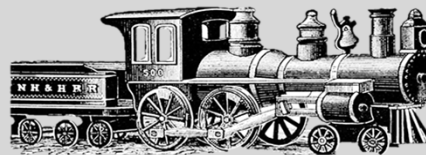


# IDENTIFYING AND MANAGING PHYSICIAN CONFLICTS OF INTEREST IN THE RESEARCH CONTEXT

2019 Research Compliance Conference: Session P4  
Sunday, June 9 from 2:45 – 4:15pm

WELCOME ABOARD!

## Boarding Pass



**Education to Implementation**

*Compliance Express*

*Compliance Express*

Terminal: P4 ½

Departure Time: 2:45 pm

3

## CONDUCTORS FOR TODAY

### Amy Joseph

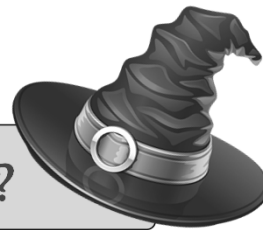
- Partner, Hooper Lundy & Bookman, P.C.
- CHRC
- No disclosures

### Becky Ryan

- Masters of Healthcare Administration
- CHC, CHPC, & CHRC
- Director, System Compliance Operations for Yale New Haven Health
- Compliance and Privacy Officer for Yale New Haven Hospital
- Member of the Center for Outcomes Research and Evaluation Conflicts of Interest Committee
- No disclosures

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*Which House are you in?*



Academic  
Medical  
Center/Hospital

Faculty Practice  
Plan/Physician  
Practices

Industry

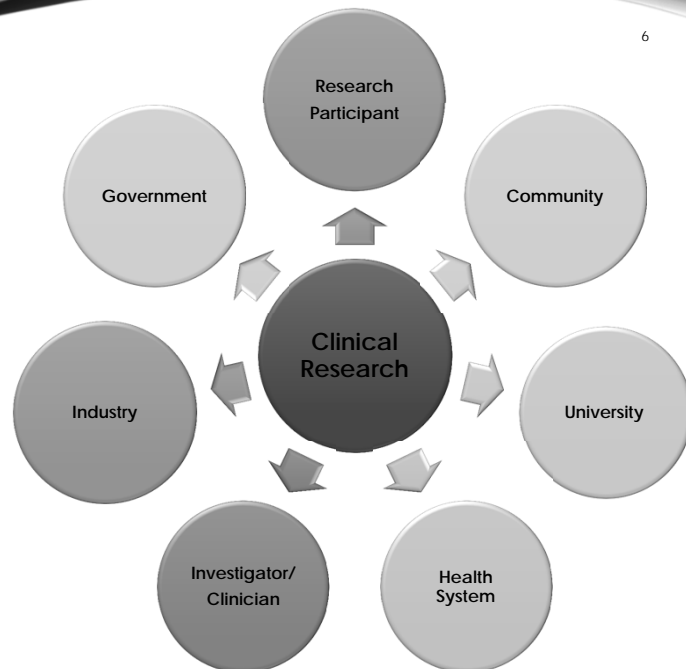
University  
Research Office

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## COI FUNDAMENTALS

6

## RESEARCH STAKEHOLDERS



7

## CONFLICT OF INTEREST DEFINED

### Conflict of Interest:

<sup>1</sup>a conflict between the private interests and the official responsibilities of a person in a position of trust

<https://www.merriam-webster.com/dictionary/conflict%20of%20interest>

<sup>2</sup>*circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.*

(Conflict of Interest in Medical Research, Education and Practice, p. 6)

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## SPECIAL RESEARCH COI CONSIDERATIONS

- Financial Conflicts of Interest
- Conflict of time commitments
- Utilization of resources (space, equipment, etc.)
- Participation in start-up companies
- Intellectual property (patents, copyrights, etc.)
- Industry Sponsorship/Funding
- Donations to Foundation
- Authorship
- Desire for professional advancement
- Recognition
- Desire to do favors for friends, family, students, or colleagues

