Focus

• Background and Definitions
• Institutional Process
• Evidentiary Standards
• Shared Goals
• Challenges
• Working Together
Research Misconduct Policies

• History as a “negotiated” regulation -- among the public, the press, the Congress, the academy and oversight agencies

• An ongoing process – push to expand definition

• Primary institutional administration through peer review and evaluation, with federal oversight and intervention as necessary (similar to IRB, IACUC, etc.)
Definitions

Federal Standards (PHS- 42 CFR 93; NSF- 45 CFR 689)

• Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results.

• Prior to 2005 the definition included “or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.

Note: many institutions exceed the federal standard and include definitions such as other serious deviation from accepted practices, unethical authorship other than plagiarism, material violations of regulations, deception involving data manipulations, etc. (Resnik DB, Rasmussen LM, Kissling GE. An International Study of Research Misconduct Policies. Accountability in Research. 2015;22(5):249-266)
What is a RIO?

A responsible institutional official who:

• Administers the institution’s procedures
• Assures Compliance with those procedures
• Fosters a research environment that discourages misconduct in all research
What do they do?

The RIO’s duties have evolved to include:

- Receiving Allegations of Misconduct
- Working with Legal Counsel
- Assessing Allegations; Triaging Complex Allegations
- Providing Notice to and Advising Respondent, Complainant
- Sequestering and Safeguarding Evidence
- Protecting Whistleblowers from Retaliation
- Informing Senior Administrators and other Regulatory Officials
- Drafting/Reviewing Inquiry and Investigative Reports
- Finalizing a Case
- Assuring Implementation of Corrective Actions (including correcting the record)
## UCSD Statistics – 10 year record

<table>
<thead>
<tr>
<th>Allegations/Assessments</th>
<th>23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inquiries Opened ¹</td>
<td>13</td>
</tr>
<tr>
<td>Investigations Opened</td>
<td>3</td>
</tr>
<tr>
<td>Number of Findings²</td>
<td>10</td>
</tr>
</tbody>
</table>

¹ Each case may contain multiple respondents and allegations.
² Findings can result from Inquiries when respondent admits to misconduct or an Inquiry can serve in place of an investigation.
Phases of an Allegation

- Complaint
- Assessment
- Investigation
- Inquiry
Complaint

To Institutional Official (preferably the RIO)

Must be Specific and Credible

About Research Misconduct
Assessment

1. Initial review of evidence
2. RIO sequesters data
3. RIO consults Campus Counsel
4. Notification to Complainant and Respondent(s)
Inquiry

1. Examine relevant research records
2. Interview Complainant and Respondent(s)
3. Provide Respondent Opportunity to Respond Orally and in Writing
4. Prepare Report
Inquiry Determines

• Allegation lacks substance or is without merit

• Allegation is about something other than research misconduct

• Probable Cause exists, to all or part of the allegation, that research misconduct may have occurred, warranting investigation
Evidentiary Standard: Inquiry Phase

• **Probable Cause** - a reasonable belief based on a standard of proof such that a person of ordinary caution or prudence would be led to believe and conscientiously entertain a strong suspicion of such violation.
Appeal of a Non-Finding

• Grounds for appeal are limited to:

(i) substantial new evidence has been discovered;
(ii) appropriate procedures were not properly followed;
(iii) one or more committee members had a Conflict of Interest.
Investigation

1. Notify extramural sponsor (as required)
2. Appoint Committee with relevant expertise
3. Conduct thorough Interviews; produce transcripts
4. Examine evidence, broaden investigation as necessary
5. Make finding
A Finding of Research Misconduct Must:

- Be proven by a **Preponderance of the Evidence**
- Be committed **Intentionally, Knowingly, or Recklessly**
- Be a significant departure from **accepted practices** of the relevant research community
Evidentiary Standard: Investigation

• **Preponderance of the Evidence** - when the greater weight of credible evidence shows that it is more likely than not that a Respondent committed the alleged act (e.g., happened more likely than not; or with at least 51% certainty).
Levels of Intent: UCSD Standard

- **Reckless**: An act is done "recklessly" if, although done without the intention to cause harm, the actor consciously disregards a substantial and unjustifiable risk that the act will result in falsification, fabrication, or plagiarism. Reckless conduct is more than negligence (negligence being the failure to take reasonable care). It is a gross deviation from what a reasonable person would do in a similar situation.

- **Knowing**: An act is done "knowingly" if it is taken with knowledge that it is certain or practically certain that a specific consequence (i.e., fabrication, falsification, or plagiarism) will follow from the act, even if the consequence is not itself specifically intended.

- **Intentional (purposeful)**: An act is done "intentionally" if it is taken with the conscious purpose of carrying out the act.
Institutional vs Federal Findings

- Institutions have **more latitude** to come to a finding of research misconduct than ORI or other agencies
  - e.g. assignment of reckless

- No federal agency can **alter or overturn** an institutional finding of research misconduct

- Institutions can require significant and **immediate corrective and disciplinary actions** including retractions, corrections, etc.

