

UNIVERSITY AND MEDICAL CENTER PHS COI IMPLEMENTATION

John Chinn, MBA, CHRC
Director, Office of Research Compliance Administration (ORCA)
East Carolina University (ECU)
Greenville, North Carolina

Dawn DeFazio, CIP
Director, Clinical Research and Regulatory Affairs
Allegheny Singer Research Institute (ASRI)
West Penn Allegheny Health System (WPAHS)
Pittsburgh, Pennsylvania

HCCA Research Compliance Conference – Session W2
June 5, 2013 Austin TX



About Us



The ASRI is the research institute for WPAHS whose mission is to practice medicine, educate and conduct research to improve the health of WPAHS patients. ASRI sponsors collaborative, interdisciplinary programs to understand, treat and prevent human diseases.



ECU is part of the UNC system whose mission is to serve as a national model for public service and regional transformation through teaching, research, and service.



Session Objectives

- Describe differences and commonalities in academic medical centers and hospitals in a health care system
- Review PHS COI regulation
- Describe sources of COI and COI issues
- Described what worked and what didn't work
- Described solutions found for COI issues
- Audience participation

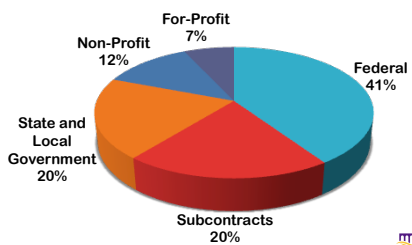
Commonalities

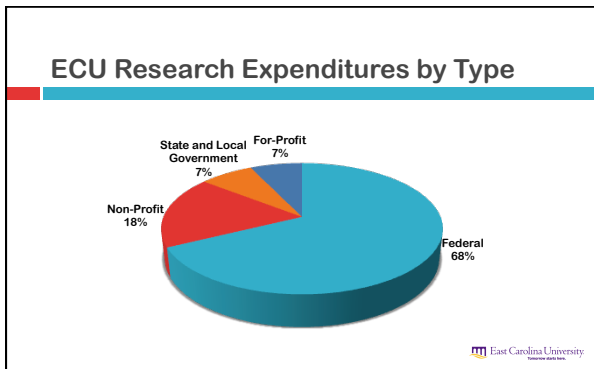
- Academic Medical Centers and Community Health Systems
 - Collaboration and local economic development
 - Common employees – Physicians, residents, interns
 - Research – Clinical trials, Oncology groups
 - Regulations – HIPAA, Open Payments Act
 - CMS billing – Standard of care versus research related cost
 - Shared facilities
 - Shared patient population
 - IRB

Differences

- | Academic Medical Center | Community health system |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">Larger research portfolioResearch emphasisDirect PHS fundingHealth worker education | <ul style="list-style-type: none">Smaller research volumeHealthcare emphasisSubcontractedHealth worker interning |

ECU Research Funding by Type





- ### ECU Employee Profile
- 4000 employees
 - 2000 (SPA/CSS) – No COI disclosure required
 - 2000 (EPA) – Annual COI disclosure required
 - 1800 teaching faculty
 - 200 non-teaching (administrative) faculty
 - 278 PHS or externally funded employees from 238 sponsors – Annual COI disclosure required

- ### ECU PHS COI Profile
- 275 employees funded by PHS
 - 53 disclosed a COI
 - 2 PHS related
 - 12 no longer at ECU
 - Types of COI disclosed
 - Board service
 - Consulting
 - Family member's occupation
 - IP
 - Own a business
 - Related person on grant
 - Speaker's bureau
 - Developed textbook
 - 12 reported travel
 - 1 was PHS related

ASRI Research Profile

ASRI's research activities are focused in six interdisciplinary areas, defined to correlate research efforts with the clinical emphases of WPAHS. These six interdisciplinary areas are:

- Cardiovascular/Pulmonary
- Oncology
- Human Genetics
- Neuroscience
- Musculoskeletal
- Lupus and Autoimmunity



ASRI Research Profile

- ACOSOG (American College of Surgeons Oncology Group)
- ACRIN (American College of Radiology Imaging Network)
- CALGB (Cancer and Leukemia Group B)
- CTSU (Cancer Trials Support Unit)
- Gynecologic Oncology Group (GOG)
- NSABP (National Surgical Adjuvant Breast and Bowel Project)
- RTOG (Radiation Therapy Oncology Group)



ASRI Employee Profile

- 1,405 employees
 - 400+ nurses and administrative staff – No COI disclosure required
 - 200 research staff – Annual COI disclosure required
 - 100 students or residents – No COI disclosure required
 - 835 medical staff physicians – Annual COI disclosure required
 - 300 PHS funded or clinical research – Annual COI disclosure required as well as per project

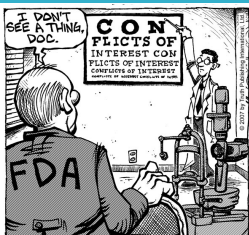


ASRI COI Profile

- 150 employees funded by PHS
- 150 disclosed
 - 5 PHS related
- Types of COI disclosed
 - Board service
 - Consulting
 - IP/Own a business
 - Equity
 - Speaker's bureau
 - Travel



What triggered PHS to revise COI regulations



PHS COI - Definition

A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

PHS Agencies

- Office of Global Affairs (OG)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Agency for Health Care Research & Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Non PHS Agencies

- Administration for Children and Families (ACF)
- Alliance for Lupus Research (ALR)
- American Cancer Society (ACS)
- American Heart Association (AHA)
- American Lung Association (ALA)
- Arthritis Foundation (AF)
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America (LFA)
- Susan G. Komen for the Cure

PHS COI Regulation Major Changes

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> □ 1995 □ SFI - \$10,000 □ SFI's disclose-related to PHS research □ Travel disclosure – none □ Reportable information □ Sub-recipient monitoring - assurances □ Public accessibility – none □ Training requirements – none □ Retrospective review - silent | <ul style="list-style-type: none"> □ 2011 □ SFI - \$5,000 □ SFI's disclose – related to institutional responsibilities □ Travel disclosure – required □ Reportable information – increased details □ Sub-recipient monitoring – increased requirements □ Public accessibility – required □ Training requirements – required □ Retrospective review - required |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

PHS COI Requirements

- Training
- Disclosures
- Travel Disclosures
- Reporting Requirements
- COI management and mitigation plans

BREAK

20 minutes

WEST PENN ALLIANCE HEALTH SYSTEM 

Sources of COI



Potential Conflict of Interest

Source of COI at Universities

University Activities:

- Teach and/or Direct Projects
- Conduct research
- Supervise staff
- Train students
- Evaluate Peers
- Develop and cultivate external relations

Other Professional Activities:

- Consulting
- Board service
- Speaking engagements

Personal Activities:

- Own stock
- Personal commitments

Source of COI at Health systems

- Business associates
- Physician's private practice
- Employee's Secondary employment
- Board members
- Leadership equity
- Surgical facilities owed by physicians
- Hospital owned IP (equipment and tests)
- Multiple hospital sites

ECU's COI Policy and Process

- Interim policy developed
 - For PHS only
 - Implemented August 24, 2012
- New policy
 - In review
 - Requires training for all
 - Affected "Covered Individuals"
 - Adds section for PHS only
- Responsible office

ASRI's COI Policy and Process

- Policy developed and implemented September 2012
- Policy posted on external website along with contact details to request COI information
- Disclosures per PHS requirements
- All research personnel must take training
- All research personnel must disclose
- Management per PHS or individual mitigation plans
- Monitored per PHS or individual mitigation plans
- Subcontractors must follow rules and/or use our COI policies, committee and disclosures



COI Issues for ECU

- Selected employees needed to disclose
- New Policy required
 - State policies and regulations
 - Faculty governance
 - Staff and student buy in
- Revised disclosure system
- Travel not consistently used
- Privacy versus FOIA
- Vidant Health
- Incongruent reports - public versus open payments
- Duplicative disclosures - IRB, CME, Vidant
- Subcontractors and small collaborators
- Students and employees who leave

Actual email from MD when given instruction on completing a COI disclosure online

Am I an EPA employee? If so, that's way to many computer instructions for me to follow! What ever happened to "sign here Doctor?"