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## AGENCY OVERSIGHT

10

## PUBLIC HEALTH SERVICE

- *Responsibility of Applicants for Promoting Objectivity for which PHS Funding is Sought* (42 CFR Part 50, Subpart F, 76 Fed. Reg. 53256 (Aug. 25, 2011))
- Who It Applies To (directly or indirectly):
  - Any Institution that applies for or receives PHS funding for research
  - Any Investigator who is planning to participate in PHS-funded research
  - Sub-recipients

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## PUBLIC HEALTH SERVICE

- What It Requires (very high level):
  - Disclosure of any significant financial interest (SFI)
  - Determination of whether the SFI constitutes an actual or perceived FCOI
  - Actions to manage the FCOI, including development and implementation of management plan
  - FCOI report to PHS awarding component, including explanation of whether the conflict has been managed, reduced or eliminated

*(a number of other requirements apply, including development and public posting of FCOI policy, training, etc.)*

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## PUBLIC HEALTH SERVICE



- SFI Defined (high level): one or more of the following interests of the investigator (or their spouse or dependent children) that reasonably appears related to the investigator's institutional responsibilities:
  - Excess of \$5,000 in remuneration and/or equity interest
  - IP rights and interests (e.g., patents) upon receipt of income
- Investigators must also disclose occurrence of reimbursed or sponsored travel

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## PUBLIC HEALTH SERVICE

### Definition of FCOI:

- Institution reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research



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## FOOD & DRUG ADMINISTRATION

- Financial Disclosure by Clinical Investigators, 21 CFR Part 54
- Requires disclosure of certain financial arrangements between sponsors and clinical investigators and clinical investigator interests in the product or sponsor, as part of marketing application for human drugs, biological products, medical devices
- "FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias"

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## FOOD & DRUG ADMINISTRATION

- High Level Summary:
  - Applicant must provide certification of absence of financial arrangements or interests, or
  - Submit Form FDA 3455 for clinical investigators to disclose:
    - Financial arrangement with sponsor where the compensation is influenced by the study outcome
    - Significant payments of other sorts (e.g., provision of equipment, consultation fees, valued at more than \$25,000)
    - Proprietary interest in the tested product (e.g., a patent)
    - Significant equity interest in the sponsor (any amount where value cannot be readily determined; more than \$50,000 in publicly traded company)
    - Steps taken to minimize the potential for bias

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## OTHER COI REGULATORY OVERSIGHT

- National Science Foundation Conflict of Interest Policies
  - Organizational COI policy must require disclosure of all investigator significant financial interests - anything of monetary value, equity interests, and IP rights, with exceptions (e.g., payments under \$10,00 during prior year)
- COI Rules for IRBs
  - No IRB member may participate in initial or continuing review of a project in which they have a conflicting interest except to provide information requested by the IRB
    - 45 CFR 46.107(d)(HHS); 21 CFR 56.107(e)

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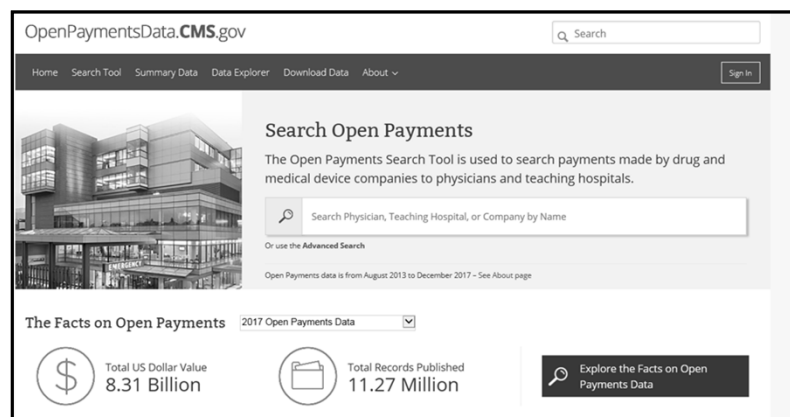
## ON A RELATED NOTE: OPEN PAYMENTS

