



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

UNC's Network for Research Professionals: Individual Conflict of Interest The Quick Kitchen Sink Version

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Disclosure Statement

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

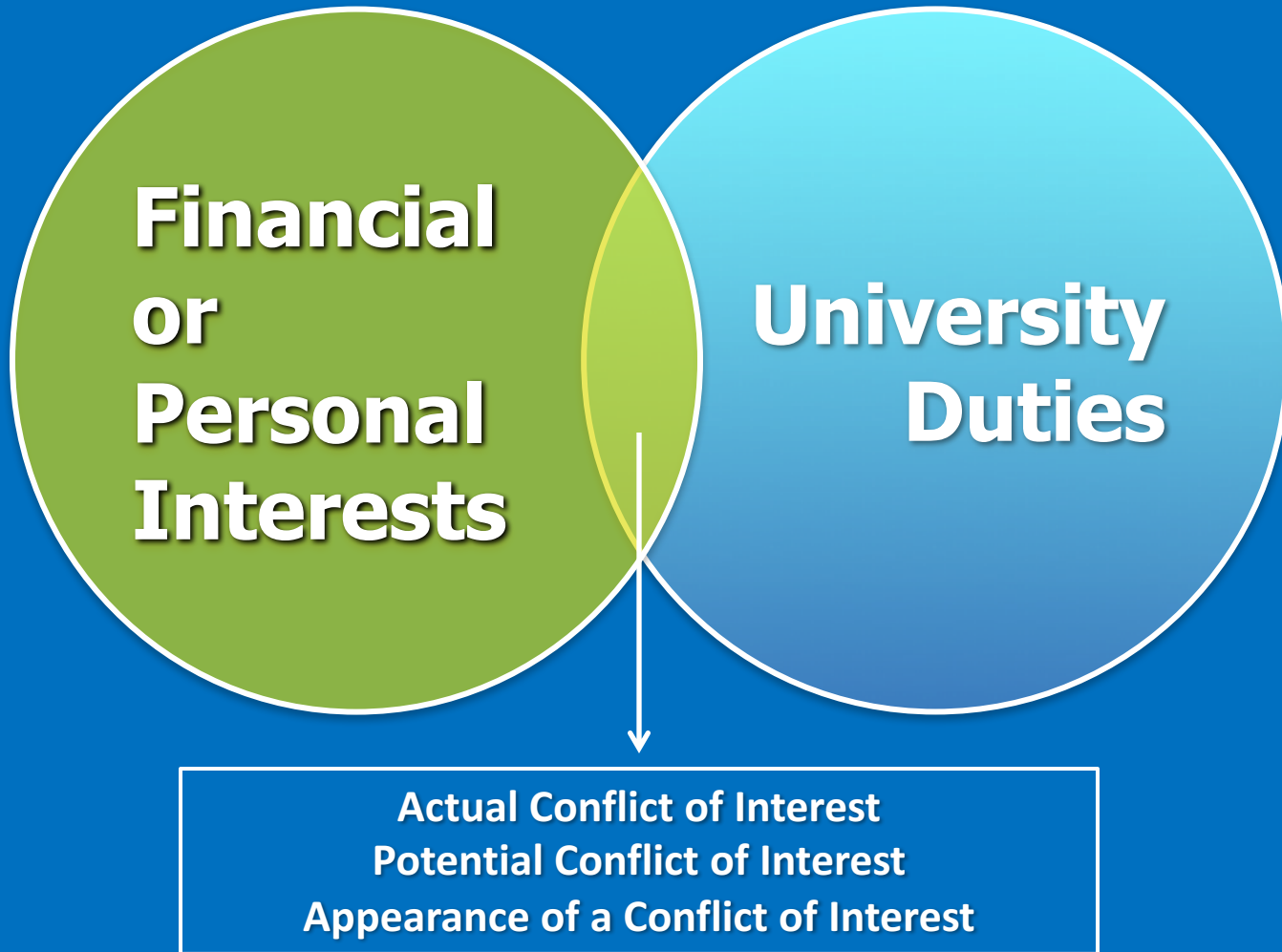


Who is Covered by the Policy on Individual Conflicts of Interest (COI) and Commitment?



