

OHRP Research Community Forum:  
An Educational Conference on Strategies for Optimizing the  
Protection of Human Participants in Research

## **OHRP Update May 2, 2013**

Elyse I. Summers, J.D.  
Director  
Division of Education and Development



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## **What's Going On?**



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## **Outline**

- A little background and context
- Activities update
- OHRP – resources



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## Office for Human Research Protections (OHRP)

(Formerly Office for Protection from Research  
Risks)





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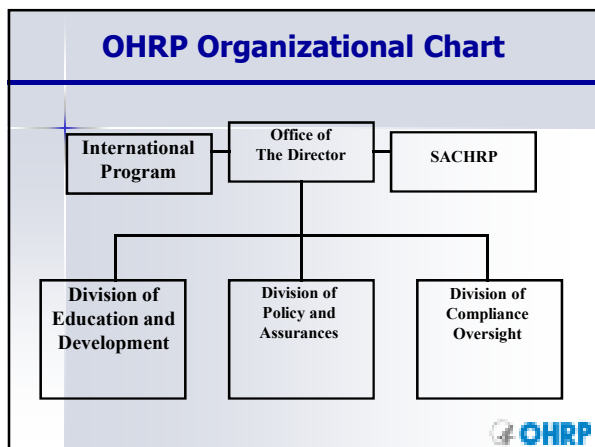
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## SACHRP

[www.hhs.gov/ohrp/sachrp](http://www.hhs.gov/ohrp/sachrp)

**Met on:**

- **March 12-13, 2013– Presentations at:**

<http://www.hhs.gov/ohrp/sachrp/mtginqs/index.html>

**Upcoming Meetings:**

- **July 10-11, 2013**
- **October 3-4, 2013**



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## International Activities

- International Compilation of Human Research Standards -- a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 104 countries and from several international organizations.
- Designed for use by IRBs, researchers, sponsors, and others. Many of the listings embed hyperlinks to the source document.
- Can be accessed in both Word and PDF formats, at <http://www.hhs.gov/ohrp/international/index.html>
- New in the 2013 Edition: Ecuador
- Disclaimer: No OHRP endorsement regarding quality of standards described therein.



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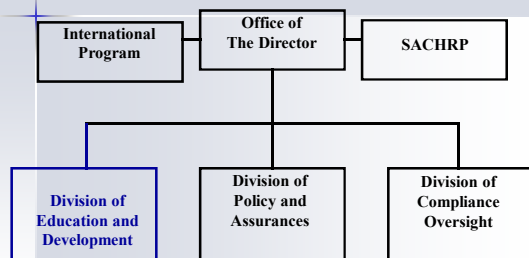
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## Update on Education Activities



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## DED: OHRP Research Community Fora (RCFs)

- Orlando, FL (Orlando Health) – March 15, 2013
- Rochester, MI (Oakland University/Beaumont Hospital) – May 2, 2013
- Ft. Worth, TX (JPS Health Network) – June 7, 2013
- Nashville, TN (Vanderbilt University) – October 24, 2013



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## Quality Assessment Program

### Quality Assessment (QA) Program

- QA Consultations
- QA Workshop 2.0: Focus on Informed Consent



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## DED: Quality Assessment Workshop 2.0 -- Focus on Informed Consent

- NOVA – late January 2013
  - Austin, TX – February 2013
  - Providence, RI – April 2013
  - Louisville, KY – May 2013
  - Portland, OR – July 2013
- ...Stay tuned for more information...*



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## DED: OHRP Webinars

### Maiden Voyage Last Year



Now Available on HHS  
YouTube Channel



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## DED: Webinars

- When The Feds Come A Knockin': How to Prepare for an OHRP Compliance Evaluation
- When the Regs Come A Knockin': Nuts and Bolts of 45 CFR part 46
- When PIs Come A Knockin': Everything Investigators Want to Know Bu Are Afraid to Ask
- When the Assurance Comes A Knockin': Everything You Need to Know About OHRP's FWA and IRB Registration Processes



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## Educational Videos



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## Online Educational Videos Now Showing

- Research use of human biological specimens and other private information.
- Reviewing and reporting unanticipated problems and adverse events
- General informed consent requirements
- IRB membership
- IRB recordkeeping
- Vulnerable populations

Available on HHS YouTube Channel



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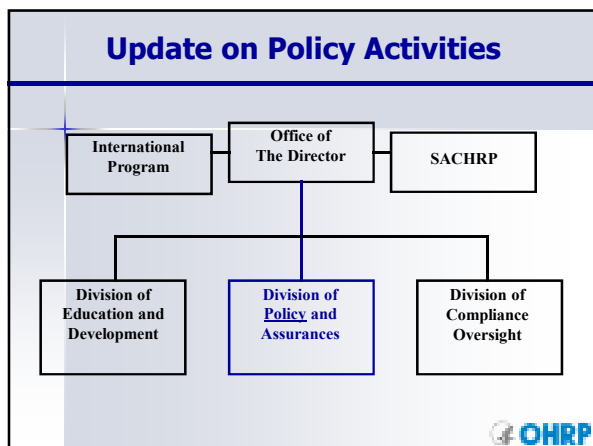
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### Correspondence on Non-engaged Scenarios September 22, 2011