- Section 6002 of the ACA, "Sunshine Act"
  - Tool to help identify and understand physician relationships with industry
  - Manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or CHIP, must report payments/other transfers of value to physicians and teaching hospitals
  - Payments/Transfers of Value examples:
    - Ownership interests
    - Speaker fees
    - Consulting fees
    - Entertainment, food, beverage, lodging
    - Royalty or License
    - Research
  - Published annually (next publication June 2019)

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## ON A RELATED NOTE: OPEN PAYMENTS

- <https://openpaymentsdata.cms.gov>



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## ON A RELATED NOTE: ANTI-KICKBACK STATUTE

- Anti-Kickback Statute, 42 USC § 1320a-7b(b)
  - makes it illegal to knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals or generate federal health care program business
  - violation may be found if “one purpose” is to induce referrals, even if there are other legitimate purposes for the payment
  - Intent-based statute
  - Voluntary safe harbors
- Potentially applicable to physician relationships in the research context:
  - Institutions
  - Pharma and medical device companies

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## ON A RELATED NOTE: ANTI-KICKBACK STATUTE

Potentially problematic arrangements:

- Research contracts that originate through the sale or marketing functions of the company
- Research that is not transmitted to or reviewed by a manufacturer’s science component
- Research that is unnecessarily duplicative or is not needed other than for the generation of business
- Post-marketing research used as a pretense to promote a product
- Research grant programs where physicians receive substantial payments for de minimis record keeping tasks (“sham” research)
- *Resources:* OIG Special Fraud Alert (Dec. 19, 1994); OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003); A Roadmap for New Physicians, Physician Relationship with Vendors, <https://oig.hhs.gov/compliance/physician-education/04vendors.asp>

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## ON A RELATED NOTE: STARK LAW

- Federal physician self-referral law, 42 USC § 1395nn
  - Prohibits a physician from referring Medicare patients for “designated” health services (DHS) to an entity with which the physician has a financial relationship
  - Prohibits the DHS entity from submitting claims to Medicare for those services resulting from a prohibited referral
  - Strict liability
  - Mandatory exceptions

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## ON A RELATED NOTE: STARK LAW

### 3 Questions to Analyze Compliance of Physician Financial Relationships with Stark

1. Is there a referral from a physician for a designated health service (DHS)?
2. Does the physician (or an immediate family member) have a direct or indirect financial relationship with the entity providing the DHS?
3. Does the financial relationship fit in an exception?

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## ON A RELATED NOTE: STARK LAW

### Example for discussion:

A physician is a full-time employee of a health system. It comes to the attention of the compliance officer that the physician is using her office practice location to conduct a sponsored research study, outside of the scope of her employment, and such activity is taking up a substantial amount of her time. The physician holds an interest in the intellectual property rights related to the study.

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## RECENT DEVELOPMENTS

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## 21<sup>ST</sup> CENTURY CURES ACT

- Section 2034 of the 21<sup>st</sup> Century Cures Act, signed into law Dec. 7, 2016: “Reducing Administrative Burdens for Researchers”
- Among other things, requires HHS to review all COI regulations and policies of funding agencies, including minimum financial thresholds and reporting timelines
- Harmonizing of existing regulations in the future?



