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The Federal Regulations - SBE

Southern Methodist University - Social & Behavioral Research

Switch View

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Introduction

Revelations in the early 1970s about egregious medical experiments provided the impetus for developing federal standards for protecting human research subjects; however, a close reading of the regulations at 45 CFR 46 will find mention of research methods and topics of inquiry relevant to researchers in the social and behavioral sciences, as well as education and the humanities.

Methods mentioned include surveys, interviews, focus groups, participant observation, observations of public behavior, and the analysis of existing data. Topics include research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

In addition to explicitly identifying these methods, the regulations include provisions that allow for appropriate review of social sciences, humanities, and behavioral research. For example, the regulations:

- Identify research activities that are low risk (for example, surveys in which no identifiers are collected), and that are exempt from some provisions of the regulations (such as the requirement for continuing review).
- Identify research activities with no more than minimal risk that can be initially reviewed by one or more Institutional Review Board (IRB) members, rather than at a convened IRB meeting.
- Allow for waivers of the requirement to obtain written consent (for example, in a study of undocumented workers).
- Include provisions that permit researchers to withhold information in the consent process. This provision is important when some degree of deception is required in order to obtain valid results.
- Allow for the amendment of approved study plans. This process can be used effectively when it is not possible to know at the outset how a study will evolve. An example would be field research.

This module provides an overview of the federal regulations, so researchers can become familiar with the basic provisions. The full text of the federal regulations is available online.

Learning Objectives

By the end of this module, you should be able to:

- Determine whether proposed research meets the criteria for exemption.
- Describe the criteria for the use of expedited review procedures and IRB review.
- Summarize the authority of an IRB.
- Describe the kinds of review that approved research may need.

45 CFR 46: Protection of Human Subjects

U.S. Department of Health and Human Services (HHS) regulations are sometimes referred to as 45 CFR 46, a label that identifies their location in the code of federal regulations.

Subpart A of 45 CFR 46 is often referred to as the Common Rule. Although these regulations were first drafted and adopted by HHS, most federal departments and agencies that fund research in the social and behavioral sciences, including the National Science Foundation (NSF) and the Department of Education (ED) subsequently adopted the regulations as part of their own codes of federal regulations.

The Common Rule remained largely unchanged until 2017. In 2017, HHS with 15 other federal agencies issued a Final Rule to update the regulations. The revisions were designed to strengthen protections for human subjects, as well as reduce administrative burdens and add flexibility for the modern research environment. Major changes were made to requirements for IRB operations, informed consent, definitions, and exemptions.

The general compliance date for the revised Common Rule was 21 January 2019, and research approved, waived, or determined to be exempt is governed by the

"2018 Requirements" version of the Common Rule. Ongoing research that was approved, waived, or determined to be exempt prior to 21 January 2019 can continue for its duration under the "pre-2018 Requirements" or be transitioned to the 2018 Requirements.

This module will refer to the 2018 Requirements version of the Common Rule, but it is important to understand which version of the regulation applies to which research, so it may be helpful to check with your organization and/or the IRB of record for guidance.

Additional Protections for Vulnerable Subjects

Three subparts (B, C, and D) were added to the basic provisions of the federal regulations to further protect vulnerable subjects in research:

Subpart B	Subpart C	Subpart D
Pregnant women, human fetuses, and neonates	Prisoners	Children

Some federal agencies that adopted the Common Rule also have adopted some or all of the other subparts of the HHS regulations, but others have not. For example, while the ED has adopted the additional protections for children, the NSF has not.

Assurances with the Office for Human Research Protections (OHRP)

Every institution conducting research with federal support is required to enter into

an agreement called an "assurance." Most assurances are filed with OHRP. An assurance identifies the regulations for protecting research subjects that the institution will abide by. In the U.S., this is the Common Rule.

The assurance only applies to studies that are funded by a Common Rule department or agency.

Some institutions apply the Common Rule to all research regardless of the funding source. This means that the Common Rule would apply to research funded by foundations, associations, internal award programs, all other sources of research support, and even when research is not funded. However, the non-federally supported research would not be subject to OHRP oversight or the assurance.

Some institutions also choose to apply the additional Subparts B, C, and D to all research regardless of the funding source. Others choose to apply the subparts only to federally funded research. Once again, this voluntary application of the regulations would not be part of the assurance.

