OHRP Guidance Development Process

Secretary's Advisory Committee on Human Research Protections Meeting
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http://www.hhs.gov/ohrp/index.html

Outline

- Selection of Topics
- Mechanisms for Guidance Development, Review and Approval
- Communicating Posting of OHRP Draft Guidance Documents and Soliciting Public Comment
- Process for Finalizing Guidance
- Communicating Posting of OHRP Final Guidance

OHRP

Selection of Topics

- OHRP mailbox queries
- SACHRP recommendations
- Update existing guidances
- OHRP-FDA collaboration to identify topic
- Requests from HHS agencies

Mechanisms for Guidance Development

- Draft document prepared by lead writer
- Draft document review by Inter-OHRP Committee
  - Chaired by Director of Division of Policy & Assurances
  - Representatives from other 2 OHRP Divisions and OD
  - Meet as needed to provide input on draft document
- More expedited process, depending on topic

Mechanisms for Guidance Development, con't

- FDA input
- Other HHS agencies & non-HHS Common Rule departments & agencies review and comments
- With ASH approval, issue Federal Register Notice announcing availability (NOA) of draft guidance and soliciting public comments, generally 60-day period

Communicate Posting of OHRP Draft Guidance Documents and Soliciting Public Comments

In concert with publishing Federal Register NOA:

- List Serv Announcement (to more than 6,000 subscribers)
- Open Docket for public comments
- Post Request for comment webpage: http://www.hhs.gov/ohrp/requests/

Process for Finalizing Guidance

- Revise draft document after considering public comments and SACHRP
- Input from FDA, other HHS agencies, and non-HHS Common Rule departments and agencies
- Complete the final guidance document

Communicating Posting of OHRP Final Guidance

When final document is released:

- Publish FR Notice announcing posting of final guidance document
- List Serv Announcement
- Post document on OHRP's Policy Guidance webpage http://www.hhs.gov/ohrp/policy/index.html