Conflict of Interest: Electronic Disclosure System (AIR)

March 20, 2014
Barry Rowan & Dixie Airey
Research & Economic Development

UNC CHARLOTTE
Goals of Presentation

- Awareness of COI Policy and Procedures
- Use of electronic disclosure system (AIR)
- Who to contact with COI questions
Conflicts of Interest

Individual Conflicts of Interests are defined by the American Association of Universities as:

“…situations in which financial considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research.”

Note: COI resides in a situation, not in an individual’s behavior.
Conflicts of Commitment

A Conflict of Commitment is defined as:

“…the distribution of effort between one’s University appointment and one’s outside activities.”

Note: may include External Professional Activities for Pay or uncompensated activities.
Conflicts of Interest & Commitment

Faculty and Staff are encouraged to engage in outside research or non-research activities if the activities are consonant with the University’s mission of teaching, research, and service.

Outside activities and financial interests must be arranged so as not to interfere with the individual’s primary University commitments.
Conflicts of Interest

Purpose of COI Regulations & Policies:

Promoting Benefits for Individuals and Institution

• Maintaining Public Trust.
• Ensuring objectivity in research.
• Protecting our reputation.

Avoiding Harms

• University and the individual can receive fines, penalties, or other sanctions for breaking State or Federal regulations.
Increasing Regulation of COI

PHS Regulation effective 8/24/2012...

NIH Provides Policy Clarification Concerning Disclosure Requirements for Reimbursed and Sponsored Travel - 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought"

Notice Number: **NOT-OD-13-004**

Key Dates
Release Date: October 18, 2012

Issued by
National Institutes of Health (**NIH**)

**Purpose**
NIH is providing policy clarification concerning investigator disclosure of reimbursed or sponsored travel under the Final Rule at 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought."

Consistent with NIH's March 2012 policy clarification concerning disclosure requirements for reimbursed and sponsored travel (See [Frequently Asked Questions F.1](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-004.html), posted on NIH's Office of Extramural Research, Financial Conflict of Interest (FCOI) Web site), investigators who are planning to participate in PHS-funded research must disclose their Significant Financial Interests (SFIs) over the previous twelve-month period to their institution no later than at the time of application for PHS-funded research. As with other SFIs defined in 42 CFR 50.603, the investigator must disclose his/her interests, as well as those of the investigator's spouse and dependent children, that reasonably appear to be related to the investigator's institutional responsibilities.

During the rule making process, we considered how to best balance the need for the institution to have information on an investigator's reimbursed or

Requires disclosure of all Significant Financial Interests related to one's Institutional responsibilities.
Conflicts of Interest

Who is covered by the updated policy?

- UNCC Policy applies to all EPA Faculty and Staff
- Anyone responsible for the Design, Conduct, or Reporting of sponsored research (PHS & NSF definition of “Investigator”)
- Subcontractors of some Federally funded research (currently PHS & NSF).
Conflicts of Interest

What does the updated policy require?

• Annual disclosure by all EPA Faculty and Staff (due by October 1st)
• Project specific disclosure by all Investigators listed on sponsored research proposals
• COI Training for Investigators
• Disclosure of sponsored or reimbursed travel for recipients of Public Health Service (PHS) funding.
• Update disclosures within 30 days of a change
Typical Conflicts of Interest

- Accepting compensation/gratuities from entity doing business with UNCC
- Using UNCC resources for personal use
- Making referrals of UNCC business to external enterprise in which the individual (or his/her family member) has a financial interest
- Serving on Board of Directors of enterprise providing financial support to UNCC when the individual or his/her family member may be recipient of this financial support.
Most Common Situations Requiring Disclosure & Review

• Consulting
• Licensing University Technology
• Participating in research funded by an entity in which the Investigator has a financial interest.
• Requiring students to purchase textbook/materials written by a faculty member who will benefit financially
Activities that are Not Allowable

• Referring University business to an entity in which the individual has a financial interest
• Profiting by trading on the reputation of the University
• Making unauthorized use of privileged information acquired via one’s University employment
• Assigning University intellectual property without prior University approval
State Law – Self-Dealing

§ 14-234. Public officers or employees benefiting from public contracts

• If making or administering a UNCC contract, UNCC employee may not directly benefit from the contract

• If UNCC employee will directly benefit from a UNCC contract, they may not attempt to influence anyone involved in making the contract

• No UNCC employee shall solicit a gift or reward in exchange for recommending or attempting to influence the award of a contract.
Some Key Concepts

