

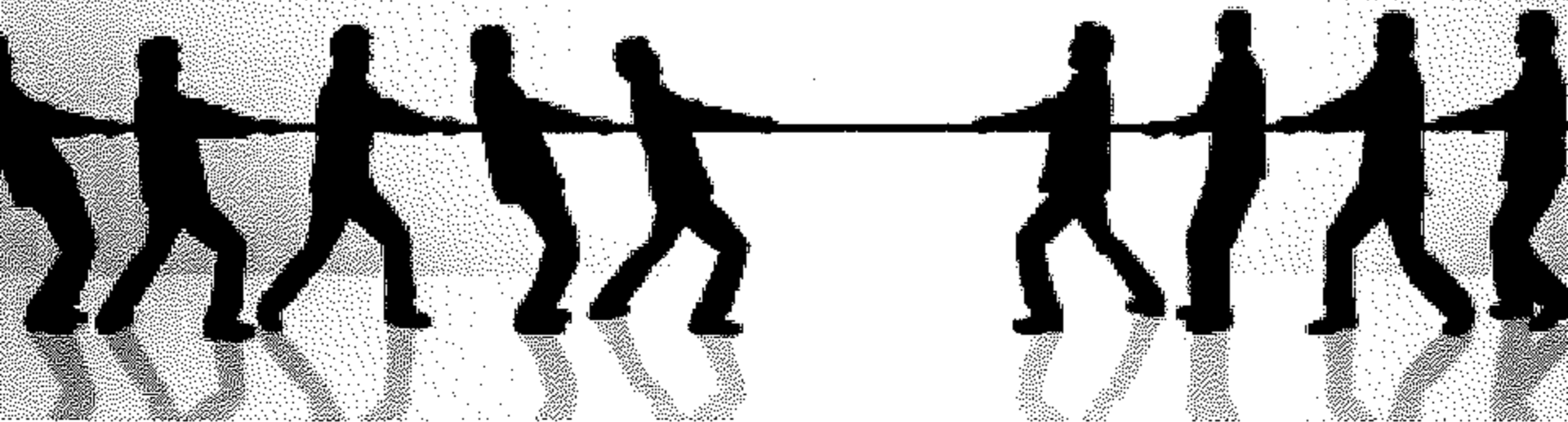
# Conflict of Interest in Research

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# UMB CoI OFFICE

- Manages the Process for **Financial Conflicts of Interest** Review and Management
  - State law
  - Federal Regulations
  - Institutional Policies
- **CoI Officer** is the UMB employee designated to administer review of exemption requests pursuant to the UMB's and USM Board of Regents Policy on Conflicts of Interest.
- The **CoI Officer** is designated as UMB's Institutional official to solicit and review disclosures of *Significant Financial Interests* from each Investigator who is planning to participate in, or is participating in, PHS-Funded Research.

# MANAGING CONFLICT OF INTEREST



# DEFINITION OF COI

- Situation in which the integrity of academic activity, especially research, may be, or may be perceived to be, compromised by financial or other interests.
- Typically an investigator has a financial interest in the research sponsor.
- Spouses (or other family members) on the same grant



*"Try this—I just bought a hundred shares."*

# Examples of potential Col relationships

- Paid consultant
- Paid Advisory Board Member
- Board of Directors
- Equity Interest
- Inventor
- Startup companies
- Spouses on the same grant

# INDIVIDUALS COVERED BY UMB COI POLICIES

- State Ethics Law and UMB Conflict of Interest Policy in Research and Development:
  - UMB Employees (Faculty and Staff)
- PHS FCOI Regulation and UMB Policy on Financial Conflict of Interest for PHS-Funded Research:
  - Anyone responsible for the design, conduct or reporting of PHS Funded Research, regardless of role in the research.

# APPLICABLE POLICIES AND PROCEDURES

- State of Maryland Public Ethics Law
- USM Policy On Conflicts of Interest In Research or Development
- UMB Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development
- UMB Policy and Procedures on Financial Conflict of Interest to Promote Objectivity in Public Health Service-Funded Research.
- UMB IRB Policies and Procedures
  - 6c: Investigator and Study Personnel Conflicts of Interest