- Awardee Institution -- institution received a grant award from NIH for the conduct of non-exempt human subjects research (i.e. was an awardee institution), but no specific human subjects research studies were described in the grant application.
- Data Center -- institution's employees helped to maintain and operate a data center that had been approved by IRB, and these employees also obtained individually identifiable private information from the data center to assist investigators from engaged institutions with certain activities
- MRI Research Facility -- Permitted use of their MRI research facility for intervention or interaction with subjects by investigators from another institution that was engaged in the research; and, involved their employees or agents interacting or intervening with human subjects in the research by providing investigators from the engaged institution with only technical assistance in operating the MRI equipment.

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### OHRP/FDA Joint Draft Guidance on Exculpatory Language September 7, 2011

- Provides guidance on the regulatory prohibition on the inclusion of exculpatory language in informed consent.
- Reverses 1996 OHRP Guidance by positing OHRP and FDA view that certain language regarding legal right to compensation for biospecimens is *not* exculpatory.
- Provides example of acceptable and unacceptable (i.e., exculpatory) language
- 18 comments received; under review

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### Revised FWA and Terms of Assurance June 20, 2011

- Same form for domestic and non-U.S. institutions
- Terms of Assurance shortened and simplified
- Need identify only internal IRBs or, alternatively, only one external IRB
- Electronic signature
- Period of Approval: 3 years → 5 years



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### Final Guidance Documents: Approval of Research With Conditions

- ***Guidance on IRB Approval of Research with Conditions – December 1, 2010***
  - When can IRB approve with conditions
  - Provides many examples
  - Works in concert with new guidance on continuing review to help institutions determine appropriate date for continuing review



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### Final Guidance Documents: Continuing Review

- ***Guidance on IRB Continuing Review of Research – December 1, 2010***
  - Greater flexibility in determining review date
  - Provides many examples
  - Works in concert with new guidance on IRB approval with conditions



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Anything Else?




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Anything Else?

*Advanced Notice of Proposed Rulemaking (ANPRM): Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*

*July 26, 2011*



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■ ANPRM

- Suggestions and comments in the ANPRM are **proposals**: they will not be implemented without further notice and comment
- Comment period for the ANPRM closed on: October 26, 2011
- Close to **1,100** received



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### ■Background

- 20 years since the “Common Rule” was adopted
- Brief history of contemporary human subjects protections
- Since Common Rule was developed, landscape of research activities has changed dramatically
- The rapid growth and expansion of human subjects research: *is current regulatory framework adequate and appropriate?*



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### ■Indications of a Need for Revision

- Institute of Medicine
- U.S. Government Accountability Office
- 2001 Report of the National Bioethics Advisory Commission
- Others



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### Seven Areas of Concern

1. Inadequate calibration of review process to risk of research
2. Inefficiencies of review by multiple IRBs for multisite studies
3. Problems with informed consent
4. Nature of risks/benefits has changed: SECURITY genetic info, biospecimens, medical records, data
5. Monitoring & evaluating/Reporting
6. Not all research subjects are protected
7. Lack of regulatory harmonization



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## Seven Proposed Changes

- I. Refinement of Risk-Based Protections
- II. Streamlining IRB Review of Multi-Site Studies
- III. Improving Consent Forms/Process
- IV. Strengthening Data Protections to Minimize Information Risks
- V. Improve Data Collection to Enhance System Oversight
- VI. Extension of Scope of the Federal Regulations
- VII. Clarifying and Harmonizing Regulatory Requirements and Agency Guidance




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## Overview of Rulemaking Process




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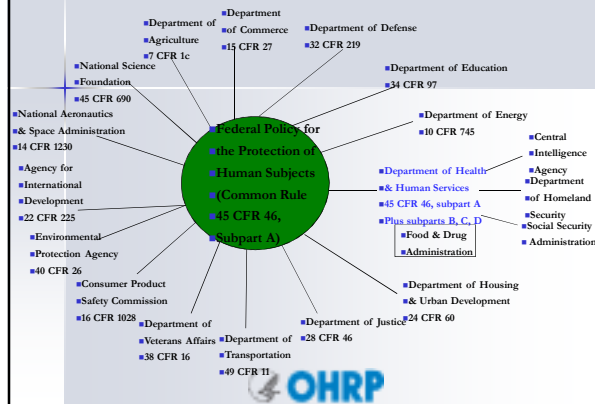
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## Common Rule Departments & Agencies




