Maintaining Research Compliance in a World of Constant Change

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HHS Office of Research Integrity (ORI)

• One of many federal offices overseeing research integrity

• Jurisdiction: PHS-funded research and funding applications with exception of regulatory research integrity activities of the Food and Drug Administration

• Mission: Protecting the integrity of PHS-supported research programs
  o Promotion of research integrity (RI)
  o Oversight of research misconduct (RM) investigations
HHS Organizational Structure

- Secretary
- Deputy Secretary
- Chief of Staff

Executive Secretariat

Office of Health Reform (OHR)

Office of Intergovernmental and External Affairs (IEA)

Office of the Secretary (Staff Divisions)

Operating Divisions

Includes OASH, Which includes ORI

Includes: NIH, CDC, FDA, CMS, IHS, HRSA, SAMHSA

Intramural and Extramural Research Programs

HHS/OS/OASH Office of Research Integrity

- Office of the Director
- Division of Investigative Oversight
  - Research Misconduct Cases
  - Technical Assistance Program
  - Compliance Program
- Division of Education & Integrity
  - Education and Research Programs
  - Conferences and Workshops
  - Assurance Program

The regulation implements federal policy on research misconduct (RM) promulgated in 2000 by the Office of Science and Technology Policy:

- Definitions of RM
- Elements of a research misconduct finding
- Procedural principles for handling RM

• Institutions receiving grant funds have primary responsibility for prevention and detection of RM and investigations
• ORI has oversight responsibility for investigations & assurance program

§ 93.103 Research Misconduct

“Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

. . .

(d) Research misconduct does not include honest error or differences of opinion”
ISSUES NOT WITHIN ORI’S JURISDICTION

- Honest error or honest differences in interpretations or judgements of data
- Authorship or credit disputes
- Collaboration agreements or research-related disputes among collaborators
- Duplicate publication
- Intellectual property/patents
- Reclaiming research funds

Institutional Responsibilities – 42 C.F.R. §93.300

General responsibilities for compliance:

(a) Have written policies & procedures for handling allegations
(b) Respond to allegations according to policy
(c) Foster responsible conduct of research (RCR) environment
(d) Protect witnesses, complainants, committee members
(e) Provide confidentiality to the extent required
(f) Reasonably ensure cooperation of institution members
(g) Cooperate with HHS in RM proceeding or compliance review
(h) Assist in enforcing actions imposed by HHS
(i) Maintain an active assurance of compliance
Fostering Responsible Conduct of Research

- Clear and widely available organizational/institutional policy
- Training – recordkeeping, data management, as well as procedural (laboratory, other hands-on)
- Reinforcement of training precepts
- Mentoring
- Resources

RCR Resources from ORI
ori.hhs.gov
DEI INFOGRAPHICS - Samples

- What Drives People to Commit Research Misconduct?
- Got Questions? Ask ORI.
- Possible Red Flags of Research Misconduct

DEI INTERACTIVE VIDEOS AND CASE STUDY VIDEOS

- The Lab: Avoiding Research Misconduct
- The Research Clinic
Institutional Assurances as Deterrence

DEI Assurance Program (42 USC 289b; 42 CFR Part 93)

• **Assurances required for PHS funding**
  - Institutions stipulate that they have a process for responding to allegations of RM, will fulfill assurance terms in PHS-supported research, and will comply with the ORI regulation (42 USC 289b(b)(3))
  - Further, under the assurance, they will report RM investigations to ORI (42 USC 289b(b)(2))

• **Funding eligibility maintained by**
  1. Filing *Annual Report on Possible Research Misconduct* (Jan 1 – April 30)
  2. Keeping policy in compliance w/ PHS regulation (42 CFR Part 93.301(b))
  3. Acting in accord w/ PHS regulation AND their own policies and procedures
Annual Report on Possible Research Misconduct

§93.302(b) Annual report. An institution must file an annual report with ORI which contains information specified by ORI on the institution’s compliance with this part.
Annual Report on Possible Research Misconduct Form

A Sample of Self Report Data from Institutions

- Fabrication (FB)
- Falsification (FL)
- Plagiarism (PL)

Sample of Institutions Reporting Activity (2017)
Some Elements of an Assurance – 42 C.F.R. §93.304

- Protect confidentiality of respondents, complainants, and research subjects
- Assess conflicts of Interest for those carrying out proceedings
- Adhere to time limits for Inquiry & Investigations
- Provide written notice to the respondent(s)
- Provide written notice to ORI
- Have protocols for handling the research record & evidence
- Provide appropriate interim actions to protect public health, federal funds, etc.
- Make reasonable efforts to protect/restore reputations, if no findings found

https://ori.hhs.gov/blog/checklist-allows-institutions-evaluate-their-policies-and-procedures
The Types of Research Institutions Filing Assurances

PERCENT OF 4,280 TOTAL (2017)

- Higher Education: 23%
- Small Business: 53%
- Research Institutes: 8%
- Independent Hospitals: 6%
- Other Health Services: 9%
- Educational Org (Other): 1%

Portion (40%) Institutional Assurances Submitted (2017)

TYPES OF ASSURANCES
- Reviewable: 93%
- Nonreviewable: 7%

NONREVIEWABLE POLICIES
- Policy Template: 21%
- IRB Policy: 26%
- Small Org Statement: 5%
- Corrupted Docs: 7%
- Other: 10%
- Conflict of Interest Doc: 14%
- RCR Training Doc: 12%
- Faculty Handbook: 5%
How Institutions Are Scoring Against Section A
(42 CFR §93.304, Policy Subsections 1 through 27)
Score: Max = 27

Institutional Policies (2017 Sample of 48)

Policy Elements Most Often Missing

- **Lowest Scoring Policy Subsections**
  - A3 – Protect confidentiality of research subjects
  - A12 – Notify additional respondents in writing
  - A15 – Notify respondent in writing of allegations before investigation begins

- **Highest Scoring Policy Subsections**
  - A2 - Protect confidentiality of respondent
  - A7 - Complete *inquiry* in 60 days
  - A10 - Complete *investigation* 120 days after start
How Might Institutional Policies be Useful in Promoting RCR?

- Include all elements required by 42 C.F.R. Part 93
- Include input from key stakeholders – not just admin & attorneys
- Perceived as serving important need – not just useless red tape, or whims
- Broadcast on institutional sites
- Discussed & reviewed during educational / training sessions
- Staff available to answer about interpretation & application
- Updated to reflect changes in technology, research environment, etc.
- Development & revision informed by research on research integrity

So What?

- Research now occurs outside of “traditional” research institutions
  - Doctors' offices, clinics, other settings
  - Patient portals that allow direct interaction
  - Wearable, implanted, or ingested devices
- Data integrity is paramount!
- Falsified or fabricated research can harm those hoping to benefit from it and wastes resources
- Public Health Service funding for research is taxpayer dollars – our money!

We ALL have a stake in compliance, assurance, and integrity!
Thank you!

ori.hhs.gov