COI Issues for ASRI

- **New Policy required**
 - Training requirement – policy, system, new rules and COI training (initial & every 3 yrs)
 - Website Disclosures
- **Revised disclosure system**
- **Subcontractors and collaborators**
- **Monitoring – staffing requirement**
- **Reporting – communication with grants office and timing**
- **Minutes and plans to system compliance office**

WEST PENN ALLEGHENY HEALTH SYSTEM

How ECU Addressed COI Issues

- **Created interim policy for PHS funded**
- **Created training video**
- **Modified online disclosure system**
- **Created travel disclosure**
- **Created University wide policy**
- **Developed process to monitor PHS COI**

How ASRI Addressed COI Issues

- **Created policy, process, website to meet PHS requirement**
 - Investigator Disclosure – who discloses, annual and per project
 - Threshold – now \$5,000
 - Public Disclosure
 - Management of Identified FCOI by Institute
 - Sub-recipients
 - Timing of Reporting
 - Investigator Training
 - Enforcement of Non-Compliance
- **Purchased online system**
- **Developed weekly training sessions on policy, changes, and new process**

WEST PENN ALLEGHENY HEALTH SYSTEM

What Worked at ECU

- Individual training on use of COI app
- Triaging COI disclosures
- Selective surveys on Travel
- FDP COI site
- Electronic disclosures
- Short brief training
- Tutorials and FAQ's

What Worked at ASRI

- Systemwide training on new policy, process and changes for disclosures
- Customized training for departments
- Online training (initial & every 3 years)
- Online disclosure system
- Good communication with regulatory committees and grants office
- New COI committee formation

WEST PENN ALLEGHENY HEALTH SYSTEM

What Didn't Work at ECU

- Change
- New technology
- Mandated training
- Applicable to all employees
- Group consensus
- Source of data

What Didn't Work at ASRI

- ❑ New technology
- ❑ Grants office communication
- ❑ Noncompliance enforcement
- ❑ Monitoring & Reporting – staffing increase
- ❑ Subrecipients and consultants
- ❑ Public disclosures



Dan Ariely (Behavioral Economist) Beware of COI



ECU and ASRI Dialogue

- ❑ Our most interesting COI case
- ❑ COI and risk management
- ❑ Useful tools
- ❑ Senior level of support
- ❑ Comments on Dan Ariely's video



Dialogue with Audience

- Examples of COI in health systems
- COI examples in Academic Medical Centers
- Issues encountered
- Solutions found
- Wish list
- Feedback

WEST PENN ALLEGHENY HEALTH SYSTEM East Carolina University

What people think I do to manage COI

Final Thoughts

- History tells the story of collaboration
- Honesty and objectivity = disclosure
- Integrity = encourages exploration of unconscious bias
- What would Cicero say?
 - There are 3 questions when considering a course of action
 - What is honorable?
 - What is useful?
 - What is apparently useful conflicts with what is right
 - "for when the useful seems to pull them forward towards itself and rectitude seems to draw them back in its direction, the mind as it reflects is tugged in opposite directions, and this makes for troubled indecision"



Final Thoughts

Flowers are restful to look at. They have neither emotions nor conflicts. - Sigmund Freud

The greatest conflicts are not between two people but between one person and himself. - Garth Brooks

I am not a victim of emotional conflicts. I am human. - Marilyn Monroe