• Secondary interests are not necessarily wrong, and are often encouraged (e.g., consulting)

• Perception of COI by reasonable third party is as important as actually being influenced by COI

• Typical approach is Disclosure and Management (in rare cases, Elimination of COI is required)
Types of Disclosures:

- Annual
- External Professional Activities for Pay (EPAP)
- Project Specific – generated by NORM
- Self-Initiated
- Disclosures only required for PHS funding
  - Paid Authorship
  - Travel
COI Disclosure & Review Process

• COI disclosure completed by individual
• If nothing disclosed, then automatically approved
• If anything is disclosed, then sent to COI Manager for initial review
• COI Manager determines if there is conflict
• If Yes, review disclosure with Dean or unit head
• If we don’t agree, COI Committee decides
• If needed, create COI Management Plan
Typical Management Options

- Public disclosure of relationship
- Removal of individual from purchasing/contracting decisions
- Divestiture of financial interest
EPAP Disclosure & Review Process

- EPAP disclosure completed by individual
- Disclosure sent to department head for review
- Department head decides whether or not to approve external activity

- EPAPs must be submitted prior to engaging in the activity, and annually thereafter
Activities, Interests, & Relationships (AIR)

~700 Disclosures since 8/13

https://uncc.myresearchonline.org/air/
Annual Disclosure

Activities Interests and Relationships @ UNC - Charlotte

This system is for use by UNCC Investigators, Inventors and Administrators in identifying circumstances that may give rise to potential conflicts of interest related to research, technology transfer or administrative responsibilities.

For each University research project (sponsored or unsponsored), the Project-Specific Conflict of Interest Disclosure form must be timely filed for each University employee, student or trainee involved in the design, conduct or reporting of the research project for whom one or more of the answers posed in the disclosure form is "yes". The University PI is obligated to ensure that any potential conflict of interest that exists in relation to the research project is reported as required by this University policy.

Faculty and staff in certain administrative positions responsible for resource allocation, personnel decisions, business contracts, purchasing, technology transfer, and other sensitive activities are required to complete an annual questionnaire regarding external relationships that might create or be perceived to create conflicts of interest with their University responsibilities.

For Help

- Questions on conflict of interest may be directed to coimanager@uncc.edu or 704-687-1876.
- For technical questions or assistance please contact COI Help Desk at 704-687-1876.

Self Initiated Disclosures

- [Click here to submit a COI Paid Authorship Disclosure]
- [Click here to submit a COI Travel Disclosure]
- [Click here to complete Notice of Intent to Engage in External Professional Activities for Pay]
- [Click here to submit a Self Initiated COI Disclosure]
- [Click here to submit a COI Disclosure Annual]
Annual Disclosure

• Required for all EPA Faculty and Staff

• Due by October 1\textsuperscript{st}

• Starting this year, all disclosures must be made electronically using AIR.
Annual Disclosure Questions

Have you…

• Received compensation from an entity related to your University responsibilities?

• Held an executive position at an entity related to your University responsibilities?

• Received financial compensation from an entity related to your University responsibilities?

• Engaged in any other activities that could give the appearance of a conflict with your University responsibilities?
External Professional Activities for Pay (EPAP)

Activities Interests and Relationships @ UNC - Charlotte

This system is for use by UNCC Investigators, Inventors and Administrators in identifying circumstances that may give rise to potential conflicts of interest related to research, technology transfer or administrative responsibilities.

For each University research project (sponsored or unsponsored), the Project-Specific Conflict of Interest form is filed for each University employee, student or trainee involved in the design, conduct or reporting of the research project for whom one or more of the answers posed in the disclosure form is “yes”. The University PI is obligated to ensure that any potential conflict of interest that exists in relation to the research project is reported as required by this University policy.

Faculty and staff in certain administrative positions responsible for resource allocation, personnel decisions, business contracts, purchasing, technology transfer, and other sensitive activities are required to complete an annual questionnaire regarding external relationships that might create or be perceived to create conflicts of interest with their University responsibilities.

For Help
- Questions on conflict of interest may be directed to coimanager@uncc.edu or 704-687-1876.
- For technical questions or assistance please contact COI Help Desk at 704-687-1876.