Policy on COI has 8 sections, most applied is Research

Visualizing Individual COI at UNC



PHS Federal Definitions

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

FCOI

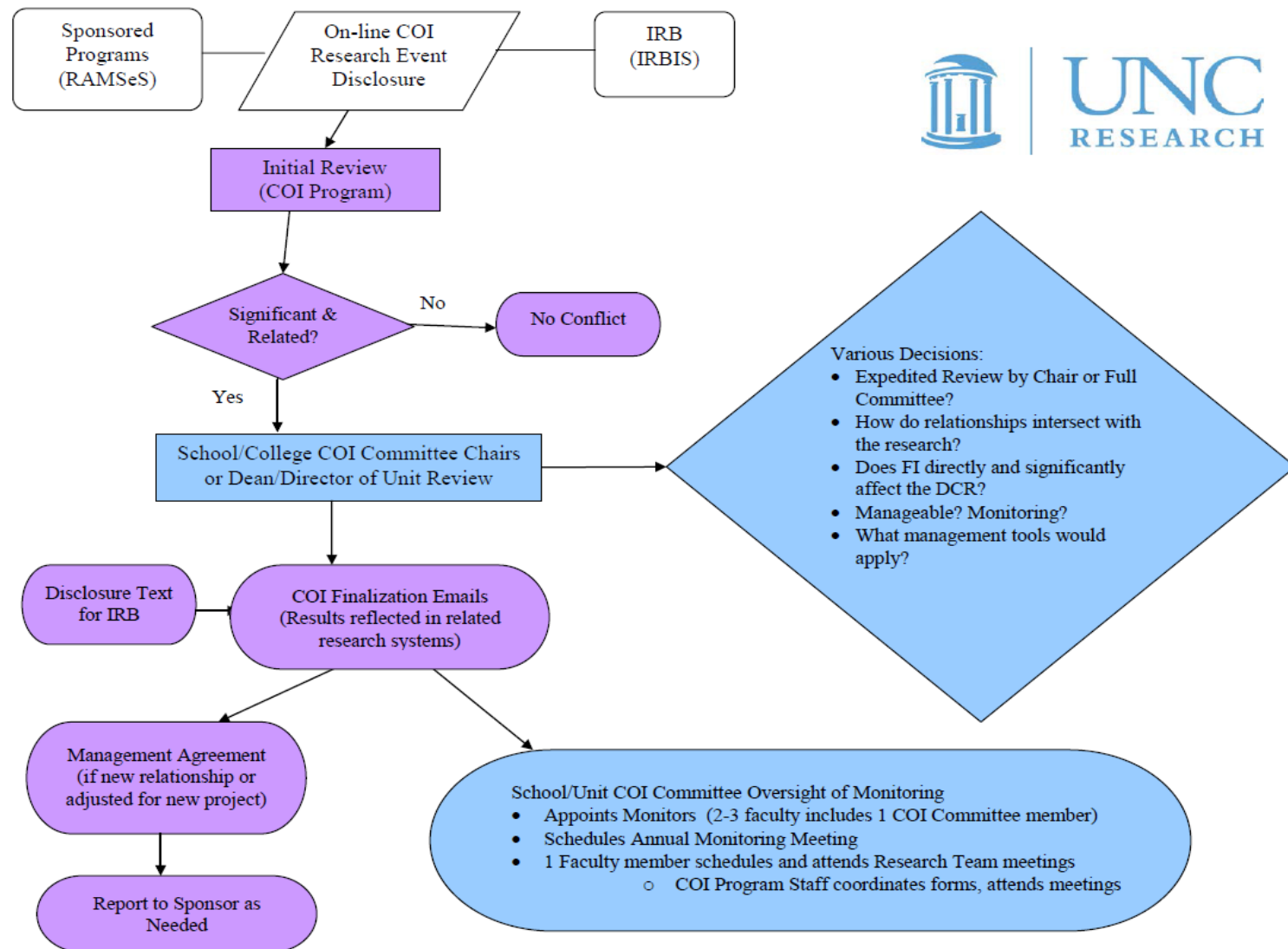
Financial Conflict of Interest means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

UNC's COI Review Approach

- ❖ Conflict does not equal guilty.
- ❖ A conflict of interest can exist even if no improper acts are a result.
- ❖ A conflict can be managed but it still exists and must be acknowledged.