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## 2019 LEGISLATION

- Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245)
- Funds appropriated for OIG oversight of NIH grant programs, including “agency efforts to ensure the integrity of its grant application evaluation and selection processes”
- OIG Work Plan reflects this directive

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## OIG WORK PLAN

Announced	Title	OIG Statement
Feb. 2019	NIH's Implementation of Financial Conflict of Interest Regulations	Review to determine whether NIH has controls in place to ensure disclosure of all sources of research support, financial interests, and affiliations
Feb. 2019	NIH Monitoring of Extramural Researchers' Conflicts of Interest	Examination of NIH's oversight and monitoring of reported FCOIs; reflects increasing risk to U.S. biomedical research IP

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## OIG 1/31/19 LETTER

- Letter in response to Senator Grassley regarding "ongoing concern about the threats foreign entities pose to the integrity of taxpayer-funded medical research"
  - As of January 2019, NIH referred 12 institutions for noncompliance related to research, primarily involving PIs at universities who allegedly failed to disclose foreign affiliations on grant applications

# IN THE NEWS

## The Daily Oracle

June 9, 2019

Issue 413

### CEO Discovers Physician Accepted Industry Gift!



**Physicians Question Vendor Relations Policy**  
By: Credence Moore

Amid confusion about relationships with vendors, Research Compliance Officer presents the new Vendor Policy to medical staff. Physicians ask tough

By: Honor Jones

Guy Walker, CEO for Academy Health Services discovered that physician accepted a Snazzy Instant Coffee Brewer from Widget Device, Inc. last Friday. AHS is a local testing site for WDI's new wingding device. If initial research results are positive, WDI could make millions. Physician stated, "I thought the gift was ok because it could be shared with office staff, and the brew cups are technically perishable.



**CEO Walker reacts to discovery of physician acceptance of Industry gift.**

CEO Walker confirmed AHS has a Code of Conduct outlining AHS's commitment to integrity and ethics in its business practices. Additionally, AHS policies specifically prohibiting employee acceptance of Industry gifts. All staff are required to take annual training. "This is a one-off situation," commented CEO Walker. "We take all potential, perceived and actual conflicts of interest very seriously." This issue was addressed immediately.

**Open Payments Data Available for Review**  
By: Clarity Steward

Brian Justice, Interim COI Committee Chairman reported that only 25 of AMC Health System's 500 physicians reviewed and disputed payment data.



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## IN THE NEWS...

- 2018 headlines in NYT and elsewhere in 2018: Failure of researchers to disclose all applicable industry relationships

*The New York Times*

*What These Medical Journals Don't  
Reveal: Top Doctors' Ties to Industry*

*The New York Times*

*Top Cancer Researcher Fails to  
Disclose Corporate Financial  
Ties in Major Research Journals*

- JAMA study, November 2018: finding that of the 100 physicians who received the most compensation from device manufacturers in 2015, conflicts were disclosed in only 37% of published articles (as compared to Open Payments data)
  - <https://jamanetwork.com/journals/jamasurgery/article-abstract/2696610>

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## IN THE NEWS...

- August 2018 NIH letter to institutions:

Unfortunately, threats to the integrity of U.S. biomedical research exist. NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities. This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time. Three areas of concern have emerged:

1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;
2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

- NIH targeted letters to certain institutions
- As of April 2019, at least one institution has terminated certain researchers in response

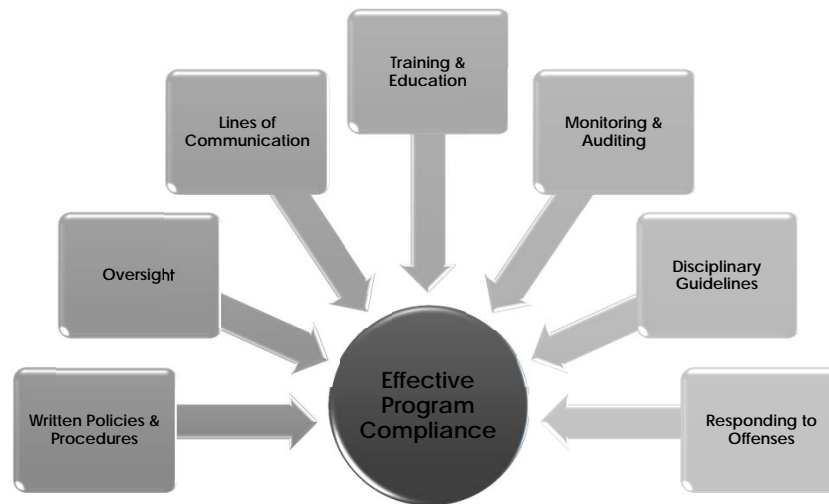
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## RISK MITIGATION OPPORTUNITIES