- Agencies can take **years to review** and/or prosecute a finding which is typically against the individual
Examples of UCSD Corrective Actions

- Series for Postdoctoral Scholars - The Ethical Challenges of Research - series includes a Mandatory Introductory Course and 5 Special Topics in Data Reproducibility, Image Manipulation, Plagiarism, Scientists and Society, and Objectivity and Overcoming Bias leading to a certificate;

- Mandatory pre-review of proposals or publications for a specified duration before submission to agencies or journals;

- Verification of errata and retractions;

- Modification to laboratory structures and record keeping for quality control of manuscript and image preparation;

- Random sampling of publications in some labs by the Office of Research Affairs;

- Required downsizing of large labs for improved oversight and mentoring;

- Dismissal
Shared Goals

- Integrity of Research Record
- Effective Research Misconduct Processes
- Protect Whistleblowers
- Minimize Legal Risk
Challenges for Institutions

Confidentiality
- Legal liability
- Possible reputational harms
- Journals do not initially have “need to know”

Timing
- Delays permit possible destruction of evidence
- Proper notification and need to follow SOPs

Process
- Need to conduct a thorough investigation
- Researcher rights regarding corrective and HR disciplinary actions
Challenges for Journals

Timing
- Is the paper good or not?
- Correcting the record as quickly as possible

Process
- Dealing with inexperienced RIOs
- Lack of access to original data
- Institutional findings vs ORI findings

Resources
- Lack of resources or SMEs to conduct investigations
How We Can Help

• Institutions can sequester data onsite (in real time) protecting integrity of the data

• Internal experts can advise on scientific matters

• Interviews often reveal other issues of concern that need addressing
Questions for Consideration

• Given confidentiality concerns and legal liability – can we find common ground?

• Are we running parallel processes? Do we need to?

• When is notification to journals appropriate?
  - Journal as complainant – in most policies, complainant serves as witness only.

• If no-finding, what is obligation of both institution and journal to restore reputations?

• CLUE Recommendations
Thank you
mgenerales@ucsd.edu
Additional Material
Key Definitions:

Allegation. An Allegation is any oral or written statement or other evidence of one or more apparent instances of Research Misconduct.

Complainant. A Complainant is a person who makes an Allegation.

Department Head. A Department Head is the head of the Academic Unit in which Research Misconduct is alleged to have occurred.

Research Integrity Officer (RIO). The RIO is responsible for assessing Allegations and determining when such Allegations warrant Inquiries, and overseeing Inquiries and Investigations. The Vice Chancellor for Research is the RIO for UCSD. General oversight of the Policy is the responsibility of the Vice Chancellor for Research.
* May occur at preceding stages as well
** Any party may challenge a finding of no research misconduct within 30 calendar days. Grounds for appeal are limited to:
1) Substantial new information 2) Appropriate procedures not followed 3) Conflict of interest of inquiry committee
Discipline Phase: for Researchers covered by Bylaw 230

**Individual**
- RIO
- Respondent consents
- Respondent does not agree
- Misconduct requires discipline more serious than censure
- RIO Imposes Written Censure
- Refers to EVC specifying charge to be filed w/P&T
- EVC
- Refers to Committee on Privilege and Tenure

**Institutional**
- RIO
- Discusses findings w/EVC, Dean/Department Chair, Respondent
- Proposes institutional corrective action to reduce risk
- Implements corrective action plan
- Ensures completion of Action Plan

* Applies regardless of Disciplinary Category
Discipline Phase: for all others

<table>
<thead>
<tr>
<th>Role</th>
<th>Action 1</th>
<th>Action 2</th>
<th>Action 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Senate w/out MOU RIO</td>
<td>Refer to supervisor w/ copy of report</td>
<td>RIO and Supervisor agree on discipline</td>
<td>Supervisor imposes discipline in accordance w/APM-150</td>
</tr>
<tr>
<td></td>
<td>Provide report to department head</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Senate w/ MOU RIO</td>
<td>Refer to authority specified in MOU</td>
<td>Discipline as prescribed in articles of MOU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff RIO</td>
<td>Refer to Department Head with recommendation of disciplinary action</td>
<td>Department Head imposes discipline in accordance w/staff PPM's</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student/Postdoc/VS RIO</td>
<td>Undergrad: Refer to Student Conduct Coordinator</td>
<td>Grad: Refer to Dean of the Graduate Division</td>
<td>Postdoc: Refer to AVC, Research (UAW contract or APM390)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Med Student: Refer to As. Dean for Student Affairs, SOM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>House Staff RIO</td>
<td>Refer to Dean of School of Medicine</td>
<td>Discipline as per House Officer Policy and Procedures</td>
<td></td>
</tr>
</tbody>
</table>

* Institutional Corrective Action as previously described