# RCR Summer Seminar Series

## Conflicts of Interest

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# Agenda

- Reminders for the session
- Logistics – polls and breakout rooms
- Research COI Program responsibilities and campus partners
- UF and federal policies
- Types of conflicts of interest
- Significant Financial Interests
- Management controls
- Case studies


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# Reminders

- You must log in with UFL email in order to receive certificate credit
- Please take the survey after the class—we value your feedback
- In order to allow for free flow of ideas and questions, we will not record the session
- Slides and other materials will be sent to attendees after the class

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# RCR Certification

- Mentor/Mentee Relationships- Finding the Right Balance
- Collaborative Research
- Conflicts of Interest
- Data Management and Artificial Intelligence
- Compliance at UF &
- Research Misconduct Overview
- Research Misconduct: Plagiarism
- Research Misconduct: ORI: The Lab
- Ethics of Authorship
- Rigors of Peer Review
- Reproducibility & Replicability
- IRB & Informed Consent
- Export Control Overview Including an overview of Dual Use Technology
- Putting it All Together

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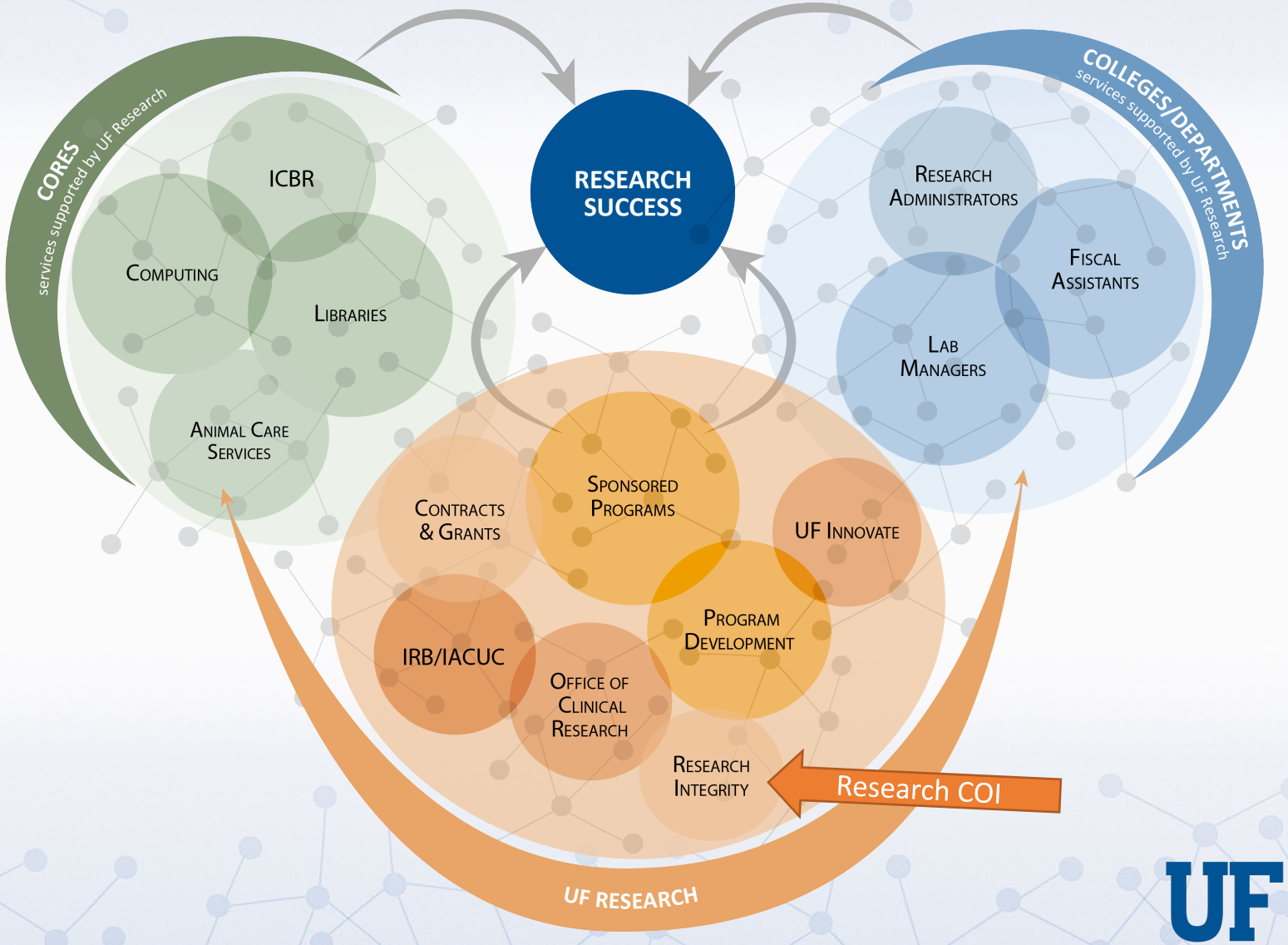
# UF Research Enterprise

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# Research Conflict of Interest (RCOI)

RCOI administers UF's Conflict of Interest in Research Policy. Our office reviews and manages Significant Financial Interests that have the potential to bias research to ensure compliance with sponsor COI regulations.