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## APPLYING THE 7 ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM



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## WRITTEN POLICIES & PROCEDURES

- Institutional Code of Conduct
- Conflicts of interest disclosure, evaluation and mitigation process
- Gifts and gratuities
- Physician non-monetary compensation policy and procedure (Hospitals)
- Travel and expense reimbursement
- Interactions with vendors/industry
- Continuing medical education
- Physician arrangements



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## WRITTEN POLICIES & PROCEDURES

### Institutional Code of Conduct



- Mission, Vision and Values
- Scope
- Conflicts of interest
- Gifts and gratuities
- Disciplinary actions
- Attestation of having received, read and accepted the Code of Conduct

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## WRITTEN POLICIES & PROCEDURES

### Conflicts of Interest Disclosure, Evaluation & Mitigation



- Define "conflicts of interest" and "significant financial interest"
- Identify who must submit COI disclosures and when
- Explain how disclosures will be evaluated
- Explain when and to what extent disclosures may be shared with other committees or organizations
- Articulate disciplinary actions for policy violations

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## WRITTEN POLICIES & PROCEDURES

### Gifts and Gratuities



- Define "gifts" and "gratuities"
- If permitting gifts, identify generally what is acceptable
  - Discuss giving & receiving of gifts
  - Provide specific examples of application of the rules
- Explain how an individual can report receipt of inappropriate gifts
- Identify where an individual may direct their "gifting" questions

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## WRITTEN POLICIES & PROCEDURES

### Physician Non-monetary Compensation (Hospitals only)



- Discuss the difference between business courtesies that are considered non-monetary compensation that should be tracked on a log and incidental benefits
- Ensure there is a process for tracking non-monetary compensation
- Identify the limits for the calendar year or link to the CMS website
- [https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPL-U\\_Updates.html](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPL-U_Updates.html)

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## WRITTEN POLICIES & PROCEDURES

### Travel and Expense Reimbursement



- Define scope/applicability
- If there are multiple processes for reimbursing travel and related expenses, be sure all of the processes are outlined
  - employed physician/employees
  - contract physician
  - facility funded
  - grant funded
  - other funding source

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## WRITTEN POLICIES & PROCEDURES

### Interactions with Industry/Vendors



- Address gifts, meals or other food, and entertainment provided by vendors
- Ensure there is a process for monitoring site access by vendors
- Have a position on clinician participation vendor sponsored speaking/education programs
- Provide guidance on consulting arrangements

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## WRITTEN POLICIES & PROCEDURES

### Continuing Medical Education



- Establish parameters under which CME activities may be provided
- Vendors should not engage in any sales or promotional advertisements within the space of the educational activity
- Vendors should not attend grand rounds where PHI may be discussed

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## WRITTEN POLICIES & PROCEDURES

### Physician Arrangements



- Partner with your legal department
- Develop template agreements
- Clearly outline the process for obtaining Fair Market Value assessments
- Ensure there is a contract approval process and centralized management of all physician arrangements
- Single policy versus policy bundle options

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## WRITTEN POLICIES & PROCEDURES

### Policy Writing Tips:



- Do not reinvent the wheel!
- Be clear and concise.
- Avoid jargon and acronyms
- Identify who is responsible to complete the defined task.
- Flow matters!
- Attach or include links to relevant forms or informational sites.
- Make sure policies do not contradict each other.
- Make sure policies accurately reflect the process and are up-to-date