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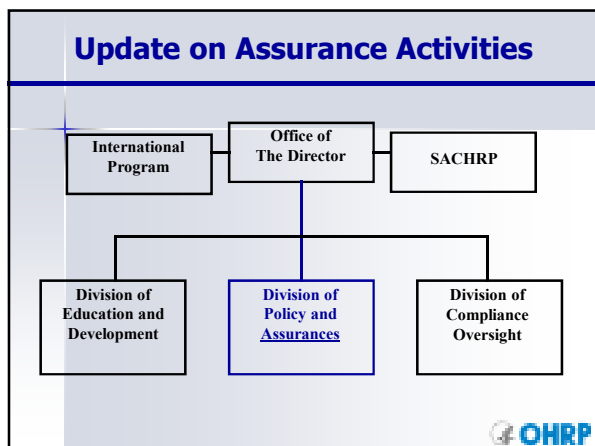
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### Federalwide Assurance (FWA) Statistics (as of 3/5/13)

- Total number of currently active FWAs: 12,068
  - Domestic: 9,163 (76%)
  - International: 2,905 (24%)
- Number of domestic FWAs "checking the box" to extend applicability:
  - 6,011 (66%)

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### IRB Registration Statistics (as of 3/5/13)

- Total number of currently active IRB registrations: 5,834
  - Domestic: 3,584 (61%)
  - International: 2,250 (39%)

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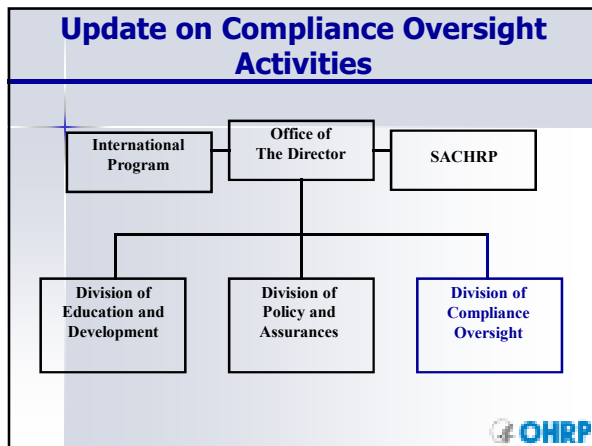
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### Compliance Oversight

- Procedures On-Line, see: [www.hhs.gov/ohrp/compliance/ohrpcomp.pdf](http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf)
- Recent Determinations ("Greatest Hits"): [www.hhs.gov/ohrp/compliance/findings/index.html](http://www.hhs.gov/ohrp/compliance/findings/index.html)
- Determination Letters: [www.hhs.gov/ohrp/compliance/letters/index.html](http://www.hhs.gov/ohrp/compliance/letters/index.html)

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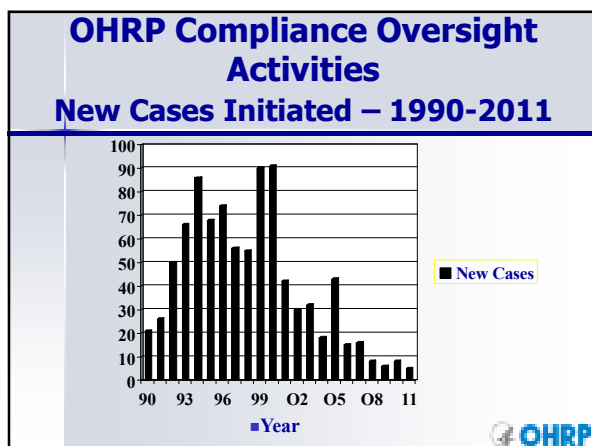
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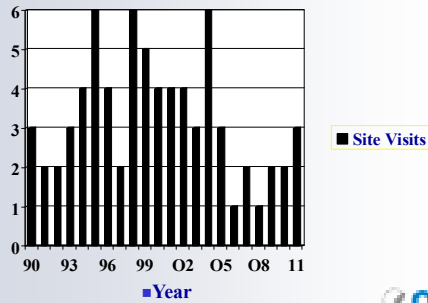
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## OHRP Compliance Oversight Activities

### Site Visits – 1990-2011




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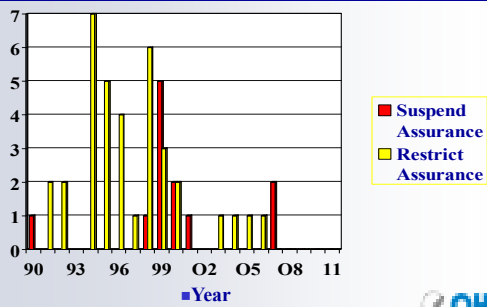
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## OHRP Compliance Oversight Activities

### Suspend/Restrict Assurance – 1990-2011




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## OHRP Contact Information

- Website: [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)
- Email: [OHRP@HHS.GOV](mailto:OHRP@HHS.GOV)
- Toll-free phone #: 1-866-447-4777
- Main phone #: 240-453-6900
- Join Listserv:  
<http://www.hhs.gov/ohrp/news/index.html>

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