OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

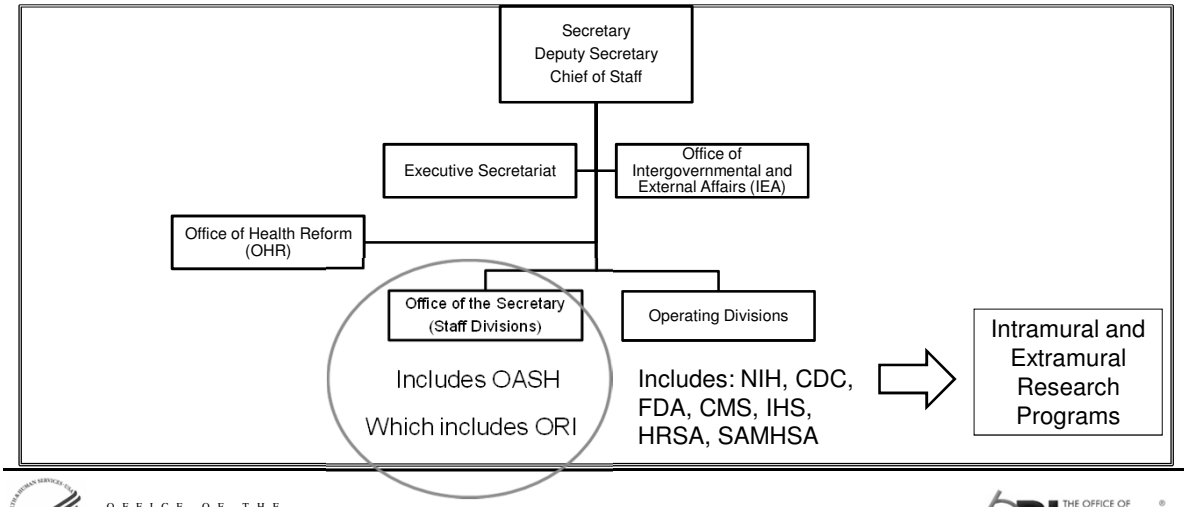
Maintaining Research Compliance in a World of Constant Change

Wanda K. Jones, DrPH
Interim Director, HHS Office of Research Integrity
June 7, 2019

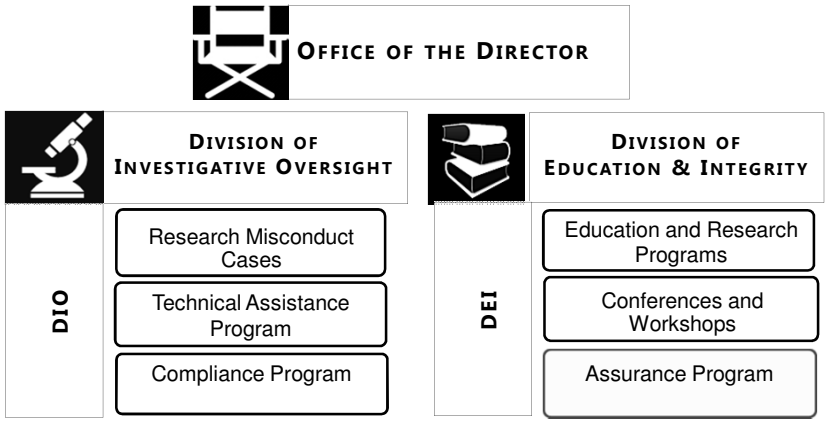
HHS Office of Research Integrity (ORI)

- 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
  - Promotion of research integrity (RI)
  - Oversight of research misconduct (RM) investigations

HHS Organizational Structure



HHS/OS/OASH Office of Research Integrity



42 C.F.R. Part 93 – "The Regulation" (2005)

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"

OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH
THE OFFICE OF RESEARCH INTEGRITY

