

# COI Update: Metrics, Survey Results and Hot Topics

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# Disclosure Statement

- The speaker has \$0 financial interest.
- The speaker would like the audience to be aware they have a significant personal interest in educating students, trainees, faculty, and staff about COI since:



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# Contents

- Conflict of Interest
  - Metrics
  - Survey Overview and Upcoming Plans
  - Facts and FAQs
  - Hot Topics

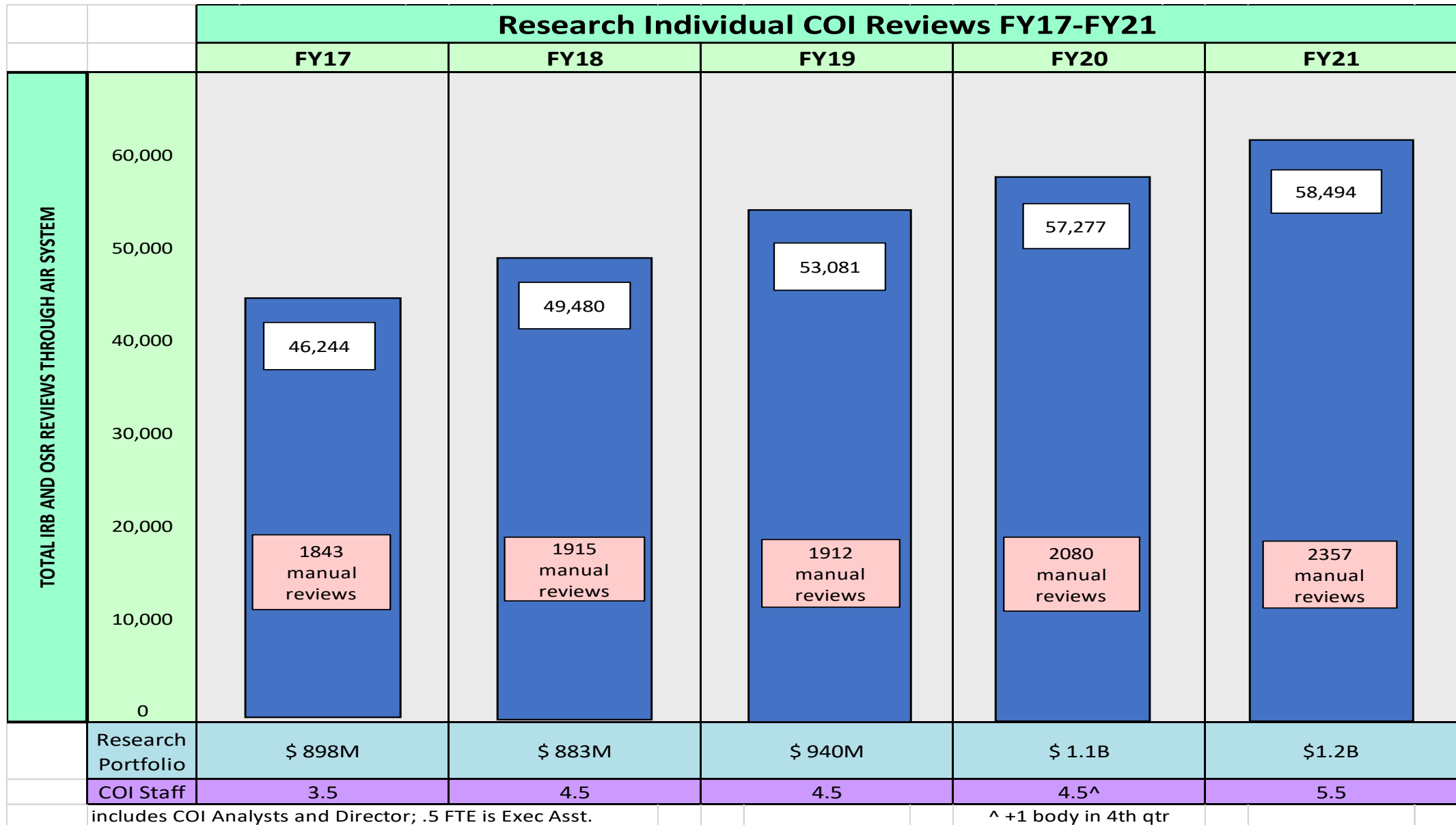


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includes COI Analysts and Director; .5 FTE is Exec Asst.

