

Office of Research Integrity: Misconduct Prevention Integrity Promotion

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Medical Research Summit

New Federal Policy on Research Misconduct in all Federally Funded Research 1 Year from 12/6/2000

- Defines “Research Misconduct”
 - Falsification, fabrication or plagiarism
 - Proposing, performing, reviewing, reporting research
 - Significant departure from accepted practices
 - Not honest error or differences of opinion
- Intentionally, knowingly, recklessly
- Preponderance of the evidence

New Policy = ORI Procedures (mostly)

- Responsibilities for Federal agencies and institutions
 - Institution performs inquiry and investigation (unless Federal investigation necessary or appropriate)
 - Federal agency
 - Oversight review of institutional findings
 - Issues federal findings
 - Imposes federal administrative actions

New Policy: Guidelines for Fair Procedures

- Goal:
 - Protect participants
 - Build confidence in the process
- Protect informants from retaliation, harm to reputation
- Provide subjects notice, opportunity to respond, access to data
- Imposes timelines
- Objectivity and expertise in decision-making
- Confidentiality

Where does ORI fit into this?

- ORI has 10+ year history in the scientific integrity field
- 2 Divisions
 - Division of Investigative Oversight
 - Division of Education and Integrity

DIO – Prosecution and Training

- Allegation assessment
- Assistance to institutions
 - Technical (RRTA)
 - Guidance/Training (collection of evidence, investigative techniques, preparation of report)
- Oversight review
- Litigation assistance

DIO Data 1992-2001

- 1531 Allegations received
- 281 Oversight reviews
- 45 ORI inquiries/investigations
- 101 Findings of misconduct

DIO – Scientist Investigators

- Advanced degrees in sciences
 - genetics, psychology, biochemistry, biomedical engineering, neuromolecular biology, virology
- Forensic training
 - Law enforcement investigative techniques
 - Computer imaging
 - Digit analysis

Division of Education and Integrity

- Institutional compliance
- Training
- Education
- Studies
- Policies

DEI – Diverse Responsibilities

- Advanced degrees in sociology, law, science, information science, higher education
- Program and policy development
- Records managers and data analysts

DEI - Misconduct Prevention

- Institutional compliance program
 - ORI assurance required for PHS funding
 - Compliance = policies + procedures for responding to misconduct allegations
 - 1200 compliance reviews per year
 - Noncompliance > suspension/revocation
 - Noncompliance warnings

DEI - Integrity Promotion

- Responsible Conduct of Research policy
 - Institutions train research staff in responsible research practices
 - Integrity, human subjects, animal welfare, conflicts of interest, peer review, etc.
 - Status: Formal policy suspended

DEI - Integrity Promotion

- Research on Research Integrity studies
 - How an instit'1 climate can foster integrity
 - The impact of RCR training on instilling integrity/preventing misconduct
 - Identifying community data acquisition and management standards

Research Integrity Branch – Office of the General Counsel

- Advice and counsel
- Regulations and legislation
- Litigation and settlement

Regulations and Legislation

- Whistleblower protection NPRM
- Gov't-wide debarment regs
- New research misconduct definition and policy
- Partial immunity legislation
- Over-hauling ORI regulation

Litigation and Settlement – Processing of Case

- Allegation - received by DIO, assessed, forwarded to Institution
- Institutional inquiry – Inquiry report to DIO if moving to investigation
- Investigation – DIO monitors/provides technical assistance
- Investigation report with findings and all evidence forwarded to ORI

Processing of Case

- ORI oversight review
 - DIO evaluation of evidence and issues
 - DIO dialogue with Institution to seek clarification, develop issues, obtain additional evidence
 - ORI makes finding on misconduct

Processing of Case

- Administrative actions sought
 - Debarment
 - 3-year standard; can be more/less
 - Mitigating/aggravating factors
 - Supervision
 - No PHS advisory comm. Participation
 - Certification of research legitimacy
 - Retraction/correction

Federal Appeal

- ORI makes recommended findings of misconduct (a.k.a. Charge letter)
- PHS issues Charge Letter to respondent
- Misconduct findings/proposed actions appealed to Departmental Appeals Board
- DAB convenes Research Integrity Adjudications Panel – scientists/ALJs
 - No “rules” – only guidelines

Federal Appeal

- Pre-trial discovery process
 - More case development
 - 6-9 months
- Administrative Trial (*de novo*)
 - 1-6 weeks
 - 30-60 witnesses
 - 15-20 exhibit binders

Federal Appeal

- DAB decision
- Appeal from DAB
 - Debarring official
 - Federal court (respondent only)

A Face on Every Case – The Victims

- Public health
- Research field
- Institution
- Lab staff
- Mentor or mentee
- Collaborators
- Journals
- Institutional investigation participants
- Families