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

OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

THE OFFICE OF RESEARCH INTEGRITY

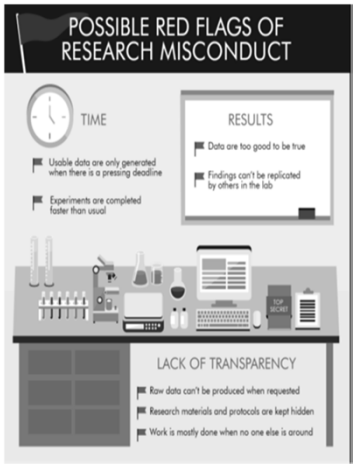
Fostering Responsible Conduct of Research

- 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

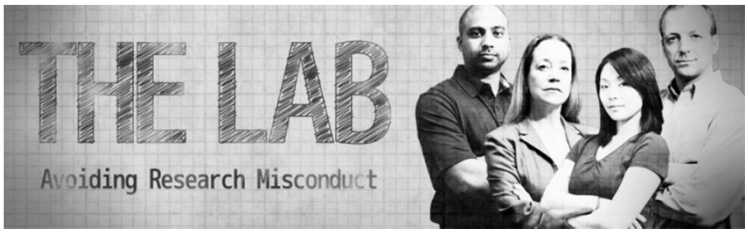
RCR Resources from ORI

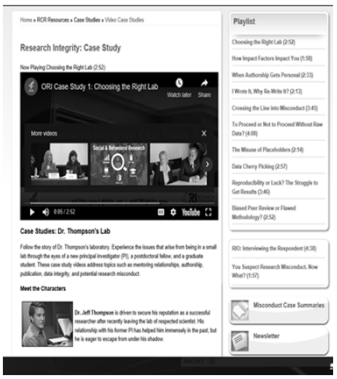
ori.hhs.gov

DEI INFOGRAPHICS - Samples



DEI INTERACTIVE VIDEOS AND CASE STUDY VIDEOS





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

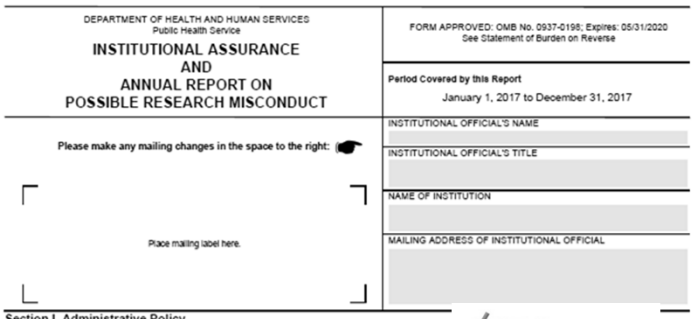
OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

THE OFFICE OF RESEARCH INTEGRITY

Annual Report on Possible Research Misconduct

What are Institutions Reporting?

§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.


DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

INSTITUTIONAL ASSURANCE AND ANNUAL REPORT ON POSSIBLE RESEARCH MISCONDUCT

FORM APPROVED: OMB No. 0937-0198; Expires: 05/31/2020
See Statement of Burden on Reverse

Period Covered by this Report
January 1, 2017 to December 31, 2017

Please make any mailing changes in the space to the right:

Place mailing label here.

INSTITUTIONAL OFFICIAL'S NAME

INSTITUTIONAL OFFICIAL'S TITLE

NAME OF INSTITUTION

MAILING ADDRESS OF INSTITUTIONAL OFFICIAL

Section I. Administrative Policy

Annual Report on Possible Research Misconduct Form

Section II. Types of Misconduct Activity Related to PHS Applications and Awards

A. ☐ **PLEASE CHECK THE BOX** (to the left) if your institution has **NOT** received any allegations or conducted any inquiries or investigations of allegations during the reporting period that (1) fall under the PHS definition of research misconduct and (2) involve receipt of or requests for PHS funding, then complete Section III. Otherwise, please complete Section II.

B. Please provide the requested information for each incident of alleged misconduct that involved a request for or receipt of PHS funds that fell within the PHS definition of research misconduct. Please note that, in accordance with section 93.310(b), all investigations are to be reported to the Office of Research Integrity (ORI) before or immediately upon commencement of the investigation.

