Office for Human Research Protections and Scientific Misconduct

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Overview

- **For-Cause Compliance Oversight Evaluations**
- **Allegations related to Scientific Misconduct**
- **Reporting to OHRP**

For-Cause Compliance Oversight Evaluations

Compliance Oversight Evaluation

- Receive allegation of noncompliance
- Determine OHRP jurisdiction
- Written inquiry to appropriate institutional officials
- Review of institution report and relevant IRB documents
- Additional correspondence/telephone interviews/site visit as needed
- Issue final determinations

Allegations Related to Scientific Misconduct

Complaints forwarded to us from ORI

- NIH-funded research being conducted without IRB review and approval--eventually led to suspension of the assurance
- Informed consent documents for genetic studies were inaccurate, outdated, and improperly administered

Types of Misconduct Allegations OHRP Receives

- Fraud within a scientific paper
- Researcher altered subject response data in a study on the use of SSRI in menopause
- Falsification and fabrication of data (e.g., fabricating subjects and data for a behavioral study)
- Complainants often refer to any untoward behavior as “misconduct”

Most Concerning to OHRP

- Falsification of human subject signatures on informed consent documents, particularly if consent was not obtained at all prior to subjects involvement in the research
- Falsification/fabrication of eligibility criteria if subjects were inappropriately involved in research, or falsification/fabrication of safety tests

OHRP refers scientific misconduct in HHS-supported research to ORI

Reporting to OHRP

These Incidents Need to be Reported to OHRP Under 45 CFR Part 46

- Any unanticipated problems involving risks to subjects or others.
- Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB.
- Any suspension or termination of IRB approval.

[45 CFR 46.103(b)(5)]

Types of scientific misconduct reported to OHRP

- Fabrication of data (studies on pain relief after surgery)
- Falsification of data (study on bereavement therapy)
- Falsification of subject signatures and subject diary entries (study on post-surgery emesis; IV drug after CABG surgery; genetic research; ED outcomes)

What Does OHRP Look for in Incident Reports?

- What was the incident?
- What is the institution's plan of action?
- Is the institution's plan adequate?
- Does the research protocol or informed consent document require modification?

When do incident reports result in an oversight investigation?

- Seldom
- Institution's response was grossly inadequate
- Serious problem (e.g. Death of a healthy subject)
- Previous complaint re: same incident