The assurance also identifies the IRBs that will review research on behalf of the institution. According to the revised Common Rule, the institution will no longer have to list all the IRBs that it relies on through reliance agreements on the assurance.

Content of the Federal Regulations

Portions of the federal regulations most relevant for researchers include:

- What research must be reviewed
- Who must review research with human subjects

- What questions should be addressed during a review
- What kinds of review need to take place during the course of a project

It is important to note that the federal regulations are intended to provide minimum standards and may be supplemented by institutional policy.

What Research Must Be Reviewed

The first step in deciding whether a project needs to be reviewed is to determine whether it meets the definition of research with human subjects. If it does not meet the definition, it does not require review by an IRB, although there may be ethical issues that must be addressed by the researcher's institution.

There are two critical definitions in 45 CFR 46.102.

"**Research**" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Research"	Defined as "Not Research"
Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.	Scholarly and journalistic activities (for example, oral history, journalism, biography, literary criticism, legal research, and historical scholarship) Public health surveillance activities Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order or criminal

	investigative purposes Authorized intelligence, homeland security, defense, or national security mission operational activities

"**Human subject**" means a living individual about whom a researcher (whether professional or student) conducting research:

i. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

If it has been determined that a project meets the definition of research and includes human subjects, the next step is to determine the type of review it needs. The type of review usually determines who will conduct the review.

Research Eligible for Exemption

Of significant interest to researchers in the social and behavioral sciences is the fact that there are activities that meet the definition of research with human subjects but are exempt from the provisions of the Common Rule. They do not require formal review as described in the regulations.

Many institutions have created review procedures for making the determination that research is exempt.

Institutional procedures vary, but most commonly it is an agent of the institution, not the researcher, that makes the determination, because researchers have an inherent conflict of interest.

Research may be eligible for exemption from the regulations if all the activities associated with the research fall into one or more of eight categories. Of the eight categories, social, behavioral, and educational research typically falls into one of these:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- Research only involving educational tests, survey procedures, interview procedures, or observation of public behavior, provided that at least one of these criteria is met:
    - The investigator records the information in such a way that subjects cannot be readily identified
    - Any disclosure of identifiable information outside the research setting would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
    - The investigator records the information and the subjects can be readily identified, and an IRB conducts a limited IRB review.
    - **Note:** If Subpart D applies, either by sponsor requirement or institutional choice, interviews, surveys, and participant observation with children as research subjects might not be exempt under Exempt Category 2 (there are specific restrictions for Exempt Category 2 research complying with Subpart D).

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
- Secondary research for which consent is not required.

A complete list of research activities eligible for exemption is provided at 45 CFR 46.104.

Expedited Review or Convened IRB Review

If research is not eligible for exemption, the remaining options are expedited review or convened IRB review for initial approval. Expedited review is conducted by one or more experienced IRB members. Convened IRB review is conducted by a quorum of the IRB.

To be eligible for expedited review for initial approval, research must meet criteria, including the following:

1. Pose no more than minimal risk to subjects
   "Minimal risk" means "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" (Protection of Human Subjects 2018).
2. Consist of only one or more research activities specified in the federal regulations as eligible for expedited review (It may be helpful to review the Categories of Research That May Be Reviewed by the Institutional Review Board [IRB] through an Expedited Review Procedure).

If the primary risk to subjects is a breach of confidentiality and the risk can be managed to no more than minimal, then the research may be reviewed through an expedited process.

There are many research activities that are eligible for expedited review.

In addition to studies involving surveys, focus groups, interviews, and observations of behavior, studies involving the collection of biological samples and data by non-invasive means may be eligible for expedited review. Biological samples include saliva and fingernail cuttings or measures of pesticide exposure using skin patches. Data collected by non-invasive means includes galvanic skin response, heart rate, and blood pressure.

A category of research activity eligible for expedited review includes the collection of blood samples within well-defined parameters based, for example, on the age of the research population.

Research involving identifiable data collected for non-research purposes may be eligible for expedited review, as may the collection of existing data from voice, digital, or image recordings made for research purposes.

