Current Regulations

- Public Health Service regulation:
  “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (1995)
Recent Developments

- **Policy on Financial Conflicts of Interest and Research (2009)** has been implemented
  - Built on 1986, 1993 policies
  - 2011 U. Senate review: the Policy working as expected.

- **CUMC Policy on COI in Clinical Care and Education for all schools.** For P&S, public website access to financial interests.

- **Revised Public Health Service regulation**
  - Takes effect Aug. 24, 2012
Revised NIH Regulation

- Broadens scope of financial interests that investigators need to disclose to the University
- Broadens scope of University review of disclosed financial interests
- Broadens requirements for the University to report to NIH
- New requirements for disclosure to the public
Overall CU Policy Approach

- 2009 Policy anticipated some changes in the new regulations.
- Some technical amendments have been made.
- We will continue to have a single overall Policy governing Columbia research.
- Some implementation will be specific to PHS-funded research and researchers.
New PHS Regulations: Who is covered?

- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Agency for Healthcare Research and Quality (AHRQ)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
New PHS Regulations: Who is covered?

- All PHS Investigators: the Project Director or Principal Investigator and any other individual who is responsible for the design, conduct, or reporting of research funded by the Public Health Service.

- Individuals who are purely advisory or are not sufficiently independent to be in a position to influence design, conduct or results of the research are not included.

- Postdocs and grad students are covered if they meet the definition of an “Investigator”
  - New designation in Rascal Proposal Tracking: “Student-Investigator”
New PHS Regulation: Investigator Obligations

- **Broader disclosure**

  - All “significant financial interests” (SFI) that relate to investigators’ “institutional responsibilities,” not only to their research.
    - We already capture research, clinical care, education
    - Our current Rascal disclosure has been updated to encompass broader requirement
  
  - SFI also includes payments from most non-profits and “any reimbursed or sponsored travel”
    - We include some travel questions but PHS researchers will have to provide more and update **within 30 days**
      - TravelUpdate@columbia.edu
      - Purpose, sponsor, destination, approximate value
New PHS Regulations: Investigator Obligations

- Mandatory training every 4 years
  - Stand-alone Rascal training available
    - TC1450 - Financial Conflicts of Interest for PHS Researchers
  - Human subjects protection training will fulfill the requirement after August 2012, including refresher training
  - Monitored through proposal/protocol submission
  - “Student-investigators” must complete training

- New hires who are PHS Investigators must complete training within 30 days of hire
New PHS Regulations: Subrecipient Requirements

- Proposal Submission: confirmation that subrecipient has its own conflict-of-interest policy that complies with the regulations.
  - New Policy Confirmation Form will be required.

- Award: agreement specifies that subrecipient will apply its own policy.
New PHS Regulation: University obligations

- Determinations project-by-project
- Management
- Reporting
- Review/Mitigation
- Public disclosure
New PHS Regulation: University obligations

Project-by-Project Determinations

1. Do the disclosed SFIs “relate” to the research project?
   - Lower threshold for SFI - $10k is now $5k
   - Assessed by Research Compliance & Training, with input from experts as needed, at just-in-time where possible

2. If yes, is there a “financial conflict of interest”?
   - Assessed by FCOI Committee
New PHS Regulation: University obligations

Management

- Implement a management plan to address FCOI
  - “To ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.”
  - FCOI Committee responsibility

- University must monitor on an ongoing basis
  - RCT/FCOI Committee responsibility
New PHS Regulation: University obligations

Reporting to PHS

- **Initial FCOI Report** prior to expenditure of funds
- **Including:** Project #, PI, conflicted investigator, SFI entity, nature and value of SFI (range), relation to research, key elements of management plan
- **Annual updates** and updates for new issues
New PHS Regulation: University obligations

Review/Mitigation

- **FCOI not identified or managed** in a timely manner (due to failure by an investigator to disclose or the institution to review or manage an FCOI)?

- University has **120 days** to conduct a retrospective review of the investigator’s activities and related NIH-funded research.

- **Was there bias** in the design, conduct, or reporting of the research?

- If bias is found, a **mitigation report** must be submitted to NIH documenting key elements of retrospective review; impact of bias on research; institutional plan to eliminate or mitigate bias.
New PHS Regulation: University obligations

Public Disclosure

- Make available to the public – either on a website or promptly in response to requests from the public – information concerning FCOI’s of key personnel identified in connection with PHS research
  - We plan to respond to written requests

- FCOI Policy must be publicly available
  - We have a Research COI website now
Implementation Strategy

- Project plan; weekly meetings; regular discussions with key partners (SPA, Rascal)
- U. Senate approved necessary “technical amendments” to Policy
- Rascal changes implemented
- Website updates
- At least monthly meetings with peer institutions
- Outreach to and input from senior leadership, FCOI Committees, members of the research community
- Briefings and targeted emails
Conflict of Interest and Research

PHS COI Regulations

The Department of Health and Human Services has issued a new financial conflict of interest regulation - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractor. The regulation, which takes effect on August 24, 2012, governs research sponsored by NIH, CDC, AHRQ, and other PHS agencies and applies to all investigators on new awards, new proposals, non-competing renewals, and no cost extensions received or submitted on or after that date. The regulation includes significant new requirements for all PHS investigators, including:

- Broader disclosure requirements of all financial interests that relate to an individual's institutional responsibilities, including compensation from non-profit entities and sponsored travel
- Mandatory training
- A lower threshold of $5,000 for "significant financial interests"

Below are resources about the new regulation for PHS-funded researchers.

University Resources

Frequently Asked Questions
Disclosure Checklist
Revised Policy on Financial Conflicts of Interest and Research (effective August 24, 2012)

Appendix 2: Compliance with Revised Public Health Service Regulations
Rascal Training on Financial Conflicts of Interest and Research for PHS Researchers

External Resources

NIH Frequently Asked Questions
PHS FCOI Regulation
Questions?

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