Self Initiated Disclosures
- Click here to submit a COI Paid Authorship Disclosure
- Click here to submit a COI Travel Disclosure
- Click here to complete Notice of Intent to Engage in External Professional Activities for Pay
- Click here to submit a Self Initiated COI Disclosure
- Click here to submit a COI Disclosure Annual
EPAP Disclosure

• Applies to all EPA Faculty and Staff

• Must be submitted prior to engaging in outside activity, and annually thereafter

• All EPAPs must be submitted electronically using AIR

• If 9 month Faculty, don’t need approval for activities performed fully outside of the academic year
EPAP Disclosure Questions

• Name of contracting organization
• Type of organization
• Does the organization directly support your University activities?
• Your role for the proposed activity
Project Specific – sponsored research in NORM

This system is for use by UNCC Investigators, Inventors and Administrators in identifying circumstances that may give rise to potential conflicts of interest related to research, technology transfer or administrative responsibilities.

For each University research project (sponsored or unsponsored), the Project-Specific Conflict file for each University employee, student or trainee involved in the design, conduct or reporting of the research project for whom one or more of the answers posed in the disclosure form is “yes”. The University PI is obligated to ensure that any potential conflict of interest that exists in relation to the research project is reported as required by this University policy.

Faculty and staff in certain administrative positions responsible for resource allocation, personnel decisions, business contracts, purchasing, technology transfer, and other sensitive activities are required to complete an annual questionnaire regarding external relationships that might create or be perceived to create conflicts of interest with their University responsibilities.

For Help
- Questions on conflict of interest may be directed to coimanager@uncc.edu or 704-687-1876.
- For technical questions or assistance please contact COI Help Desk at 704-687-1876.

Self Initiated Disclosures
- Click here to submit a COI Paid Authorship Disclosure
- Click here to submit a COI Travel Disclosure
- Click here to complete Notice of Intent to Engage in External Professional Activities for Pay
- Click here to submit a Self Initiated COI Disclosure
- Click here to submit a COI Disclosure Annual

Link to disclosure is emailed to each Investigator on project.
Project Specific – sponsored research in NORM

Project-Specific COI Disclosures must be completed using a link in the email generated by NORM, which is linked to the proposal.
Travel & Paid Authorship (PHS only)

This system is for use by UNCC Investigators, Inventors and Administrators in identifying circumstances that may give rise to potential conflicts of interest related to research, technology transfer or administrative responsibilities.

For each University research project (sponsored or unsponsored), the Project-Specific Conflict of Interest for the University employee, student or trainee involved in the design, conduct or reporting of the research project for whom one or more of the answers posed in the disclosure form is “yes”. The University PI is obligated to ensure that any potential conflict of interest that exists in relation to the research project is reported as required by this University policy.

Faculty and staff in certain administrative positions responsible for resource allocation, personnel decisions, business contracts, purchasing, technology transfer, and other sensitive activities are required to complete an annual questionnaire regarding external relationships that might create or be perceived to create conflicts of interest with their University responsibilities.

For Help
- Questions on conflict of interest may be directed to coimanager@uncc.edu or 704-687-1876.
- For technical questions or assistance please contact COI Help Desk at 704-687-1876.

Self Initiated Disclosures
- Click here to submit a COI Paid Authorship Disclosure
- Click here to submit a COI Travel Disclosure
- Click here to complete Notice of Intent to Engage in External Professional Activities for Pay
- Click here to submit a Self Initiated COI Disclosure
- Click here to submit a COI Disclosure Annual
Research Related Disclosures

• Project-specific COI disclosures: required for anyone involved with the Design, Conduct, or Reporting of sponsored research

• Travel & Paid Authorship disclosures: only required for recipients of Public Health Service (PHS) funding

• All disclosures must be updated within 30 days of acquiring or discovering a new significant financial interest
COI Training – for sponsored research

https://uncc.myresearchonline.org/coi-training/
COI Training

- Required for recipients of sponsored research

- Must be completed once every 4 years

- Must be completed before receiving new funding
Frequently Asked Questions

• I don’t have any conflicts of interest, do I need to submit an annual disclosure?
  Yes

• I’m not sure how to answer a particular question, who should I contact?
  Contact the COI Manager

• Are my COI disclosures confidential?
  Yes, disclosures are part of your personnel file and are considered confidential, unless otherwise required by law

• What do I do if AIR is down or I can’t login?
  Contact the COI Manager
Final Messages

• Increased awareness of COI Policy and Procedures
• Perception of a conflict is as important as an actual conflict of interest
• Many outside activities are encouraged, but disclosure is important
• Disclosures are submitted via the AIR system
• If in doubt, contact the COI Manager
Conflict of Interest

Contact:
Barry Rowan
Conflict of Interest Manager
704-687-8270
browan1@uncc.edu
320 Cameron