Mantra: Disclose and Manage

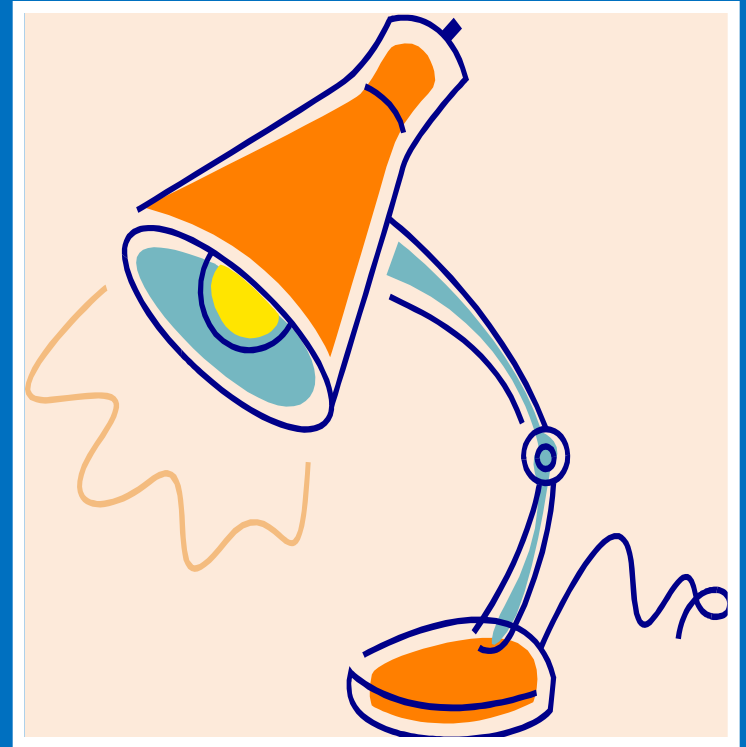
Research - Individual COI Process



Management Principles

Principles

- Transparency
- Honoring the Student/
Trainee Experience
- Protection of the
credibility of the
individual doing the
work



Key Knowledge for Human Subjects

Additional Scrutiny: Like anything with related to human subjects research, the University maintains a **higher standard** in which **Significant Financial Interest**, including in intellectual property, for any investigator is subject to additional scrutiny, **especially for the Principal Investigators**. This standard is regardless of source of funding.

- IRB SOP's state approval **cannot proceed** until COI review is complete, regardless of source of funding.



- When all IRB COI designated personnel who are covered by UNC's policy have submitted their disclosure and review is complete. OR when non-UNC have provided verification of coverage by another institution.



Key Knowledge for Funding

COI Training – Required of all personnel involved in research. “New” individuals should complete immediately, otherwise funding of new projects or their addition to a grant may be delayed.

COI Disclosures to be completed upon application.... but will be reviewed upon funding.

- Federal requirements state funding cannot begin until COI review and COI training is complete.
- At UNC, rule extended to all sources of funding.



- Accounts or FPGs can be set up when COI review and training is completed for all personnel covered by UNC's policy.



COI Places to Stumble



IPF or IRB
is not
submitted
in a timely
fashion



Are people
named on
the Sub or
Proposal
have
correctly
matching
emails?



Was the
right
“Jane
Smith”
chosen
on the
personnel
list?



COI
disclosures
OR trainings
are not
submitted



Subs /or
non-UNC
people
assume
their
policy is
sufficient

Biggest Piece to COI Puzzle



**Bad Data in =
Delays/Approvals
going out**

**COI process is
downstream from
IRB, OIC, OSR**

Contact Information

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