What happens when COI is not well managed Tales from the Crypt

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Overview of presentation

- Context
- COI breaches and consequences
- Reflections

CONTEXT

Tri-Agency Framework: Responsible Conduct of Research

- Joint framework of the three federal research agencies
- Describes responsibilities of researchers, institutions and Agencies
- Defines breaches of the RCR Framework
- Sets out the minimum requirements that must be included in institutional RCR policies regarding allegations
- Sets out the process that the Agencies follow for addressing allegations of breaches of Agency policies

Responsible Conduct of Research (RCR)

An umbrella term that refers to conducting research responsibly throughout the entire life cycle of a research project

- Application for funding
- Conduct and analysis of research
- Management of research funds
- Dissemination of research results

RCR Framework: Objectives

- Ensure that funding decisions made by the Agencies are based on accurate and reliable information;
- Ensure public funds for research are used responsibly and in accordance with funding agreements;
- Promote and protect the quality, accuracy and reliability of research funded by the Agencies;
- Promote fairness in the conduct of research and the process for addressing allegations of policy breaches; and
- Promote transparency in instances of serious breaches. (Art. 1.3)

RCR Guidance on COI

Tri-Agency Framework on Responsible Conduct of Research (2016) (RCR Framework)

Positive obligation to manage conflict of interest (Art. 2.1.2.f) Researchers are responsible for ...appropriately identifying and addressing any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest in research, in order to ensure that the objectives of the RCR Framework are met.

Obligation extends to participation in Agency peer review processes (Art. 2.6.a)

Participants in Agency review processes must comply with the Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations.

RCR Guidance on COI (cont'd)

Breach of that obligation is a breach of the Framework (Art. 3.1.1.h)

Failure to appropriately identify and address any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest in research, preventing one or more of the objectives of the RCR Framework (Article 1.3) from being met.

Responsibilities: Researchers

- Promote research integrity
- Provide true and accurate information to the Agencies
- Manage Agency funds responsibly
- Comply with Agency requirements for certain types of research
- Rectify breaches

Responsibilities: Institutions

- Develop and administer their own RCR policies that meet the minimum requirements of the RCR Framework
- Ensure researchers comply with the RCR Framework
- Investigate allegations in accordance with their RCR policies
- Report to Agencies when Agency funds are involved

Responsibilities: Agencies

- Ensure institutions respect the timelines for conducting inquiries and investigations
- Examine institutional inquiry/investigation reports
- In cases of breach, determine whether to take recourse
- Respond to RCR questions and interpret RCR Framework

Intentionality

- Any contravention of the RCR Framework is a breach
- Not relevant to consider whether breach was intentional or a result of honest error in determining whether there has been a breach of Agency policy (Art.3.1)
- It is a consideration only when determining the appropriate recourse to impose

WHY?

 Because any breach can undermine the integrity of the research and the research record

Statistics (December 5, 2011 to March 31, 2017)

Categories of confirmed breaches :

- Plagiarism (23% or 26)
- Mismanagement of funds (15% or 16)
- Misrepresentation in an Agency application or related document (13% or 14)
- Lack of rigour (9% or 10)
- Falsification (8% or 9)
- Redundant publication / self-plagiarism (8% or 9)
- Breach of Agency policy or requirement for certain types of research (6% or 7)
- Mismanagement of conflict of interest (5% or 5)
- Invalid authoriship (5% or 5)
- Fabrication (3% or 3)
- Other (5% or 5)

EXAMPLES OF COI BREACHES

Example #1

Applicant for post-doctoral fellowship submitted letter of support from supervisor, without disclosing they were married. They were also research collaborators. Applicant was awarded the fellowship.

No false or misleading facts in application.



Example #1 - Recourse

Institution:

- Assigned Applicant to a new supervisor;
- Took steps to ensure no COI in future with respect to the two Respondents (applicant and supervisor)
- Implemented new procedures in its application process for post-doctoral research awards in order to prevent similar situation from recurring

Agency:

- Revoked Fellowship
- Letter of admonishment to Supervisor (failure to disclose spousal relationship)
- Letter of admonishment to Institution (failure to disclose spousal relationship)

Example #2

Student received stipend from supervisor's research grant. Supervisor was student's parent. Relationship had not been disclosed to institution.

Example #2 - Recourse

Institution:

- Increased awareness/education of its professors regarding research integrity and responsible conduct of research
- Required all faculty to complete Module 7 of TCPS 2 CORE tutorial
- Implemented oversight process by Institution's Finance Dept. for Respondent's grants, for 24 months

Agency:

- Ineligible for funding for two years (but allowed to retain existing grant)
- Ineligible to participate in Agency peer review processes for two years
- Letter of awareness to student with information on student's responsibilities re RCR and importance of identifying and addressing any COI issues
- Letter to Institution suggesting faculty be required to undergo specific training on COI, including on its institutional COI policy

Example #3

Respondent supervised nephews during their graduate studies, and provided them with funds from an Agency research grant. Relationship not disclosed to institution or Agency.

Example #3 - Recourse

Institution:

- Took steps to broaden awareness of its COI policy and attendant obligations (including, among other steps, increased face to face RCR training, promotion of online training courses, making completion of RCR training a milestone requirement within faculties)
- Revised its COI declaration form

Agency:

- Letter of admonishment to Respondent
- Require Respondent to take COI training at Institution
- Acknowledged steps taken by Institution

Example #4

Respondents applied for a research grant involving an industry partner. Respondents (through institution) hired President of industry partner while application adjudication process was underway, and after grant had been awarded.

Example #4 - Recourse

Institution:

- Required validation by Finance Office and Research Partnerships Office of the two academic Respondents' future hirings, for 24 months
- Third Respondent barred from being employed by Institution as a research professional while s/he owns enterprise that could receive research grants from Institution
- Make the completion of Module 7 of TCPS 2 CORE mandatory for all faculty

Agency:

- Academic Respondents ineligible to participate in Agency peer review processes for two years; reminded to identify and address COI when working with industry partners
- Letter of admonishment to third Respondent with reminder to appropriately identify and address COI when working with Institutions, in whatever capacity

Example #5

Respondent submitted invoice for professional services by certain companies, to be paid for under research grant. Expenses were legitimate, but Respondent did not disclose that s/he was President and a shareholder of the companies seeking payment.

Example #5 - Recourse

Institution:

 Disciplinary notice requiring Respondent to complete COI declaration forms

Agency:

- Respondent ineligible to participate in Agency review processes for two years
- Institution required to vet all Respondent's Agency grant applications before submission, for three years
- Respondent required to take COI training at Institution

REFLECTIONS



Sometimes COI is complicated and difficult to identify.

Sometimes IT IS NOT.



Sometimes COI results in real harm to the legitimacy of decisions made, funds received.

Sometimes IT DOES NOT.



Sometimes breaches of COI, especially perceived COI, seem trivial.

Sometimes, despite appearances, THEY ARE NOT.

Conclusion

- Conflicts of interest in research are inevitable
- Researchers are responsible for managing those conflicts, through disclosure to relevant authorities, withdrawal or other appropriate mechanisms;
- Institutions and funders must make guidance clear, ensure training is available (or mandatory) and facilitate access to assistance on interpretation

Questions?



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