WELCOME
New Faculty!
These materials are intended to orient new faculty to the University of North Carolina School of Medicine and provide resources for additional information.

Topics covered in this slide deck include:

» Office of Research Overview
» Conflict of Interest
Office of Research:
Team & Translational Science as an Institutional Priority

Basic Biomedical Research
- Theoretical
- Model Systems
- Knowledge Expansion
- Innovation

Technological Innovation and Discovery

Human Clinical Research
- Applied
- Patient Care
- Precision Medicine

Health and Genetic Information

Focus Across the Translational Spectrum
Office of Research Strategic Priorities

- Facilitate basic and clinical research
  - Pilot awards (TTSA and ECBR)/NC TraCS partnership

- Strengthen research infrastructure
  - Core Facilities—Genomics (HTSF)/Human Stem Cells

- Enable access to cutting edge technologies
  - Key equipment—Cryo EM/High Res Microscopy

- Strategic investments
  - Faculty recruitment/retention, bridge funding

- Manage research space

- Graduate education
  - BBSP
Conflict of Interest
Overview

Jennifer Brennan, PhD
Director, Office of Research
SOM Conflict of Interest Committee Co-chair
Visualizing COI at UNC

Financial or Personal Interests

University Duties

COI- UNC GA definition
Actual Conflict of Interest
Potential Conflict of Interest
Appearance of a Conflict of Interest

FCOI- federal definition
A financial interest which could directly and significantly affect the design, conduct and reporting of the research
Potential Impacts of COI

The bias that such conflicts may impart can affect many University duties, including:

- decisions about personnel
- the purchase of equipment and other supplies
- the collection, analysis and interpretation of data
- the sharing of research results
- the choice of research protocols
- the use of statistical methods
- and the mentoring and judgment of student work
Key Knowledge for Faculty

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 are submitted upon application.... but will be reviewed when funded.

• 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.
Research - Individual COI Process

Sponsored Programs (RAMSeS) → On-line COI Research Event Disclosure → IRB (IRBIS) → Initial Review (COI Program) →

- Significant & Related?
  - Yes → School/College COI Committee Chairs or Dean/Director of Unit Review
  - No → No Conflict

- Disclosure Text for IRB
- COI Finalization Emails (Results reflected in related research systems)

- Management Agreement (if new relationship or adjusted for new project)
- Report to Sponsor as Needed

Various Decisions:
- Expedited Review by Chair or Full Committee?
- How do relationships intersect with the research?
- Does it directly and significantly affect the DCR?
- Manageable? Monitoring?
- What management tools would apply?

School/Unit COI Committee Oversight of Monitoring:
- Appoints Monitors (2-3 faculty includes 1 COI Committee member)
- Schedules Annual Monitoring Meeting
- 1 Faculty member schedules and attends Research Team meetings
  - COI Program Staff coordinates forms, attends meetings

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Management Principles

Principles

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

Tools

• Management Plans
  – Public Disclosure
  – Independent Review of Data
  – Change in Roles
  – Monitoring Committee
• Alternative Options for Trainees
• Alternative Administrative Routing

NOTE: Human Subjects Research requires a higher standard of scrutiny and management
EPAP (External Professional Activities for Pay)

External professional activities for pay (EPAP) means any activity that

1) is not included within one's University employment responsibilities;
2) is performed for any entity, public or private, other than the University employer;
3) is undertaken for compensation; and
4) is based upon the professional knowledge, experience and abilities of the EPA employee.

NOTES:
• In the SOM, all EPAPs are also subject to review under the Vendor Relations Policy by the Dean’s Office.

Submit via air.unc.edu

Per University Counsel, building equity in a startup is a form of compensation. Any faculty member must submit an EPAP for review when starting a company.
Final Thoughts

As a reminder:

- Conflict does not equal guilty.
- A conflict of interest can exist even if nothing improper occurs.
- A conflict can be managed but it still exists and must be acknowledged.

Mantra: Disclose and Manage
Websites/Contact Information

Portal: AIR.UNC.EDU
Submit and track COI disclosures, EPAP requests. General Email for questions: coi@unc.edu

Websites: coi-training.unc.edu
Website: http://research.unc.edu/offices/coi/

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