# Compliance Universe

A133  
ARRA Terms and  
Conditions

Select Agents  
rDNA  
Biohazards

Research Involving  
Animals

Authorship  
Standards

Time & Effort  
Reporting

Conflict of Interest

Research Misconduct

Human Subjects  
Research

A110

Property  
Management

A21

Hazardous Materials

RCR  
Training

Radiation Safety

HIPAA

Employment  
Issues

Clinical Trial and  
Publication Registration

GLP

Procurement  
Issues

OSHA

GAAP

F & A  
Cost Accounting

Dept/School/UMB  
Requirements

Facilities Issues

Technology Transfer  
Requirements

Public Access Policy

Employment  
Issues

Sponsor/Project-Specific  
Requirements

ITAR and EAR

Export Controls

# Maryland State Public Ethics Law

## Public-Private Partnership Act



# STATE PUBLIC ETHICS LAW

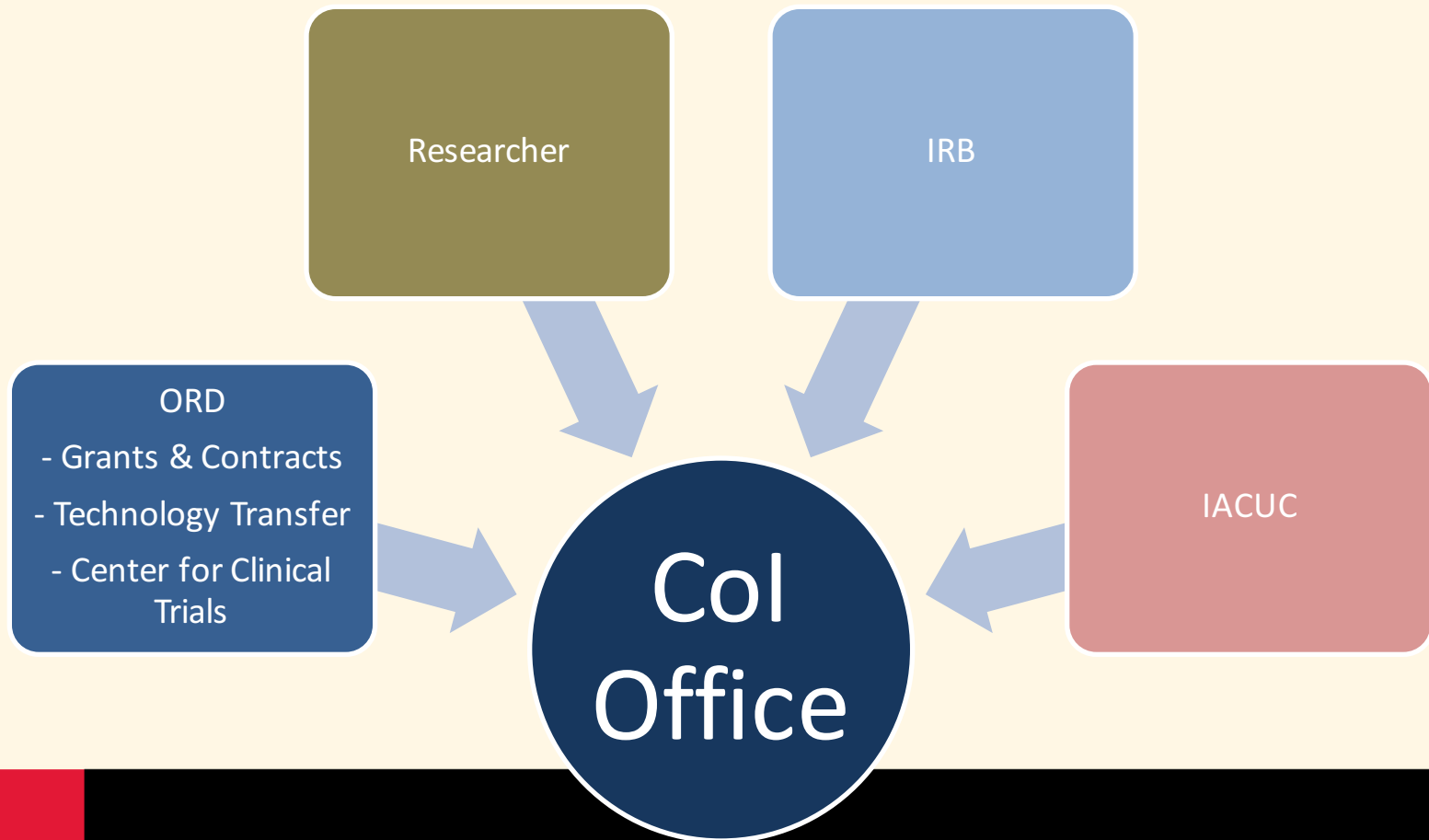
- Business relationship between an entity and the University
- Financial relationship with same entity
- Spouses on the same grant
- Campus review
  - Col Officer
  - Supervisor
  - Department Chair
  - Dean
  - Col Advisory Committee
- President grants Col Exemption (approval) with Conditions
- Annual Reports and Ongoing Management

