

**NIH REGIONAL SEMINAR ON
PROGRAM FUNDING AND
GRANTS ADMINISTRATION**
Salt Lake City

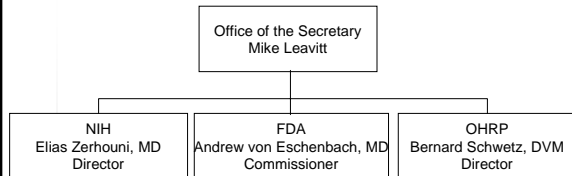
NIH Mini's: OHRP

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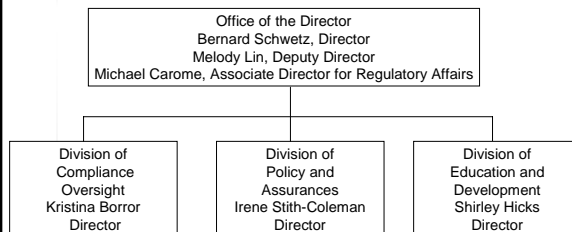


Department of Health and Human Services
Organizational Structure





**Office of Human Research Protections
Organizational Structure**





Office for Human Research Protections (OHRP)

- Exercises compliance oversight relative to HHS regulations for the protection of human subjects
- Promotes and coordinates appropriate HHS regulations, policies and procedures relative to human subjects protections
- Promotes education on issues in human subject protection



OHRP Oversight

All research involving human subjects conducted or supported by the Department of Health and Human Services (HHS)



Federal Regulations and Policy

- **45 CFR 46 - Basic DHHS Policy for Protection of Human Research Subjects**
Originally adopted May, 1974, Revised January 13, 1981, Revised June 18, 1991
 - Additional protections for vulnerable populations in Subparts B-D
- **Federal Policy for the Protection of Human Subjects - "The Common Rule"** June 18, 1991
 - Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and HHS. NSF, NASA, EPA, AID, CIA, and the Consumer Product Safety Commission.



Federal Regulations and Policy

Additional Protections included in 45 CFR 46:

- **Subpart B** - Additional DHHS Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research (revised November 13, 2001)
- **Subpart C** - Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- **Subpart D** - Additional DHHS Protections for Children Involved as Subjects in Research



Determining Applicability of Regulations

Prerequisite:

- Nonexempt research involving human subjects conducted or supported by HHS (or other Federal Department or Agency that has adopted the federal policy)
OR
- Non-exempt human subject research covered by Assurance of Compliance



Determining Applicability

- Does activity involve Research?
- Does research involve Human Subjects?
- Is human subjects research Exempt?

Basic Protections

The regulations provide three basic protections for human subjects in research:

- Assurance of Compliance
- IRB Review and Approval
- Informed Consent

Assurances

What is an Institutional Assurance?

- Documentation of institutional commitment to comply with the Common Rule
 - Federally-supported OR
 - ALL human subject research
- Principal method of compliance oversight
- OHRP Federalwide Assurance (FWA)

Terms of Assurance of Compliance

- Statement of principle governing conduct of research
- Designation of one or more IRBs
 - established in accordance with the regulations, and
 - provisions for
 - meeting space
 - sufficient staff to support the IRB's review and record keeping duties
- Written IRB & institutional procedures §46.103(b)

Institutional Review Board (IRB)

- IRB: A committee charged with, among others, review of human subjects research to assure that the subject's rights and welfare are adequately protected.
- Review by IRB designated in assurance

IRB Review

- Must be substantive and meaningful
 - Expedited review
 - Convened IRB
 - Continuing review
- Criteria for IRB approval

Informed Consent

- Legally effective informed consent
- each prospective subject or legally authorized representative
 - in accordance with and to extent required by §46.116
 - - unless waived in accordance with §46.116(c) or (d), § 46.408(c), or §46.101(i)

Informed Consent Process

Key principles of the informed consent process include:

- full disclosure of the nature of the research and the subject's participation,
- adequate comprehension on the part of the potential subjects, and
- the subject's voluntary choice to participate.

Reporting to the IRB: Unanticipated Problems and Adverse Events

- Definition:
 - Unanticipated Problem
 - Adverse Event (AE)
- Prompt reporting

Guidance available at:
<http://www.hhs.gov/ohrp/policy/AdvEvtGuid.pdf>

Assessing Adverse Event

- Unexpected
- Related or possibly related to research
- Places subjects or others at greater risk of harm



Compliance Oversight Procedures

- Written complaint is received
- OHRP initiates inquiry - notifies the institution and asks them to conduct an investigation
- OHRP receives a written report, may conduct telephone interviews or on-site evaluation
- OHRP issues written determinations and may require corrective actions



Possible Outcomes

- Compliance
- Compliance but recommend improvements to some aspect of protection program
- Not in Compliance and requires a corrective action plan
- Assurance restricted or suspended
- Recommend additional actions by other HHS agencies



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