

OHRP Update

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OHRP Update - Presentation Overview

- **Staff changes**
- **Federalwide Assurance (FWA) -
electronic submission**
- **45 CFR part 46 and HIPAA**
- **Updated guidance**
- **IRB Registration – pending notice of
proposed rulemaking**

OHRP Staff Changes

- **Dr. Bernard Schwetz, Acting Director, OHRP**
- **Dr. Kristina Borrer, Director, Division of Compliance Oversight**
- **Ms. Shirley Hicks, Acting Director, Division of Education and Development**
- **<http://ohrp.osophs.dhhs.gov/phonstf.htm>**

Web-Based Electronic Submission of Federalwide Assurance (FWA)

- **<http://ohrp.cit.nih.gov/efile/>**
- **Must have an e-mail address**
- **Will expedite FWA processing by OHRP**
- **Must still mail in original signatory page**
- **Approval notification sent by e-mail**
- **IRB registration will be web-based soon**

OHRP, 45 CFR Part 46, and HIPAA (1)

- **General comment: The HIPAA Privacy Rule does not preempt any requirements of 45 CFR part 46 and vice versa. In situations where both rules are applicable, institutions must adhere to both sets of regulations.**
- **Will OHRP assess compliance with the requirements of the HIPAA Privacy Rule during its compliance oversight evaluations?**

OHRP, 45 CFR Part 46, and HIPPA (2)

- When must an IRB review and approve patient authorizations for use or disclosure of protected health information related to human subjects research activities in order to satisfy requirements of 45 CFR part 46?**

OHRP, 45 CFR Part 46, and HIPPA (3)

- The preparatory to research provision of the HIPAA Privacy Rule addresses certain circumstances in which seeking patient authorization for use or disclosure of protected health information is not required, nor is obtaining Privacy Board or IRB waiver of patient authorization required. When do the requirements of 45 CFR part 46 related to IRB review and informed consent apply to such activities?**

OHRP Guidance Updates (1)

- **New or recently updated guidance:**
 - **Written IRB procedures (7/2002)**
 - **Continuing review (7/2002)**
 - **Certificates of confidentiality (2/2003)**
 - **Fetal tissue transplantation research (2/2003)**
- **New documents are flagged as “NEW” on the “Guidance Topics by Subject” page (<http://ohrp.osophs.dhhs.gov/g-topics.htm>)**

OHRP Guidance Updates (2)

- Outdated documents on the “OPRR Reports ‘Dear Colleagues Letters’” page (<http://ohrp.osophs.dhhs.gov/dearcoll.htm>) are labeled as “Archived.”
- “Archived documents” page (<http://ohrp.osophs.dhhs.gov/archive.htm>)

OHRP Regulatory Update

- **On December 9, 2002, HHS published in FR in its Unified Agenda notice of proposed rulemaking proposing to add subpart F to 45 CFR part 46, IRB Registration requirements (67 FR 74523)**
- **Registration would require: approximate number of active protocols, accreditation, and staffing**

OHRP Updates

- <http://ohrp.osophs.dhhs.gov/>
- **Subscribe to OHRP Listserv**