Understanding Conflicts of Interest (COI)

Gunta Liders
gunta.liders@rochester.edu
Kelley O’Donoghue
kelley_odonoghue@urmc.rochester.edu
Michael Ritz
Michael.Ritz@rochester.edu
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COI in Research

- A divergence between an individual’s private interests and their professional obligations
- Real: A financial interest that the University reasonably determines could directly and significantly affect the design, conduct or reporting of research (e.g., compensation, equity, fiduciary role)
- Apparent: Relationships that might question the objectivity of research
Examples of Potential Research COI

- Undertaking evaluative research when the investigator or related individuals have a financial, managerial, or ownership interest in the sponsoring company

- Using students or employees of the University to perform research services for a company in which the individual has an ownership interest or from which he/she receives any type of remuneration

Perceived/Potential Risks

- To study subjects in clinical trials
  - Protection of human subjects is paramount

- To investigators
  - Financial, sponsored funding and reputational risks

- To the institution
  - Financial, sponsored funding and reputational risks
General Principles - COI

- **Fact:** There will be conflict, but:
  - Not all significant financial interests are financial conflicts of Interest (fCOI)
  - Not all apparent or perceived conflicting interests are necessarily impermissible
  - Complete and timely disclosure is essential
  - Case by case analysis and management

- When human subjects are involved, there will be a higher level of scrutiny

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**UR COI Policy**

The UR Conflict of Commitment and Interest Policy was substantially revised in August 2012.
UR COI Policy - Definitions

- **Faculty**: All individuals holding a paid academic, clinical or research appointment with the University

- **Investigator**: Any individual who is responsible for the administration, design, conduct or reporting of research.
  - Study coordinators generally meet the “investigator” definition, thus they will be subject to the annual and ad hoc reporting requirements effective immediately.

UR COI Policy - Disclosure

- Annually for all faculty (and for others as specified) done through the Medical Center electronic reporting system

- Ad hoc at any time of the year, PRIOR to entering into University sponsored projects, technology licensing arrangements, etc. or within 30 days

- At research proposal sign-off, if necessary
UR COI Policy – Decision Making

- Dean will decide to eliminate, reduce, or manage any conflict.
- Conflict of Interest Advisory Group (CIAG) is advisory to the Dean of SMD.
- Dean may establish oversight committees to review the activities of situations that are complex (e.g., monitor conduct, ensure timely publication of research results).

UR COI Policy – Reporting to NIH

- ORPA will report to NIH when the Dean determines that a financial interest constitutes a financial conflict of interest related to an NIH grant.
- As of August 2012, we are required to report a lot more information.
UR COI Policy – Clinical Trials

“Transparency” Policy

- Whenever an investigator has a financial interest (FI) related to a clinical trial, certain requirements will apply regardless of whether the FI is determined to be a fCOI.

- These requirements are as follows:

1. Disclose FI in publications, presentations and press releases related to the research;
2. Disclose FI to anyone involved in obtaining the subject consent and clinical team members involved in the study;
UR COI Policy – Clinical Trials

Requirements For Investigators with FI

3. Include RSRB-approved disclosure in the subject consent form; and

4. Notify the Dean of any additional FI related to the research that is received or expected.

UR COI Policy – Clinical Trials

- An investigator with a fCOI related to a clinical trial may not conduct such research unless there are compelling reasons to do so, as determined and approved by the Dean.

- Compelling reasons could include the nature of science, nature of SFI and how closely related to the research, how the research could be affected by the interest.

- When the fCOI is an equity interest in a start-up company that licenses or manufactures the investigational product, participation in any manner other than a consulting role is prohibited.
PHS Revised COI Regulations

Significant Financial Interest (SFI) Threshold

- $5,000 instead of $10,000

More Inclusive

- Now includes not-for-profit entities other than governmental entities, institutions of higher education and affiliated organizations

PHS Revised COI Regulations

30-Day Reporting

- Faculty and Investigators must submit an updated disclosure of SFI within 30 days of discovering or acquiring the SFI

- Reporting is done through UR’s online COI system
PHS Revised COI Regulations

Reporting of Sponsored and Reimbursed Travel

- All travel related to institutional responsibilities must be disclosed, except that reimbursed by excluded entities
- Disclosure must occur within 30 days of the travel
- Required of PHS investigators only

PHS Revised COI Regulations

COI Training

- Each PHS investigator must complete training:
  - prior to engaging in PHS funded research;
  - every four years; and
  - under certain circumstances
- Blackboard online course at UR
PHS Revised COI Regulations

COI Training

• Enforcement:
  • For faculty, account numbers for PHS projects will not be released until training is completed
  
  • For study coordinators, completion of training is by the “honor system” (i.e. no ability to identify all coordinators expending effort on at least one PHS study)