^ +1 body in 4th qtr



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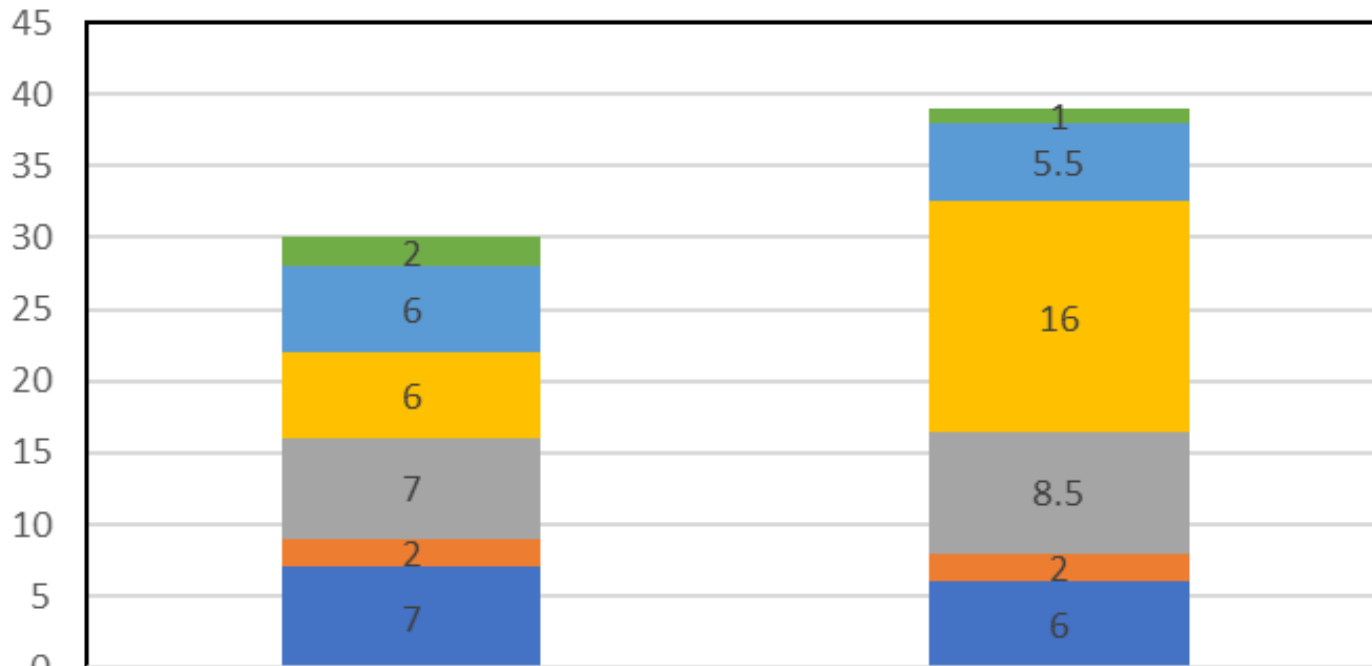
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# Research COI Review Metrics FY21

Median Days Research COI Review FY21



- COI Program Review
- Chair Review
- Committee Review
- Waiting on Sponsor/Other
- Submitter Total
- COI Program Close

- Standard is currently set to have 90% of reviews touched by COI Program for no more than 30 days total.
- For IRBIS, 89% of reviews – from submission to COI finalization letter sent – were completed with all steps in 20 business days.
- For Ramses, COI met 90% for their time but only 67% of Ramses reviews were completed all steps in 30 days. Due to increased time on campus, with submitter and/or sponsor.