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## OVERSIGHT: COI COMMITTEE

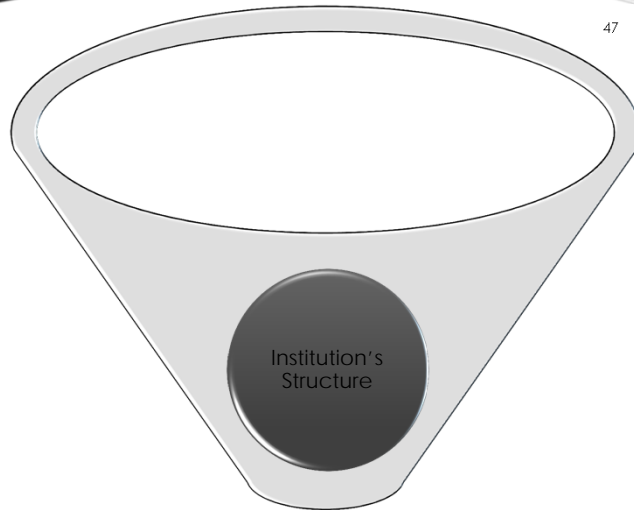
### Conflicts of Interest Committee

- Identify who is on the committee
- Define the committee's responsibilities and the individual committee member responsibilities
- Identify the committee's reporting relationship within the organization (and/or external reporting if relevant)
- Establish relationships with other relevant institutional committees
- Establish relationships with affiliated organizations' COI committees

## COI COMMITTEE CONSIDERATIONS

### Institution's Structure

- Academic Medical Center/Hospital
- Faculty Practice Plan/Physician Practices
- Industry
- University Research Office
- Combination of above

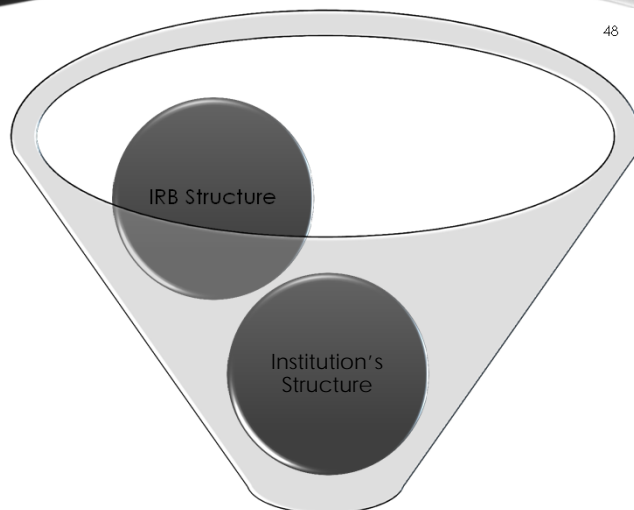


**COI Committee**

## COI COMMITTEE CONSIDERATIONS

### IRB Structure

- Internal v. external
- One organizational IRB v. IRBs for each facility/school
- IRB authority and responsibilities

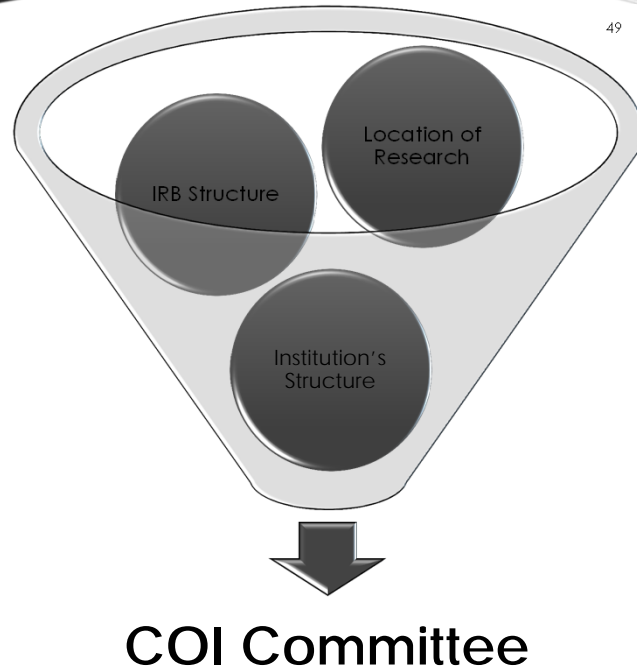


**COI Committee**

## COI COMMITTEE CONSIDERATIONS

### Location of Research

- Location where research is being performed
- Employment v. contract status of principal investigator
- Organization receiving funding