RCOI partners with the COI Program (UFOLIO), Division of Sponsored Programs (UFIRST) and UF Institutional Review Boards (myIRB and WIRB Checklist) to receive disclosures of Significant Financial Interests.

RCOI serves as a resource to staff, students and faculty on conflicts of interest related to research.

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# UF Conflicts of Interest Program

The UF Conflicts of Interest (COI) Program is an office established under the purview of the Provost and Senior Vice President for Academic Affairs.

The UF COI Program administers UFOLIO (UF Online Interest Organizer), UF's online reporting system for Outside Activities and certain financial interests (prospective approval).

In collaboration with campus partners, the UF COI Program seeks to identify and manage conflicts of interest that could undermine institutional integrity.

# Federal Regulation & Policy

- Key elements of the PHS and NSF COI policies:
  - Individual financial conflicts of interest
  - Disclosure required for actual financial interests (within specified timeframes)
  - Disclosure prior to proposal submission and annually
  - Investigators ("anyone responsible for design, conduct or reporting") must disclose
  - Specific thresholds for what is considered a Significant Financial Interest
  - Reporting obligations to the sponsor (varies by sponsor)
  - Subrecipient compliance
  - Training requirements (PHS)
  - Public accessibility (PHS)
  - Retrospective review for non-compliance (PHS)


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# Types of Conflicts of Interest
## (Research Projects/Contracts)

- **Individual** (PHS and NSF COI policies, UF Research COI Policy)
  - In the context of research, an individual conflict of interest exists when an investigator's private interests may compromise, or have the appearance of compromising, an investigator's professional judgment in the design, conduct or reporting of the research.

- **Institutional** (no federal requirement, best practice and risk mitigation)
  - In the context of research, an institutional conflict of interest may exist when the institution or one of its senior officials has a financial interest related to research.

- **Organizational** (contractual language and FAR clauses)
  - Government is typically concerned about three things: unequal access to information, biased ground rules, and impaired objectivity.

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# Significant Financial Interests


Ownership

Consulting, Advising and Speaking


Intellectual Property

Reimbursed and Sponsored Travel

Thresholds: RCOI Website and Policy

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# Management of Research COIs

- Management is aimed at:
  - Reducing opportunity for bias
  - Preserving public trust
  - Protecting human subjects
- For interventional human subjects research, there is a **rebuttable presumption** that the UF interested investigators and/or UF, if also financially interested, should not conduct the research.
- Presumption can be overcome if compelling circumstances exist.


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# Special Considerations for Human Subjects Research

## Compelling Circumstances

- the nature of the research;
- the magnitude of the significant financial interest and the degree to which it is related to the research;
- the extent to which the significant financial interest could be directly and substantially affected by the research;
- the degree of risk to the human subjects involved that is inherent in the research protocol;
- the extent to which the conflicted Investigator is uniquely qualified to perform a research study with important public benefit, and;
- the extent to which the FCOI is amenable to effective oversight and management.

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# What is a COI management plan?

The purpose of a COI management plan is to document management of potential conflict(s) of interest related to the research and includes:

- A summary of the research purpose, aims & procedures
- Any relevant approvals (human, animal, etc.)
- The role of the investigator in the study
- Outside entities involved in the research
- Amount and nature of interest
- Trainees working on the study
- Inherent controls
- Additional controls
- Compelling circumstances, if applicable
- Summary of discussion/rationale
- Monitoring schedule

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# Inherent Controls

**What are the inherent qualities of the study that protect against or neutralize bias on the part of an investigator?**

Management plan identifies inherent controls such as:

- Investigators blinded to treatment groups
- Low percentage of enrollment at the investigator's site
- Non-interested co-investigators conducting the research and/or data analysis
- External, non-interested lab involved in sample and/or data analysis
- Objective endpoints
- Early stage/pilot research that requires additional studies prior to commercialization
- External monitor

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# Additional Controls

**What additional controls can be added to the study to that may also protect against bias on the part of an investigator?**

Institution may also add controls such as:

- Public disclosure in presentations and publications
- Safe harbor for students
- Disclosure to human subjects research participants through informed consent
- Notification to research personnel on the study
- Limited role for interested investigator (e.g. does not obtain consent or recruit)
- External IRB review (for institutional conflicts)
- Monitoring of research by an independent reviewer(s) or DSMB
- Reduction or elimination of SFI or severance of relationships