PHS Revised COI Regulations

Public Accessibility

• Information (as specified by the PHS regulations) regarding fCOI held by “senior/key personnel” will be made available to any requestor within 5 business days.
Reporting to the RSRB

- For each study, report outside financial interests for all individuals involved in the **design**, **conduct**, or **reporting of research**:
  - PI (1.4), PI Spouse, PI dependent children
  - Study personnel, Study Personnel Spouses, Study Personnel dependent children
  - Co-PI (1.5), Sub-I (1.6), Study Coordinators (1.7/1.7.1), Persons Obtaining Consent (85.1), Individuals Analyzing Adverse Events (78.1/78.2), Individuals Collecting/Analyzing Data
Reporting to the RSRB

Institutional – University owns stock, stock options, has licensed intellectual property (e.g., patents or copyrights), or has other financial/fiduciary interests.

2.2 * Are you aware of any potential institutional conflicts of interest the University has in this study?  no

If Yes: Explain

Process for RSRB/WIRB Studies

- Review the Application…response to:

2. Conflict of Interest

- **Who is the Sponsor?**
  - Industry-Sponsored…do some more investigating
  - Check RSRB COI database
    - Connection between Study Personnel and Sponsor
    - Institutional Conflict
**RSRB: Financial interest identified?**

- **Financial Interest – Transparency Policy**
  - Disclosure to study staff
  - Consent form language
    - Language from transparency policy should be in the consent

- **Significant Financial Interest – Transparency Policy** *(or possibly a modified transparency policy as required by the COI Committee)*
  - Transparency Policy
  - Special circumstances for recruitment/consenting
    - Should be outlined in the protocol

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**RSRB: Financial COI identified?**

- **Financial COI – Management Plan**

- **Review Management Plan**
  - Disclosure to study staff
  - Consent form language
    - Language from management plan should be in the consent
  - Special circumstances for recruitment/consenting
    - Should be outlined in the protocol
  - Possible that the individual can not be involved in the research **at all**. *Not be PI, Sub-I or Study Coordinator*
RSRB: When an interest is Identified?

- **RSRB** – any changes/additions are included in the review process as a stipulation for review

- **WIRB** – RSRB communicates required changes/additions to WIRB before study is submitted to WIRB. WIRB does not receive the transparency policy or management plan

*Check approved documents!!!*

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Study Team: New Study?

- **Is it Industry Sponsored?**
  - Talk to PI and study staff
    - Any consulting with this company?
    - Receive external monies?
    - Is there any existing Transparency Policy checklist or Management Plan?
Study Team: New Study?  

$\$$ with no transparency policy or management plan? – Contact ORPA

Transparency policy or management  
– Ensure that items are addressed within RSRB/WIRB application

Study Team: New Financial Interest?

- Annual reporting for all faculty…March  
  - Talk to PI and other study staff  
  - Do they have any **NEW** transparency policy checklists or management plans?  
  - Regular team meetings…keep as a running agenda item

- 30-day reporting all year

- At research proposal sign-off

  *Understand that these may not be easy conversations…**but very important to have***
Study Team: New Financial Interest?

- **RSRB/WIRB**
  - Submit an amendment to revise RSRB/WIRB application, including protocol and consent, to be compliant with transparency policy or management plan
  - **WIRB:**
    - Different COI policy than UR
    - Need to follow UR policy (transparency policy/management plan)…be persistent

Compliance Improvement Initiatives

- Better communication with ORPA/Dean’s Office about transparency policy checklists and new/revised management plans
- Check new plans against ROSS
- Random checks to ensure that current studies are in compliance
Disclosing Conflicts to Staff

- DOCUMENT, DOCUMENT, DOCUMENT
  - When?
  - Who?
  - What?

- Develop a process for how this will occur and follow it.

Take Home Message

- Communication about potential conflicts with PIs and Study Personnel throughout the life of a research study
- Recognize that COIs can occur at any time during a study…need to be aware and pay attention to ensure that these are addressed accordingly
Anticipated Questions

- Who determines that an individual meets the criteria for consideration as an “investigator”?
- Consultants are used on a PHS funded study. Do the consultants need to complete the training course and the disclosure process?
- Do study coordinators need to report sponsored and reimbursed travel?

Anticipated Questions

- Do study coordinators need to complete the annual and ad hoc reporting of external financial interests?
- If a PHS funded investigator serves on an NIH study section and is compensated for those services, does that compensation need to be disclosed to UR?
Anticipated Questions

- If a faculty member attends a study section sponsored by the American Heart Association or the American Cancer Society, they typically pay for travel and also reimburse participants for incidental expenses. Does this need to be reported to UR?