PLEASE NOTE: For each incident of alleged research misconduct resulting in an allegation, inquiry, and/or investigation at your institution: (1) provide the ORI case number, if assigned; (2) check the type of activity (allegation, inquiry, and/or investigation -- may include more than one activity type for each reported incident); and (3) check the type of misconduct involved with each activity (may include more than one type of misconduct). Attach a separate sheet if additional space or clarification is required.

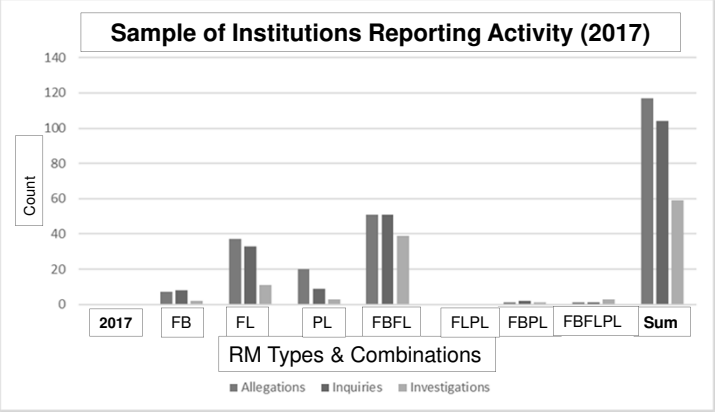
Do **NOT** include any alleged fiscal misconduct, human or animal subject abuses, conflicts of interest, or violations of FDA regulated research.

1. Activity continued into 2017:

Incident Number	ORI Case Number, if assigned:	Type of Activity	Type of Misconduct: Fabrication	Type of Misconduct: Falsification	Type of Misconduct: Plagiarism
1.		☐ Inquiry	☐	☐	☐
		☐ Investigation	☐	☐	☐
2.		☐ Inquiry	☐	☐	☐
		☐ Investigation	☐	☐	☐
3.		☐ Inquiry	☐	☐	☐

A Sample of Self Report Data from Institutions

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



Some Elements of an Assurance – 42 C.F.R. §93.304

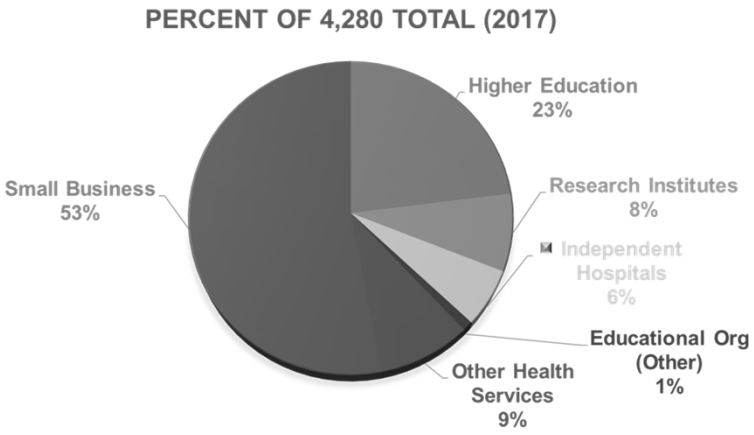
- Protect confidentiality of respondents, complainants, and research subjects
- Assess conflicts of Interest for those carrying out proceedings
- Adhere to time limits for Inquiry & Investigations
- Provide written notice to the respondent(s)
- Provide written notice to ORI
- Have protocols for handling 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

