Audits: Making It Work for Everyone -- part 1: the IRB
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Presentation Overview
- Background and OHRP compliance oversight procedures
- Preparing for an OHRP evaluation
- Corrective actions
- Some statistics
- Conclusions and resources

OHRP’s Jurisdiction
- Research involving human subjects conducted or supported by HHS that is not otherwise exempt
- Non-exempt human subject research covered by Assurance of Compliance
**For-Cause vs. Not-For-Cause**

- For-Cause: Responds to substantive allegations or indications of noncompliance in HHS-supported research or under an applicable assurance; usually through correspondence (>90%)
- Not-for-Cause: Assesses institutional compliance with 45 CFR 46 in absence of specific allegations; can be partially "for-cause" (previous compliance problems or vague allegations); often through site visit (~1/3)

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**Compliance Oversight Investigation – For Cause**

- Receive allegation or indication of noncompliance
- Determine OHRP jurisdiction*
- Send written inquiry to appropriate institutional officials
- Review institution report and relevant IRB documents
- Communicate with institution as needed (correspondence/telephone interviews/site visit)
- Issue final determinations

*May refer to FDA, other agency

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**Compliance Oversight Investigation – Not For-Cause**

- Select institution within jurisdiction
- Send written inquiry to appropriate institutional officials
- Review institution report and relevant IRB documents
- Communicate with institution as needed (correspondence/telephone interviews/site visit)
- Issue final determinations
Opening a Compliance Case

- Possible OHRP responses to initial institutional response:
  - Ask additional questions, express concerns
  - Conduct phone interviews
  - Conduct an on-site evaluation of human subject protections

Preparing for an OHRP evaluation

Suggestions on Preparing for an Inquiry

- Review “OHRP Recent Compliance Oversight Determinations” 02-04-2009
  http://www.hhs.gov/ohrp/compliance/findings/index.html
- Re-review regulations, particularly the subparts
- Review OHRP guidance documents
- Review your institution’s SOPs and update as necessary
- Ensure clear and consistent documentation of IRB activities
- Designate one contact person for the compliance oversight coordinator who will coordinate requests, questions, etc.
OHRP evaluations

- Vast majority of OHRP compliance evaluations handled through correspondence
- But sometimes...

OHRP Site Visits – Two Kinds: Similarities and Differences

<table>
<thead>
<tr>
<th>For-cause</th>
<th>Not-for-cause</th>
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<tbody>
<tr>
<td>Triggered by open compliance case</td>
<td>No open compliance case</td>
</tr>
<tr>
<td>Site visit team includes OHRP lawyer, 2-5 OHRP staff, 2-4 outside consultants</td>
<td>Site visit team consists of 1-3 OHRP compliance staff plus 1-3 outside consultants</td>
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<td>3-4 days</td>
<td>2-3 days</td>
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<td>Dual focus on allegations and systemic protections</td>
<td>Focus on systemic protections</td>
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OHRP Preparation for Site Visit

- Request protocols and other documents to be reviewed
- Describe/name officials/groups to be interviewed
- Provide ample lead time to institution; work cooperatively to set schedule
Institutional/IRB Preparation for OHRP Site Visit

- Location, logistics, and staff availability
- Records – make them easily accessible; chronological; minutes available; respond to specific OHRP requests
- Interviews – ensuring that appropriate role players will be available when OHRP comes to town

After Site Visit

- OHRP will send a letter with official findings and additional questions/concerns within a few weeks
- Institution will be asked to respond with corrective action plans within about 6 weeks
- OHRP will evaluate adequacy of corrective action plans

Compliance Oversight Investigation Possible Determinations/Outcomes (1)

- Protections under an institution’s Assurance are in compliance
- Protections under an institution’s Assurance are in compliance, but recommended improvements have been identified
- Noncompliance identified, corrective actions required
- Noncompliance identified, Assurance restricted/suspended pending required corrective actions
Compliance Oversight Investigation
Possible Determinations/Outcomes (2)

- Noncompliance identified, OHRP approval of Assurance withdrawn
- OHRP may recommend to appropriate HHS officials or PHS agency heads that
  - an institution or investigator be temporarily suspended or permanently removed from participation in specific project
  - peer review groups be notified of an institution’s or an investigator’s past noncompliance prior to review of new projects

Compliance Oversight Investigation
Possible Determinations/Outcomes (3)

- OHRP may recommend that institutions or investigators be declared ineligible to participate in HHS-supported research (debarment). Debarment initiated in accordance with procedures specified at 45 CFR Part 76.

Solutions to Correct/Prevent Noncompliance

- Education
- Adequate IRB staff and resources
- Adequate number of IRBs
- Adequate IRB documentation (in particular, adequate minutes of IRB meetings)
- Periodic self-assessment of institutional system for protecting human subjects
- Adequate written procedures
- “Culture of conscience”
OHRP Compliance Oversight
New Cases Initiated – 1990-2011

OHRP Compliance Oversight
Site Visits – 1990-2011

Common Findings

- Determination letters: http://www.hhs.gov/ohrp/compliance/letters/index.html
- Significant findings: http://www.hhs.gov/ohrp/compliance/findings.pdf
OHRP Education Resources

- Research Community Forums
- Speaking invitations
- OHRP website -- http://www.hhs.gov/ohrp/
- OHRP Email Box -- ohrp@hhs.gov
- Quality Assessment Program
- Training videos and other materials
  http://www.hhs.gov/ohrp/education/training/ded_video.html

OHRP Quality Improvement (QI) Resources

- Quality Assessment (QA) Self-Assessment Tool
  http://www.hhs.gov/ohrp/education/qip/ohrp_de_d_qatool.html
- QA Consultation
- QA Workshops

OHRP Contact Information

- OHRP website: http://www.hhs.gov/ohrp/
- OHRP telephone: 1-866-447-4777
- OHRP e-mail: ohrp@hhs.gov