Institutional policy, local conditions, and subject vulnerability may require review by the convened IRB even for a study with no more than minimal risk, such as a study of individuals with impaired decision-making.

If research involves more than minimal risk and/or does not fall into one of the categories of research eligible for expedited review, it must be reviewed by a convened IRB. This review involves consideration by a larger, more diverse group, thus bringing more perspectives and more experience to the review.

Who must review research with human subjects?

As described in the federal regulations and implemented by institutional policy, there are three possible sets of reviewers.

Individuals identified by the institution to screen research for exempt status.

One or more experienced IRB members designated by the IRB Chair to conduct expedited reviews.

Members of a convened IRB forstudies requiring IRB review. A convened meeting is generally understood as a majority of the members of the IRB present either in person or via telephone conference call.

Description of an IRB

An IRB is a review committee established to ensure that the rights and welfare of human research subjects are protected. Although federal regulations use the term IRB, institutions may choose a different name for the committee, such as Research Ethics Board or Independent Ethics Committee.

Membership

The minimum size and required composition of an IRB is described in detail in the federal regulations. An IRB must have at least five members (including a person not otherwise affiliated with the institution, a scientist, and a non-scientist). The non-affiliated member can also be the non-scientist or scientist (the individual may be the same person fulfilling two requirements). Its membership must be diverse, including race, gender, and cultural background. The committee is expected to:

- Be sensitive to community attitudes
- Have knowledge and experience with vulnerable populations (persons potentially vulnerable to coercion or undue influence)
- Be conversant with applicable regulations, state and local laws, and standards of professional conduct

The most important requirement is that an IRB must have the expertise and professional competence to evaluate the research it reviews. One or more members must have familiarity with the discipline and methods under consideration. If not, the IRB must seek that expertise through consultation. For example, if an IRB reviews research on sensitive topics using web-based surveys, it must have expertise about security issues in the internet environment or seek outside consultation.

Authority of the IRB

Federal regulations stipulate that an IRB can:

- Approve research
- Disapprove research
- Require modifications to secure approval
- Conduct continuing reviews
- Suspend or terminate approval

- Observe, or have a third party observe, the consent process and the research procedures

An IRB must notify researchers, in writing, about the outcome of its reviews, including modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, the written notification must provide the reasons for its decision and give the researcher an opportunity to respond in person or in writing.

Other Institutional Reviews

Research approved by an IRB may be subject to additional review by institution officials, for example, department heads, deans, or research directors. The institution may decide that IRB-approved research may not take place. However, if an IRB has disapproved the research, the institution may not override that determination.

What questions should be addressed during a review?

Exempt Research

When research is exempt from the provisions of the Common Rule, it follows that the review criteria provided for expedited review and convened IRB review would not apply.

For most exempt determinations, an experienced staff member may make the determination for exemption. However, for limited IRB review, the determination must be made by an IRB member. Further, in the case of limited IRB review as a condition for exemption, the IRB reviewer must review the research per limited IRB

review criteria and make the determinations required for limited IRB review.

All research should abide by the three basic ethical principles outlined in the *Belmont Report:* respect for persons, beneficence, and justice. The principle of respect for persons would entail securing informed consent from research subjects.

Many institutions have developed forms designed to gather sufficient information to determine not only that a project is exempt, but also that it will be conducted in accordance with the basic ethical principles.

Expedited and IRB Review

The same questions must be asked when an IRB member is conducting an expedited review and when the convened IRB is conducting the review.

- Have the risks to subjects been minimized using procedures that are consistent with sound research design?
- Are the risks reasonable in relation to anticipated benefits?
- Is the selection of subjects equitable?
- Are adequate procedures in place to ensure privacy and confidentiality?
- Is there a plan to monitor the data and safety of the subjects, if necessary?
- Will informed consent be sought and appropriately documented? Do proposed alterations or waivers of informed consent meet the criteria for approval?
- Are safeguards in place to protect vulnerable populations?

Comparison of Expedited and Convened IRB Review

Review procedures for expedited review and convened IRB review are similar in several ways:

- The review criteria are the same.
- Reviewers using the expedited review procedure or the convened IRB can request modifications to research plans and approve the plans.

A key difference between the two processes is that expedited reviewers cannot disapprove a research plan. If an expedited reviewer thinks a research plan is not approvable, the plan must be submitted to the IRB for review.