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# COI Submitter Survey

- Survey designed to capture experience from individuals who submit COI disclosures, have a determined result and who may be “under management”.
- Survey requests sent to following groups, person unique to group and assigned to most “complex” level of result:
  - No Conflict – submitted form, determined by COI Office
  - COI – submitted form, determined COI w/Administrative Considerations, determined by Chairs
  - FCOI – submitted form, determined FCOI, frequently required report to sponsor, determined by Chairs/Committee



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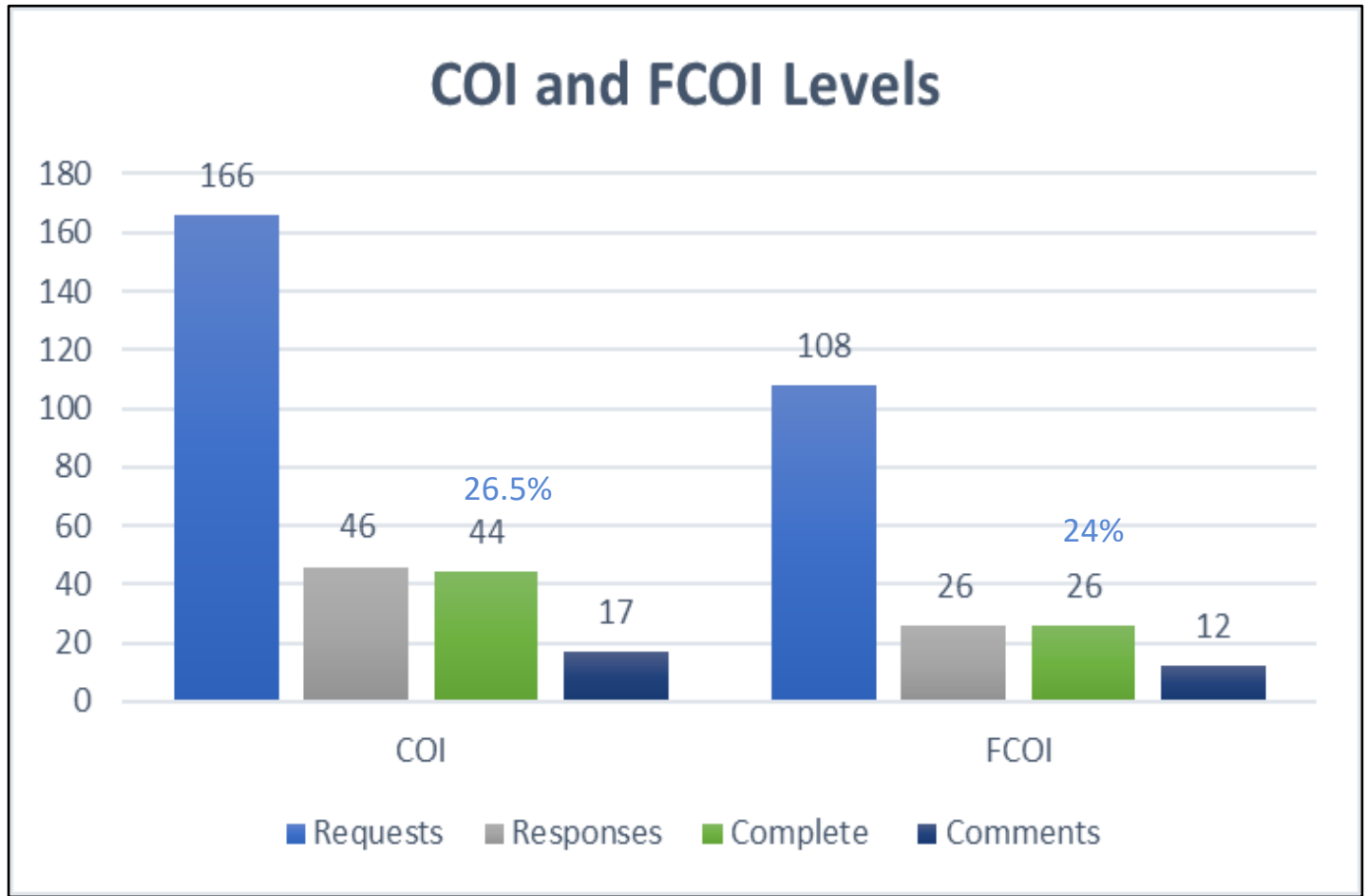
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# Survey Data