# DISCLOSURE

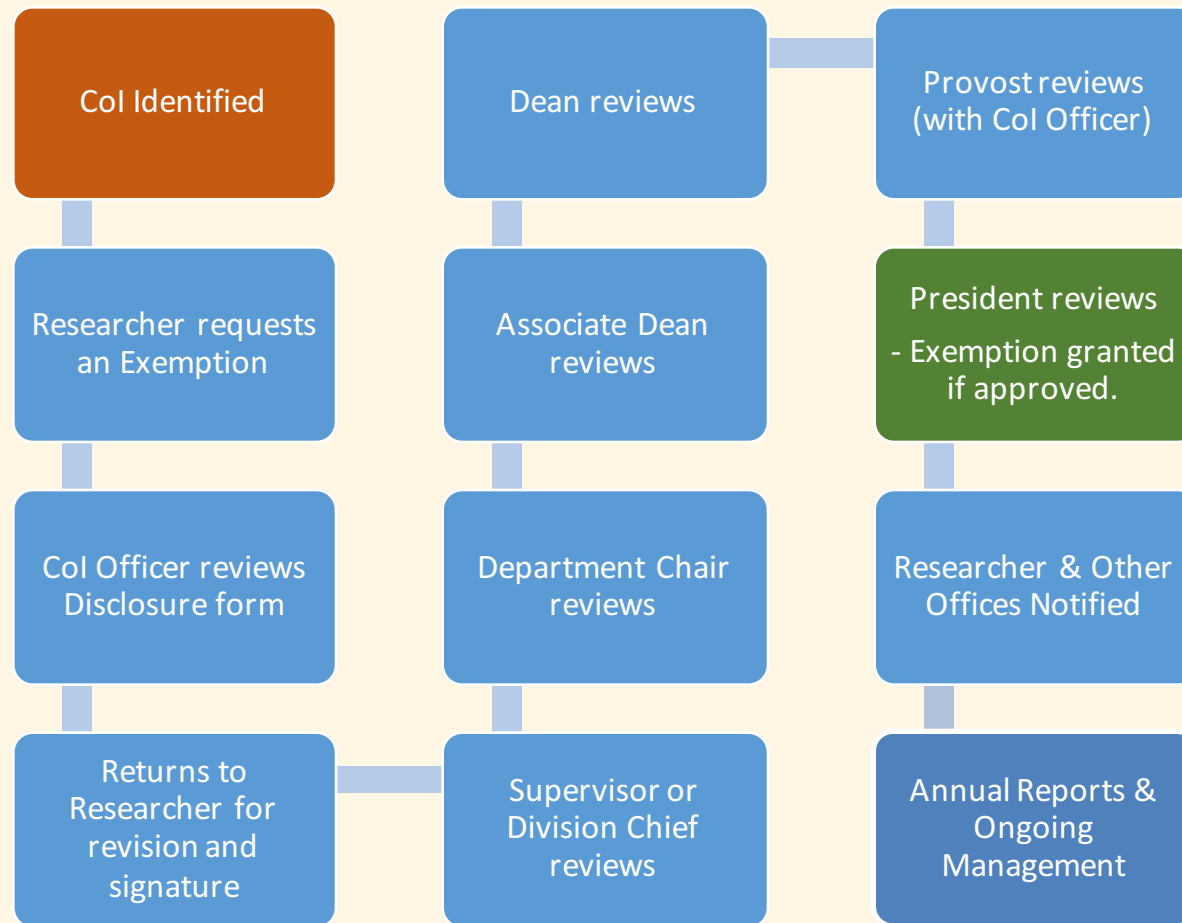
- **Maryland Public Ethics Law** prohibits state employees from having a financial interest in an entity that does business with their “governmental unit” unless exempted by the President of the University)
- **University Policy**
- Institutional Reputation
- Preserve Academic Integrity
  - Scientific Community’s reliance on accurate reporting of data
  - Public Trust
- “the people have a right to be assured that the impartiality and independent judgment of the State’s officials and employees will be maintained...it is evident that this confidence and trust is eroded when the conduct of the State’s business is subject to improper influence or even the appearance of improper influence.”
  - Annotated Code of Maryland §15-101



# Initial Col Disclosure



# CoI EXEMPTION Review Process



# U S Public Health Service Objectivity In Research

Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

# Applicable Policies

- UMB Policy and Procedures on Financial Conflict of Interest to Promote Objectivity in Public Health Service - Funded Research.
- <http://grants.nih.gov/grants/policy/coi>