## OVERSIGHT: DISCLOSURE PROCESS

### Improving the Quality of Disclosures:

- Consider researcher/discloser fatigue when establishing the COI process
- Provide training as the kickoff or in conjunction with the annual COI disclosure process
- Evaluate the length and clarity of the COI Disclosure Questionnaire
- Include a cover memo/letter and the COI policy and procedure
- Schedule and send reminder notifications
- Follow-up with delinquent responders
- Annually evaluate the convenience, efficiency and effectiveness of the response process from the perspective of the respondent

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## OVERSIGHT: COI EVALUATION

<b>SBAR*</b> (Clinical Analysis & Communication Tool)	<b>IRAC**</b> (Legal Analysis & Communication Tool)
Situation	Issue
Background	Rule
Assessment	Application
Recommendation	Conclusion

\*<http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>

\*\*<https://www.csun.edu/~kkd61657/brief.pdf>

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## OVERSIGHT: COI EVALUATION SITUATION/ISSUE

### SBAR

Briefly describe the current situation.

### IRAC

Describe the legal question(s) that is being asked.

**Establish why the analysis is needed.**

\*<http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>

\*\*<https://www.csun.edu/~kkd61657/brief.pdf>

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## OVERSIGHT: COI EVALUATION BACKGROUND/RULE

### SBAR

Briefly state the pertinent history.

### IRAC

Identify the Federal and State statutes, regulations, or other rules of law and institutional policies that may apply to the situation.

**Identify the parameters for the analysis.**

\*<http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>

\*\*<https://www.csun.edu/~kdd61657/brief.pdf>

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## OVERSIGHT: COI EVALUATION ASSESSMENT/APPLICATION

### SBAR

Give your best assessment of the known facts.

### IRAC

Apply the identified rule(s) to the fact pattern presented.

**Analyze the known facts against the rules, and identify any missing data.**

\*<http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>

\*\*<https://www.csun.edu/~kdd61657/brief.pdf>

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## OVERSIGHT: COI EVALUATION ASSESSMENT/APPLICATION

### Factors to consider in an analysis:

- What type of COI is being evaluated?
- Is the COI 1) potential, 2) perceived or 3) actual?
- What information do you have about the parties with the COI?
- What is the source of the financial incentive or funding?
- Is there publicly available information about the funding source?
- Does the individual with the COI have an opportunity to impact decision-making?
- Was the individual with the COI honest and transparent in his/her disclosure, or was the disclosure made by a concerned party?

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## OVERSIGHT: COI EVALUATION ASSESSMENT/APPLICATION

### Factors to consider in an analysis:

- Is there potential for referrals from a physician for a designated health service (DHS) to be influenced by the arrangement?
- Does the physician (or an immediate family member) have a direct or indirect financial relationship with the entity providing the DHS?
- Does the financial relationship fit in a Stark exception or Anti-kickback safe harbor?
- Are there any concerns related to fair market value?
- Are the activities commercially reasonable?
- What are the possible negative outcomes of permitting and/or not managing the COI?

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## OVERSIGHT: COI EVALUATION RECOMMENDATION/CONCLUSION

### SBAR

Propose next steps and explain why those steps are the most appropriate in the given situation.

### IRAC

Briefly summarize the results of the analysis.