NC Who: Faculty 61%, Staff 29%  
 NC Where: SOM, CAS



COI Who: Faculty 88%, Staff 7.5%  
 COI Where: SOM, CAS  
 FCOI Who: Faculty 96%, Staff 4%  
 FCOI Where: SOM, SOP

# COI Survey – Comments and Next Steps

- No Conflicts
  - Remarks as to volume, one check box
  - IRB Coordination
  - Suggestions to form to ease use
  - Positive comments on email prompts and better system than prior institutions
- COI
  - Process
- FCOI
  - Trigger review at funding score, not NOA
  - Want default no conflict
  - Positive comments

## Next Steps

- Implement suggestions for form where practicable
- Look at number of clicks
- Second Survey with campus research coordinators, grants administrators and colleague groups



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# COI Facts

- Research COI Disclosure Frequency
  - Required by federal law on a project-specific basis for grants and contracts.
    - Effective August 2012
    - Determined by then Chancellor Thorp, confirmed since then, to apply to all OSR projects.
  - Required by our IRB Accreditation project-specific for each study.
    - Started with AAHRP re-accreditation in 2012 for new standard
- IRB and COI Disclosure Requirements
  - Schedule set by OHRE as listed in their SOPs
    - New study (or annual renewal)
    - For a new person when added to a study
    - For all investigators when new external funding is added to the study
    - For a new PI when switched into that role
  - IRB retains final approval for all COI in human studies
    - IC text AND management





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# COI Most Common FAQs

- How can I check the status of the COI review?
  - <https://iirm.unc.edu/coi/resources/>
    - [RAMSeS - Compliance Tab/Conflict of Interest \(COI\) Grid](#) 
    - [IRBIS - Personnel Tab/Conflict of Interest \(COI\) Grid](#) 
- Review Process: <https://iirm.unc.edu/coi/conflicts-of-interests/individual-coi/>
  - Look for Research tab then: **COI REVIEW PROCESS MAP**
- Confidentiality of the COI information/management plan
  - Determined by University Counsel
  - Based on a state law



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# COI Most Common FAQs

- The data – email, role, sponsor, no longer on study - is wrong. Can COI fix the form?
  - No, COI cannot fix it. The data is supplied to the COI disclosure form from the IRBIS system, the RAMSeS system, the UNC directory or the PID system. The data must be corrected in those systems AND then the COI form can be re-generated.
- Why does COI not publish meeting “deadlines” like the IRB?
  - COI does not maintain campus-wide committees. Only SOM has enough volume and meets regularly – 2x per month. Agenda items are added up to the day before the meeting.
  - All other committee meet 1x per semester and date of meeting varies. CAS meets monthly (or every other) during semester.



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# Hot Topics

- COI - Science & Security
  - NIH/NSF Notices indicate no change to FCOI process but increasingly want to see foreign activities reviewed for possible COI
- Relation to Conflict of Commitment (COC)
  - Different areas but some similar information
  - Pending guidance for all federal agencies from Office of Science & Technology Policy (OSTP) November 2021
  - Currently no federal definition but that will change....
- Hiring Deputy Director, COI Program



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# Submitted Question

## 1. Interested in any updates about subawards that fall under UNC's COI.

- There have not been any changes to the process of which sub-awards might need to fall under UNC's COI. In accordance with PHS/NIH and NSF regulations, a sub-recipient on our awards may need to fall under UNC's COI policy IF the entity does not have its own policy which is compliant with the PHS/NIH or NSF regulations, as applicable. The OSR Sub Award team is checking that information in a variety of ways and occasionally asks the COI Office for a sub-recipient policy review. Given all of the additional reporting requirements for international contracts currently posed by these federal agencies, additional attention is being given to those sub-contracts to ensure appropriate compliance.



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# Contact



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