Council on Government Relations (COGR) Confidentiality Working Group

Confidentiality Considerations in Research Misconduct Proceedings
Moderator:
- Lauran Qualkenbush, Director, Office for Research Integrity, Northwestern University

Presenters:
- Sheila Garrity, Assoc. VP for Research Integrity, George Washington University
- Ann Pollack, Assist. Vice Chancellor, Office of Research Policy and Compliance, UCLA
- Kris West, Chief Compliance Officer, Emory University
Genesis of the Project

- Limited regulatory guidance & need for common institutional guidance.
- Confusion over language in ORI letters declining to pursue findings
  - “Consistent with federal law and ORI policy, research misconduct proceedings that result in no PHS finding of misconduct remain confidential for ORI. We ask that you respect this policy.”
- Grass roots efforts. Hallway conversations. Desire for more guidance.
- Common need for institutional guidance on confidentiality
- COGR supported effort thanks to Pamela Webb – University of Minnesota, Jackie Bendall and Toni Russo
- ARIO engagement and subject matter experts
• Ann Pollack, Chair - UCLA
• Lizbet Boroughs – AAU
• Lois Brako, Ray Hutchinson, Patricia Ward – University of Michigan
• Gretchen Brodnicki – Harvard Medical School
• Eric Everett – University of North Carolina
• Grace Fisher-Adams – Caltech
• Sheila Garrity, The George Washington University
• David King – University of Louisville
• Lauran Qualkenbush – Northwestern University
• Gerianne Sands – Fred Hutchinson Cancer Research Center
• Naomi Schrag – Columbia University
• Emily Sobiecki – Partners Healthcare
• James Tracy – University of Kansas* partial participation due to retirement
• Kristin West – Emory University
• Supported by COGR: Jackie Bendall and Toni Russo
• How are the regulations/policies interpreted and applied by institutions?
• Is communication from federal agencies to institutions consistent?
• What does “need to know” mean?
• What must be kept confidential and for how long?
• What can be shared with journal editors who want to work with universities to ensure the research record is correct and when?
• What can be said in response to questions about postings on websites and blogs such as PubPeer and Retraction Watch?
• Is there value in benchmarking the confidentiality provisions of academic and research institutions?
• What are reasonable deliverables?
First Steps

- Council on Governmental Relations (COGR) agreed to support an ad hoc working group under the auspices of the standing committee on Research Compliance and Administration (RCA)
- COGR committed to providing staff support
- Quickly became clear that membership on the Work Group needed to include RIOs from major research institutions, legal counsel involved in advising RIOs, and others who work closely with RIOs in responding to allegations of research misconduct
- Determined that the working group should be a joint endeavor supported by the Council on Government Relations (COGR) and the Association of Research Integrity Officers (ARIO)
Mission & Goals

- The work product:
  - should *not* create new audible standards; and
  - should *not* reduce institutional flexibility in interpreting and applying regulations and policies

- Any position and/or work product must be vetted by institutional Research Integrity Officers

- The work product should be an educational document/guidance

- In order to be as useful as possible the guidance should be focused on fairly common issues

- The focus is *only* confidentiality and not other matters related to research misconduct
Scenario-Based Discussions

- Examination of several commonly encountered scenarios in research misconduct proceedings that prompt questions on what may or may not be disclosed in connection with the proceeding.
Applicable Regulations

- OSTP Model Federal Policy
- PHS Regulations
- NSF Regulations
- Others (e.g., DOE)
Applicable Regulations

- PHS Regulations 42 CFR Section 93.108(a)
  - “Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law.”

- Section 93.300(e) 7 93.304(a)
  - Institution has the responsibility for, and must develop policies and procedures that “Provide confidentiality to the extent required by § 93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence.”
Defining “Need to Know”

- Role of institutional policy and interpretation.
- Impact of stage of the proceeding
- Impact of “collateral damage” (e.g., public health implications)
- Impact of need to obtain evidence
Journal X will publish a manuscript submitted by Professors Oak, Pine and Cedar. All are on the faculty of Daffodil University. Professor Pine is the corresponding author. The research being reported was supported by NIH grants.

A post-doctoral student making final edits notes that the manuscript contains a figure that appeared in a prior publication (also supported by an NIH grant) in Journal W by the same three authors, but which was labeled differently. Specifically, although both figures appear to be duplicates, they are labeled as the results of different experiments. The post-doctoral student contacts the RIO for Daffodil University to relay the concerns.

In accordance with Daffodil University’s policy on research misconduct, the RIO conducts a preliminary assessment of the allegations and determines that they meet the federal-wide definition of research misconduct (incorporated into the university’s policy), and are sufficiently substantive, specific, and credible to warrant an inquiry. The RIO identifies the corresponding author, Professor Pine, as the respondent.

*pending final revisions and editing
Issues & Management Considerations

Issues:

• Should the RIO notify Journal X of the decision to conduct an inquiry? Journal W?
• What information should the RIO provide concerning the matter?

Discussion:

• Each scenario has a discussion of management considerations based on:
  • Applicable regulations
  • Institutional policy considerations
  • Guidance issued by journals
Considerations:

- When do you notify journals?
- Do you need an institutional finding? Federal finding? What about when you know data is false?
- What information should be shared?
- Who should notify journals?
Scenario II: Notification of Co-Authors, Collaborators and Media Inquiries

**Coauthors and Collaborators:**
- Who has a need to know?
- When should notifications take place?
- What information should be shared? How does this vary by audience?
- Should all co-authors always be informed? Timing of notification?

**Media Inquiries:**
- Should you respond?
- How should communications be coordinated?
- Plugging leaks
Scenario III: Notifications
When Respondents Leave Institutions

- Notification of current employer?
  - Do you need an institutional finding?
  - Federal finding?
- What if you get notified of an ongoing investigation at a former institution concerning a researcher who recently joined your institution?
Did we miss anything?

• Other considerations for the current three scenarios that were not mentioned?
• Other common scenarios?
Next Steps

- Presentation at this meeting
- Final editing and revising in progress
- COGR committee review, approval and endorsement
- ARIO review and endorsement
- Publication of scenarios as community driven guidance