

CornellResearch

Conflicts of Interest (COI) Reporting & Research Administration Support System (RASS)

Presented by:

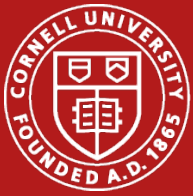
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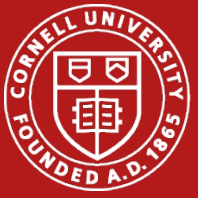
- **Conflicts of Interest Reporting**
 - Why it is important
 - Changes to COI reporting at Cornell
- **Research Administration Support System & Conflicts of Interest Reporting (RASS-COI)**
 - Benefits of the new RASS-COI system
 - RASS-COI demonstration
- **General RASS updates**



Why is COI Reporting Important?

Federal Regulations:

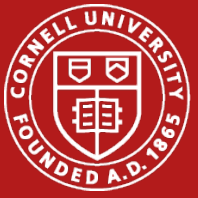
- PHS: Each institution shall specify a time period for the subrecipient to report all identified financial conflicts of interest to their institution....
- PHS: Each investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring a new significant financial interest...
- PHS: Each institution must certify in each application for funding that the institution has processes to identify and manage COIs... and agrees to make information available upon request.
- NSF: An institutional conflict of interest policy should require that each investigator disclose to their institution all significant financial interests of the investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.
- DOE: each entity must have an up-to-date, written, and enforced administrative process to identify and manage conflicts of interest with respect to all projects for which financial assistance funding is sought or received from DOE. At a minimum, the non-Federal entity's policy must address financial and organizational conflicts of interest.



Why is COI Reporting Important (cont.)?

Penalties

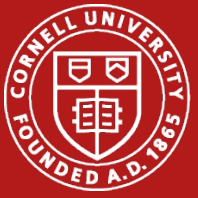
- Loss of funding
- Debarment from funding
- Order to pay back funding
- Fraud prosecution
- False claims act prosecution
- From the headlines: "**University Researcher Sentenced to Prison for Lying on Grant Applications to Develop Scientific Expertise for China**"
 - “Reporting potential conflicts of interest when seeking grant funding from the National Institutes of Health is imperative in ensuring the public’s trust in the research being conducted and how it is utilized,” said Special Agent in Charge Lamont Pugh III for the U.S. Department of Health & Human Services’ Office of Inspector General, Chicago Region. “Making false statements to conceal potential conflicts violates that trust and the law. The OIG is committed to identifying and investigating instances where individuals intentionally fail to report or falsify information regarding their sources of research support in order to ensure the proper use of taxpayer dollars.”



What's Changing?

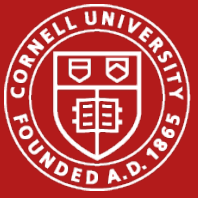
- Moving from an annual to a rolling reporting cycle
- Project-specific disclosures
- System generated notifications
- Expanded reporting requirements
- One system with OSP and IRB
- Changes to sanctions communications





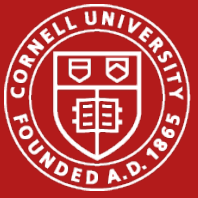
What's NOT Changing?

- **Who** – Cornell faculty and researchers are required to report.
 - <https://researchservices.cornell.edu/resources/who-needs-submit-coi-report>
- **When** – COI reporting is still required *annually*. The switch to a rolling cycle means that the date of your annual report will shift with the date of your last report.
 - <https://researchservices.cornell.edu/resources/coi-reporting-when-and-what>
- **What** – The types of relationships that should be included in your COI report has not changed. There are some changes to the information needed about these relationships to comply with evolving federal requirements.
 - <https://researchservices.cornell.edu/resources/coi-reporting-when-and-what>



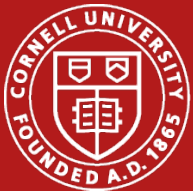
Introducing RASS-COI

- New RASS-COI reporting system to replace eCOI
- Gradual roll out of RASS-COI across campus starting December 2022
 - Notifications will be sent incrementally to campus users based on a specific schedule
 - Reporters won't need to report until they receive a notification that it is time either because their unit is required to report or because they've been named on a sponsored project to IRB protocol.
- For more details about RASS-COI launch:
<https://researchservices.cornell.edu/news/conflict-interest-system-launch-plan>



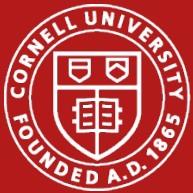
RASS-COI Features

- COI in same system as other RASS modules.
- Transparency improving processing times of awards and protocols.
- System communications provide clarity.
- Routing of management plans within RASS-COI.
- Integration with CITI updating COI training.
- Unit level reporting available.



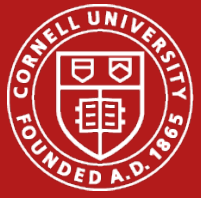
RASS-COI with Proposals & Awards

- Pre-Proposals & Proposals
 - Annual COI requirement for each person listed as key personnel.
- Awards & Award Amendments
 - Annual COI requirement for each person listed as key personnel.
 - Project-specific disclosure for each person listed as key personnel.
 - No action required if key person has not reported any significant financial interests (SFI).
 - Requirement is completed when COI team completes review.
 - Requirement on Award Amendments only if not done during Award or a new SFI reported since award.



RASS-COI with IRB Protocols

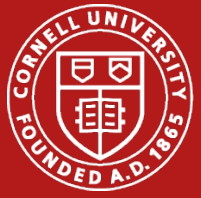
- New Protocols, Continuing Reviews, & Amendments
 - Annual COI requirement for each person listed on the research team.
 - Project-specific disclosure for each person listed on the research team.
 - No action required if team member has not reported any significant financial interests (SFI).
 - Requirement is completed when COI team completes review.
 - Requirement on Amendments or Continuing Reviews only if not done during in previous stages or a new SFI reported.



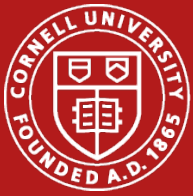
RASS-COI

Let's take a look

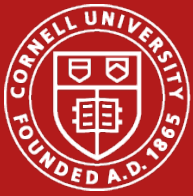




Questions?



- **Current & Pending Management Tool**
 - Move Current/Active Awards to Previous Five Years section
 - Included/Not Include option in all sections
 - Column sort of records in each section
- **Project Deliverables (Sponsored Projects/NFAs/Subawards)**
 - Filter by Deliverable Type
 - Additional column sorting
- **IRB Protocol Approvals & Attestations**
 - Faculty Advisor/PI Attestations possible in collaborative editing mode
 - Approvals possible when another user is in the protocol
- **IRB Protocol Reminders**
 - New terminating soon reminder task for Prescreening Protocols
 - Annual reminder to close protocol if research no longer in progress



COI Resources & Guidance

- Questions?

Contact the COI office: coi@cornell.edu

- Sarah Schlagter, Esq. Director Research Integrity
- Bridget MacRae, Conflicts and Education Supervisor
- Ciara Schiess, COI & RCR Compliance Assistant

- COI Launch Plan: <https://researchservices.cornell.edu/news/conflict-interest-system-launch-plan>

- COI Website: <https://researchservices.cornell.edu/compliance/conflict-of-interest>



- RASS resources:
 - <http://guide.rass.cornell.edu/>
 - System logins
 - “How-To” guidance
 - Contact RASS for support: rass@research.cornell.edu
 - Attend office hours
 - Learn about new features:
<https://guide.rass.cornell.edu/timeline/>
 - Share your feedback on RASS