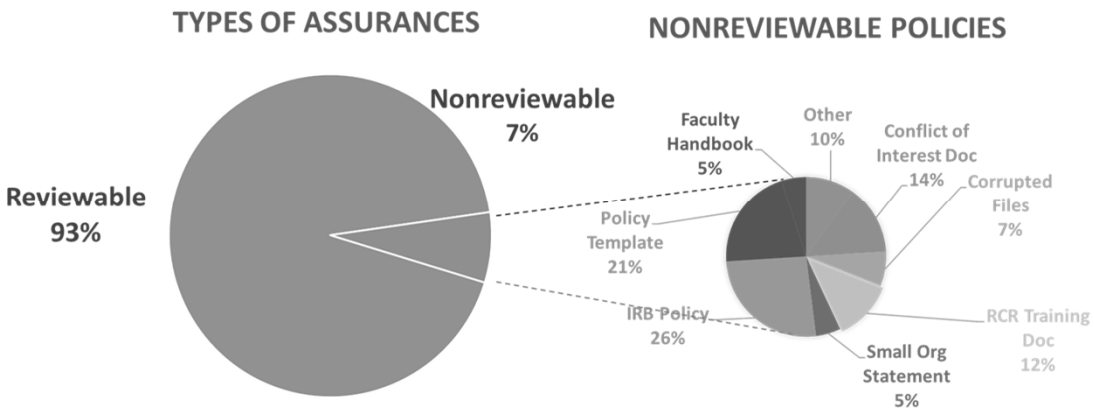
OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

THE OFFICE OF RESEARCH INTEGRITY

The Types of Research Institutions Filing Assurances



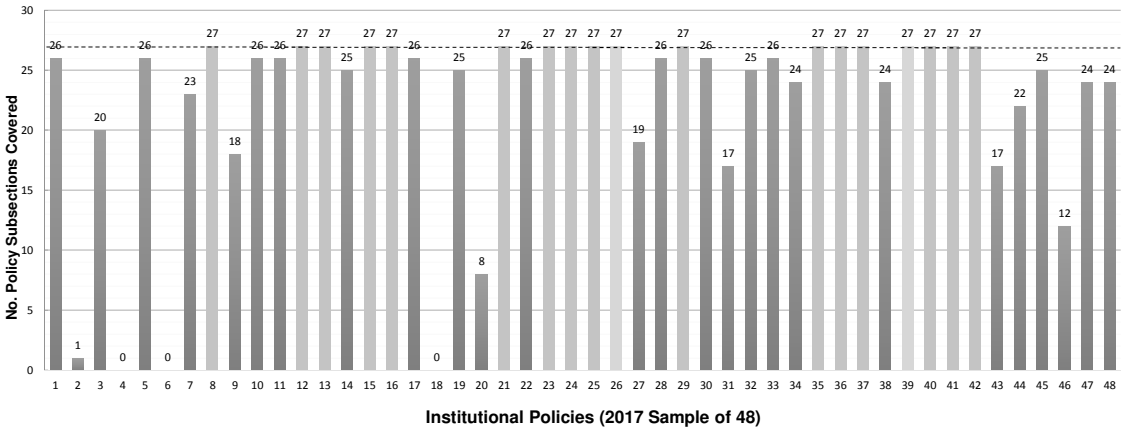
Portion (40%) Institutional Assurances Submitted (2017)



How Institutions Are Scoring Against Section A

(42 CFR §93.304, Policy Subsections 1 through 27)

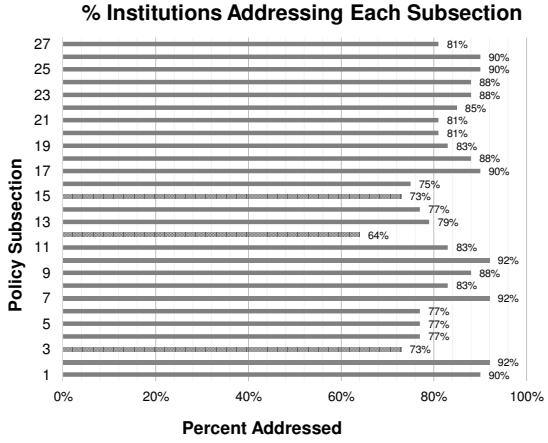
Score: Max = 27



OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

THE OFFICE OF RESEARCH INTEGRITY

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

OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

THE OFFICE OF RESEARCH INTEGRITY

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