# FEDERAL REGULATIONS (PHS)

- U.S. Public Health Service (PHS) financial conflict of interest regulations
- August 24, 2012
- **APPLICABILITY:** Anyone involved in PHS funded research
- **REQUIREMENTS:**
  - Mandatory training
  - Online (CITI)
  - Submission of financial disclosure form
    - [disclosure@umaryland.edu](mailto:disclosure@umaryland.edu)

# U S PHS Agencies

- Agency for HealthCare Research and 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)

# PHS PROCESS

- Before an Application is Submitted
  - Investigator Training on PHS regulations
  - Submission of Significant Financial Disclosure Form (SFI Form) to University (even if there is nothing to disclose)
- Before Funds are Expended
  - University's determination of Financial Conflict of Interest (FCOI)
  - Development of a Management Plan
  - Report of FCOI to PHS Awarding Agency
- Required Retrospective review of research for failure to disclose Significant Financial Interests in a timely manner

# SIGNIFICANT FINANCIAL INTERESTS

- Remuneration of any value from any entity during the twelve (12) months preceding the disclosure
- Any equity interest
- Intellectual property rights and interests
- Reimbursed Or sponsored travel
- **Excluding:** salary through umb, income from investment vehicles such as mutual funds, income from seminars, lectures, teaching engagements sponsored by federal, state, or local govt agency or institutes of higher education.

# PHS FCOI TRAINING

- Online
- Anyone participating in PHS funded research
- Completed prior to engaging in PHS funded research
- At least every four (4) years
- compliance training & disclose database routinely reviewed by campus administrators especially before submitting grant proposals.

# PHS SFI DISCLOSURE FORM

- Who:
  - anyone involved in PHS funded research
- What:
  - submit sfi form of any significant financial interest related to investigator's institutional responsibilities.
  - must submit, even if you have no financial interest to disclose
- When:
  - before submitting phs application
  - within 30 days of acquiring a new sfi
  - annually (even if there is nothing to disclose)



# PHS FCOI Review Process

## Begin

- Disclosure of Significant Financial Interests and List of PHS-Funded Research

## FCOI Review

- Determine if Financial Interests could significantly impact PHS-Funded Research
- Review PHS research against financial interest, process includes a review from the Department Chair or other Supervisor.

## FCOI

- FCOI determination
- Development of Management Plan
- Report to PHS-Funding Agency
- Annual Report submitted by Researcher to Col Office
- Annual Report submitted by Col Officer to PHS-Funded Agency

## No FCOI

- No FCOI determined
- No further review
- Recorded and Filed
- Annual Report submitted by Researcher to Col Office



# PHS Timelines

Disclosure **At or Before Submission** of Application **and Annually**

Training **Before Engaging** in Research and **every 4 years**

Disclosure of new interest within **30 days** of acquiring that interest

Institution's Review and Disclosure of FCol to PHS **before funds are expended**  
**And within 60 days of disclosure.**

**Retrospective Review**

If SFI is not disclosed or reviewed in a timely manner



# PHS Retrospective Review

- If SFI is not disclosed in a timely manner by Investigator, or it was not reviewed by UMB or was not timely reviewed or reported by a subrecipient.
- Col Officer shall **within 60 days** of the disclosure:
  - Review the disclosed interest
  - Determine whether it is related to the PHS-Funded Research
  - If related, determine whether a FCOI exists
  - If a FCOI exists, develop a management plan on an interim basis.
  - **Within 120 days**, Col Officer shall conduct a retrospective review of Investigator's activities and PHS-Funded research to determine if there was bias present and notify PHS agency accordingly.
  - Depending on nature of FCOI, Col Officer may determine that additional measures are necessary.

# Non-Compliance process

- Col contacts have been identified in each UMB school to assist UMB's Col Office with ensuring compliance with PHS training, disclosure and annual reporting requirements.
- The Col Office will attempt to reach an investigator twice, if there is no response, that individual is placed on a non-compliance list, which is then forwarded to the Col contact in the respective school.
- Noncompliance with University policies is considered a violation of UMB policy, and is subject to disciplinary action.

# Suggested Approach

## Analysis

- Does any investigator have a financial interest in the sponsor of the research?
- Are there any investigators participating in PHS-funded research?
- Does the research involve human subjects?
- Are there any spouses or family members participating on the same research project?

## Disclosures

- Conflict of Interest Office
- ORD Coeus Application
- CCT Service Request
- IRB Cicero Protocol
- IACUC Protocol

# CONTACT US

- Erin Burch
  - Research Compliance Specialist
    - [Erin.burch@umaryland.edu](mailto:Erin.burch@umaryland.edu)
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