**Describe conclusion and propose next steps.**

\*<http://www.ihl.org/resources/Pages/Tools/SBARToolkit.aspx>

\*\*<https://www.csun.edu/~kkd61657/brief.pdf>

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## MANAGEMENT PLANS

### Elements of a Management Plan:



- Plan date
- Clear outline of the conflict of interest that is being managed by the plan
  - Parties to the conflict of interest
  - Type of conflict of interest
  - Any other relevant facts
- Identify all the actions that the investigator/discloser will be expected to take
- Instructions, including timeframe for researcher/discloser to respond
- Signature of agreement by the researcher/discloser

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## Management Plan Options

### Management Plan Options

#### MITIGATION PLAN OPTIONS

1

Disclosures

2

Restrictions

3

Notifications to Government  
Agencies

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## OPEN LINES OF COMMUNICATION

- **Compliance Office**
  - Anonymous hotline
  - Intranet site
  - Main phone line, email options
  - Training materials
  - Posters, tchotchkes, etc.
- **COI Office** (if different from Compliance)
  - Intranet site
  - Training materials
  - Contact information on all COI communications
- **Disclosure Process**
- **Training initiatives**



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## TRAINING & EDUCATION

### Training upon hire

#### Delivery method

Live, online, or paper

#### Content

Purchased or prepared in-house

Make sure content is current

### Annual Training

#### Delivery method

Live, online, or paper

#### Content

Purchased or prepared in-house

Make sure content is current

### Ad hoc training

#### Delivery method

Live, online, or paper

Newsletters and/or blast fax

#### Content

In response to current events

In response to identified issues

#### Training Tips:

- 1) Refresh annual training regularly to keep adult learners engaged.
- 2) Coordinate with other departments to ensure staff are not on training overload.

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## MONITORING & AUDITING

### *According to Compliance Monitor (July 13, 2010),*

**Monitoring** is less structured than auditing, although some audit techniques are occasionally employed. Monitoring includes:

- Completion by operations personnel, as opposed to audit personnel
- Ongoing checking and measuring of fraud and abuse
- Periodic spot checks based on daily, weekly, or monthly tests
- Identification of the need for an audit

**Auditing** is a formal review governed by professional standards. To be an audit, one must include:

- Completion by professionals who are independent of the operation under review
- A methodical and structured approach that includes planning, sampling, testing, and validating
- Formal communication with recommendations and corrective-action measures, followed by a documented follow-up of corrective actions

<http://www.hcpro.com/CCP-253726-862/Tip-Auditing-vs-monitoring.html>

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## MONITORING & AUDITING

### Ways to Monitor a COI Program:

- Prior to hire/execution of a contract and monthly thereafter, monitor the OIG exclusion list, state exclusion lists, state licensing board adverse action listings, etc.
- At least annually, compare open payments data to provider disclosures
- Routine review of compliance with management plans
- Monthly monitoring and/or annual review of non-monetary compensation to physicians
- Review physician contracts, and associated payments
- Review accounts receivable for payments from sponsors
- Audit grant receipts and expenditures
- Routine program effectiveness review, including evaluation of the COI committee and its charter

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## DISCIPLINARY GUIDELINES

### Sources of Disciplinary Guidelines:

- Human resources policies
- Medical staff bylaws
- Specific guidance in COI-related policies
- Contract provisions

### Challenges Associated with Implementing Discipline:

- Existing policies and contract provisions may be silent on issues related to COI
- Determining which disciplinary guidelines apply
- Consistent application across workforce member type
- Consistent application based on the offense



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## RESPONDING TO OFFENSES

Investigation

Mitigation

Corrective or  
Disciplinary  
Action

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## IMPLEMENTATION

COI Program implementation is not a “one-size fits all” solution.  
There are as many solutions as there are programs.



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## DISCUSSION

- What are some of the biggest challenges to getting sufficient information in your disclosure process?
  - Resistance to sharing personal financial information?
  - Confusion/lack of understanding about the questions on the form?
- What are strategies that you have seen work to make this process more effective?

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## DISCUSSION

- What are some of the biggest challenges with determining, implementing and tracking management plans?
- What are strategies that you have seen work to make this process more effective?

## DISCUSSION

- Does your organization and its affiliates have more than one COI process and what are the associated challenges?