# Case Study #1

- Dr. Hammond is a highly-respected researcher who has several research grants, both federal and non-federal funding. Dr. Hammond is also on an advisory board for DrugMaker Inc., a pharmaceutical company, and has received between $10,000 and $20,000 over the past 12 months for advising.
- Dr. Hammond advises on a particular disease state and the company's clinical trial progression for relevant treatments.
- DrugMaker Inc. is conducting a multi-center, placebo-controlled, double-blinded, Phase 3 clinical trial, and Dr. Hammond proposes to be the PI for one of the trial sites.
- The trial will enroll 2,500 patients, and the UF investigational site will enroll 12 patients.
- Dr. Hammond and all UF study staff will be blinded to the treatment and control groups.
- DrugMaker Inc. is using a Clinical Research Organization to monitor the study and perform data analysis.

# Breakout Room

- What are the inherent controls (aspects of the research design the limit Dr. Hammond from introducing bias into the research)?
- What additional controls would be appropriate for this research?
- What questions do you have for Dr. Hammond?


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# Case Study #1: Inherent Controls

- Investigators blinded to treatment groups
- Low percentage of enrollment at the investigator's site
- Monitoring of research and data analysis by CRO

- Additional questions:
  - What are the roles of the interested investigator?
  - Are the study endpoints objective?
  - Does the study include any non-interested faculty/physicians?


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# Case Study #1: Additional Controls

- Dr. Hammond may not obtain informed consent.
- The informed consent document will contain COI disclosure language.
- Dr. Hammond must disclose the interest to research personnel and in resulting publications or presentations.

- Additional questions:
  - Are there trainees working on the study?
  - Should there be an independent data reviewer?
  - Is this study being reviewed by an external IRB?

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# Case Study #2

AKA Conflict of Interest management isn't just for clinical research!

- BikeSafe is a small, non-publicly traded company seeking to develop a new product line that includes additional embedded technologies.
- Dr. Linter developed a bicycle technology to help bicyclists be warned of potential dangers. UF Innovate has submitted a patent application for the technology.
- BikeSafe proposes to license the technology and also to sponsor a study testing the technology with Dr. Linter, the inventor, as an investigator on the project.
- UF accepts an equity interest in the company as part of the license agreement.

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# Breakout Room

- What are the inherent controls?
- What additional controls would be appropriate for this research?
- What additional questions do you have for Dr. Linter?


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# Case Study #2: Inherent Controls

Need additional information for existing inherent controls:

- What are the roles of the interested investigator?
- Are the study endpoints objective?
- Are there any non-interested investigators?
- Is the research basic & in early stages?


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# Case Study #2: Additional Controls

- Dr. Linter must disclose the interest to research personnel and in resulting publications or presentations.
- Dr. Linter must disclose the university's interest in resulting publications and presentations.
- An external IRB will conduct the ethical review of the human subjects research

- Additional questions:
  - Are there students working on the study? If so, what protections should be implemented for them?


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# If You Suspect Research Misconduct…

**Research Misconduct** means **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing research, or in reporting research results.

**Questionable Research Practices** are reports of **careless**, **irregular**, or **contentious research practices**, as well as authorship disputes, may not meet the standard for research misconduct but may be a research integrity violation.

Make a **confidential report** to the UF Research Integrity Officer (RIO)

**Cassandra C. Farley**
(352) 273-3052 | cfarley@ufl.edu

You may also report anonymously
UF Compliance Hotline: 877-556-5356

*Still not sure if it is Misconduct or a QRP?* The RIO can help you better understand the situation. You can speak in hypotheticals as you consider making an official allegation.

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# Federal and State Regulations

| | |
|---|---|
| PHS Regulation | https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf |
| NSF Proposal & Award Policies & Procedures Guide | https://www.nsf.gov/bfa/dias/policy/ |
| Florida State Statute 112.313 (Standards of conduct for public officers, employees of agencies, and local government attorneys) | http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0100-0199/0112/0112PARTIIIContentsIndex.html |
| Florida State Statute 1012.977 (Disclosure of contracts that affect the integrity of state universities or entities) | http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=1000-1099/1012/Sections/1012.977.html |

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# University of Florida Online Resources

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|---|---|
| Research COI \| UFRI | https://research.ufl.edu/compliance.html |
| UF COI Program | https://coi.ufl.edu/ |
| UFOLIO | https://compliance.ufl.edu/ufolio/ |
| Disclosing Foreign Activities | https://research.ufl.edu/foreign-activities-disclosure.html |
| UFIRST | https://grants.research.ufl.edu |

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