Another very important difference is that research initially approved in accordance with expedited review does not need continuing review. By regulation, continuing review is also not required for research that is in data analysis only, or research that is accessing follow-up clinical data only (Protection of Human Subjects 2018). The IRB may determine otherwise, however, and require continuing review on a study-by-study basis and must document how requiring continuing review increases protection for human subjects participating in the research.

The institution may also require researchers to submit annual progress check-ins based on institutional policy.

Approved Research: Additional Reviews

Once a research plan has received initial approval through expedited or convened IRB review procedures, additional reviews may be required.

1. For more than minimal risk research only (approved by an IRB), continuing review must be conducted at intervals appropriate to the degree of risk, but not less than once per year.
2. For all research, changes to approved research plans must be reviewed and approved before implementation.
3. For all research, reports of unanticipated problems involving risk to the research subjects or others also must be reviewed through procedures developed by the researcher's institution where the research is conducted.

Continuing reviews and reviews of proposed amendments to approved research may be reviewed by the IRB or through expedited review procedures. The determination about what type of review is appropriate is based on a number of factors, including the level of risk and the extent of proposed changes. The IRB or the expediting reviewer(s) must determine that all the requirements for initial review continue to be satisfied.

Continuing Review: Expedited or IRB Review?

Federal regulations permit expedited review procedures to be used for continuing review if the initial review was conducted by a convened IRB under some specific conditions, such as: (1) when during the initial review the IRB determined that the research involves no more than minimal risk and no additional risks have been identified, or (2) where no subjects have been enrolled and no additional risks have been identified (OHRP 1998).

IRB review is required for continuing review for active research studies that are greater than minimal risk and initially approved by the convened IRB.

If research that is more than minimal risk is only in data analysis or collecting follow-up clinical data from subjects, continuing review may not be required under

the regulations, depending on if the research is subject to the pre-2018 Requirements or the 2018 Requirements version of the Common Rule.

Amending Approved Research Plans

Changes to approved research plans must be approved prior to their implementation. The federal regulations (Protection of Human Subjects 2018) state that expedited review procedures may be used to approve "minor changes in previously approved research during the period (of one year or less) for which approval is authorized."

What constitutes a "minor" change is not described in the regulations and therefore, will be a matter of institutional policy.

Reports of Unanticipated Risks or Harms

Institutions that have an assurance with the Office for Human Research Protections (OHRP) are required to develop written procedures for reporting and reviewing unanticipated problems involving risks or harms to research subjects.

Limited IRB Review

There may be cases of research for which limited IRB review is a condition of exemption. Although not technically an expedited review, this limited review requires that the IRB reviewer determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, among other requirements for the condition of exemption (Protection of Subjects 2018). Continuing review is not required for exempt studies approved via limited IRB review.

Other Issues

The federal regulations cover other issues not addressed in this module such as working with collaborators on cooperative research, international research (taking place in foreign countries), required record-keeping, and the suspension or termination of IRB-approved research.

SBE Research as Clinical Trials

Research that meets the definition of a "clinical trial" is subject to additional regulatory requirements and policies (as applicable). For example, Common Rule-governed clinical trials must post informed consent forms on a publicly available website, and NIH-supported clinical trials have additional training requirements (such as good clinical practice) for key study personnel.

Summary

Federal regulations define which research activities require IRB review, the types of review, who conducts the review, and the criteria for approval. Because the federal regulations establish a minimum standard, it is important to check with your institution to find out if there are additional procedures and criteria.

References

- Office for Human Research Protections (OHRP). 1998. "OHRP Expedited Review Categories." Accessed June 12, 2017.
- Protection of Human Subjects, 45 CFR § 46 (2018).
- U.S. Department of Health and Human Services (HHS). 2017. "Final rule

enhances protections for research participants, modernizes oversight system." Accessed January 30.

Additional Resources

- Here are the U.S. Food and Drug Administration (FDA) regulations related to IRBs and the protection of human subjects
  - Institutional Review Boards, 21 CFR § 56 (2014).
  - Protection of Human Subjects, 21 CFR § 50 (2014).
- U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). 2003. "Guidance on Expedited Review Procedures."

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This module has a quiz.

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