared **oral history excluded** from regulatory oversight, insofar as it is “**not research aimed at generalizable knowledge**”.
- Insofar as **most social science research** using oral history interviewing methods aims to produce generalizable knowledge, such projects are **not excluded**.

What exemptions of the Common Rule are most appropriate to social science research?

- Research in educational settings involving educational practices.
- Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior.

UNLESS:

- Individual human subjects can be identified

AND:

- Disclosure of their identity could place them at risk of criminal/civil liability, or damage to their financial standing, employability, or reputation

What flexibility does the IRB have in applying the Common Rule?

- The regulations require the IRB to come to an **independent, informed judgment** using **common sense and expertise** (fevered imagination is NOT appropriate).
- The regulations require that the IRB **document the procedures** followed to arrive at its decision.

Must informed consent always be written?

- Informed consent is the procedure whereby the researcher respects the autonomy of participants.
- Since written documentation of informed consent can create harm for research participants in some circumstances, it **should not** be routinely required in all cases.

Your IRB can authorize a waiver of written consent forms or other formal consent procedures under specified conditions.

Waiver of Written Consent

§ 117 (c) An IRB may waive the requirement for a signed consent form if :

(1) The only record linking the subject and the research would be the **consent document** and the principal risk would be **potential harm** resulting from a **breach of confidentiality**. ... **or**

(2) The research presents **no more than minimal risk of harm** to subjects and involves no procedures for which written consent is normally required outside of the research context.

How Should IRBs Deal with Research in Foreign Countries?

→ If a suitable local (foreign) IRB exists, it should be used to review the research.

→ Whether or not a suitable foreign IRB exists, the primary IRB review rests with the US institution.

→ It is common for foreign IRBs to specialize in biomedical research and to ignore social-behavioral science.

Group Consent, Implied Consent, and Ethnographic Research

- Some local communities require that an esteemed elder or public official consent to the research before any individual can consider participating.
- Ethnographic research in the natural setting of participants often uses informal interviewing and participant observation. Consent is implied by a participant's continued participation. Openness about research goals and confidentiality apply.

Are “Third Parties” Human Subjects in the Regulations?

- If the resulting data is de-identified, third parties are not human subjects.
- Normal confidentiality procedures apply.

Does Research done as a Classroom Exercise Count as Human Subject Research?

- Research activities not intended to lead to published results do not fall under the Common Rule.
- Departments should review classroom research and keep records in a manner consistent with local IRB standards.

Do “Public Use Data sets” require IRB Review?

- A normal “public use data set” has been de-identified.
- Therefore no further IRB review is called for.

How Should Researchers Deal with IRBs?

- Join them.

How Should IRBs Deal with Researchers?

- Educate them about the regulations.
- Encourage departments to support an ethical climate of research.
- Use common sense, do not fall prey to an over-rich imagination to over-regulate research. Deal with potential harms that are reasonably expectable in the research.



<http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm>

- DIAS Organization**
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Frequently Asked Questions and Vignettes

Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research

Click on the applicable heading to go to a specific subject:

- [The Common Rule and Sub-Parts](#)
- [Social Science and the Common Rule](#)
- [Exempt and Expedited Review and Informed Consent](#)
- [Problems and Advice on Dealing with them](#)
- [Confidentiality-Privacy](#)
- [Ethnography](#)

The Common Rule and Sub-Parts



<http://www.nsf.gov/bfa/dias/policy/guidance.htm#top>

Human Subjects

The National Science Foundation supports research involving human subjects when the project has been certified by a responsible body to be in compliance with the federal government's "Common Rule" for the protection of human subjects.

The official NSF version of Code of Federal Regulations 45CFR690.101-124 is available at <http://www.nsf.gov/bfa/dias/policy/docs/45cfr690.pdf>.

The regulations give grantee institutions the responsibility for setting up "Institutional Review Boards" (IRBs) to review research protocols and designs and ensure the protection of the rights of human subjects.

Basic principles of human subjects protection

The fundamental principle of human subjects protection is that people should not (in most cases) be involved in research without their *informed consent*, and that subjects should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday life. The regulations are designed mainly to pertain to biomedical research, based on the philosophical principles contained in a key document, "The Belmont