OHRP: Who We Are, What We Do, and Why We Do it

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Learning Objectives

• Explain the history and ethical principles that underlie the Federal regulations for human research protections

• Recognize the role of the HHS Office for Human Research Protections (OHRP)

• Understand the background of the revisions to the Common Rule

• Describe the basics of when research falls under the regulations with particular reference to the 2018 revisions
HHS Regulations On Protecting Human Subjects in Research
Ethical Challenge

Protecting the rights & welfare of individual research subjects so that they are not merely a means to an end.

Furthering research to maximize societal benefits.
Why Regulations?

The Need for Rules to Protect Research Participants

As a result of the public outcry from publicized cases of unethical research, Congress passed a law requiring federal rules to protect people who participate in research. The rules rely on ethical principles that were laid out in the *Belmont Report*, which was written by an advisory committee created by Congress and published in 1979.

Foundational Ethical Principles:

- Respect for Persons
- Beneficence
- Justice
Bioethical Principles Applied

Principles of the Belmont Report

- **Respect for Persons**
  - Informed Consent (information, understandability, & voluntariness)
  - Subject’s assent, permission from LAR

- **Beneficence**
  - Minimize risk of harm
  - Favorable risk/benefit assessment

- **Justice**
  - Select individuals/groups of subjects equitably
  - Link burdens to benefits

Requirements of 45 CFR 46
HHS Regulations on Human Research Protections: 45 CFR Part 46

HHS Regulations:

**Subpart A – The Common Rule**

Subpart B – Pregnant women & fetuses

Subpart C – Prisoners

Subpart D – Children

Subpart E – IRB Registration

**Regulatory Authority:**

Office for Human Research Protections (OHRP)

OHRP has a distinct role from these HHS agencies:

- **FDA** – regulates clinical investigations involving drugs, devices, and biologics
- **NIH** – conducts and supports research that must comply with OHRP regulations
2018 Revisions to the Common Rule

• Original Common Rule was promulgated in 1991

• Recently revised to:
  o Better protect research subjects and promote individual autonomy
  o Reduce administrative burden on IRBs

• General compliance date: **January 21, 2019**
  o Commonly referred to as: the **2018 Requirements**, the revised Common Rule, the new Rule, the revisions, etc.
What Version of the Common Rule Do I follow?

Studies initiated* before this date must comply with the pre-2018 Requirements.

General Compliance date for 2018 Revisions to the Common Rule

January 21, 2019

Studies initiated* after this date must comply with the 2018 Requirements.

Ongoing studies continue to comply with the pre-2018 Requirements (*unless institution determines to transition study(ies) to comply with 2018 Requirements)

* Initiated = determined to be exempt, initially approved by an IRB, or granted a Secretarial Waiver
Protecting Research Subjects: A Shared Responsibility

- Regulators
- Sponsors
- Research institutions
- IRBs
- Investigators
## Shared Responsibility for HHS-funded Research: The Federalwide Assurance (FWA)

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<th>OHRP</th>
<th>Research Institutions</th>
<th>IRBs</th>
<th>NIH</th>
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<td>Requires institutional assurance of compliance with the regulations through an active FWA</td>
<td>Commit to the ethical treatment of human subjects</td>
<td>Review, approve, and oversee the research</td>
<td>Requires sponsored research to comply with 45 CFR 46 when applicable</td>
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<td>Maintain an active FWA</td>
<td>May apply institutional policies beyond the requirements of the Common Rule</td>
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<td>Ensure that a registered IRB reviews and approves the research of its employees and agents</td>
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<td>May “check the box”</td>
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Overview of the Human Subjects Review Process for NIH Grant Applications

**NIH PEER REVIEW** (CONTACT NIH PROGRAM OFFICER FOR ASSISTANCE)

- Follow NIH policies and instructions to submit application
- Peer review for adequacy of human subjects protections described
- NIH ready to release grant award

**IRB PROCESS** (CONTACT IRB OFFICE FOR ASSISTANCE)

- Submit study to IRB office according to institutional policies
- IRB reviews, as appropriate
- IRB reviews and approves non-exempt human subjects research according to regulatory criteria
- Institution must provide certification of IRB review and approval for non-exempt HSR to NIH before federal money can be used to do human subjects research

Institution must provide certification of IRB review and approval for non-exempt HSR to NIH before federal money can be used to do human subjects research
Welcome
Glad you’re here!