

Stop! Or Else I'll Say Stop Again!

Institutional Responses to COI Noncompliance

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Agenda

- Examples of conflicts of interest policies
- Various types of COI noncompliance
- Consequences of COI noncompliance
- An institution's culture of compliance and risk level comfort
- A framework for setting up an institutional response to COI noncompliance

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What is a Conflict of Interest?

- *Definition:* a conflict of interest occurs when an individual's financial, academic, professional, commercial or personal interests or activities outside of the institution affects, or appears to affect, their professional judgment or obligations to the institution.
- Ordinary financial conflicts
- Self-dealing
- Influence for gifts
- Conflicts of Commitment

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Conflicts of Interest Policies - Examples

- Research conflicts of interest policy
- Individual conflicts of interest policy
- Interaction with Industry policy
- Vendor/purchasing disclosure policy
- Gifts and/or Ethics policy
- *Sunshine Act*

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Research COI Policy

- PHS Regulation (42 CFR 50, Sub. F)
- *Definition:* A financial conflict of interest exists when the recipient’s designated official(s) reasonably determines that an investigator’s significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- *Investigator:* the PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research...
- Shall maintain an up-to-date, written, enforced policy and make it publicly accessible
- Training required initially and every four years thereafter
- Has specific noncompliance reporting requirements

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Research COI Policy

Summary of FCOI Noncompliance and FCOI Reporting	
FCOI Report (within 60 days of identification)	Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.
Retrospective Review (to determine bias)	If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.
Update/Revise FCOI Report (following retrospective review)	If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.
Mitigation Report (promptly after retrospective review)	If bias is found, <ul style="list-style-type: none"> • Notify NIH promptly • Submit mitigation report through FCOI Module
Annual FCOI Report	Submit annual FCOI report thereafter through FCOI Module

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Individual Conflicts of Interest Policies

- Language varies across institutions
- Governs outside activities, employment, consulting, etc.
- Addresses employee service on outside boards
- Disclosures of stock or company ownership interests
- May address gifts or other ethical interactions
- Management plans to govern the activity

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Interaction with Industry Policies

- Often governs faculty and employee interactions with pharma or device manufacturers; vendors
- May include gifts or food from vendors as part of sponsored events on or off campus
- Sales pitches
- Speaker's bureaus

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Vendor or Purchasing Disclosure Policies

- Guidelines for individual interaction with vendors
- May require disclosure of familial or financial ties to current or proposed vendors
- May dictate guidelines for when vendors are on campus; interaction with students, patients, etc.
- Management plan may be implemented

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Gifts and/or Ethics Policies

- Language can be included in another policy or in a stand alone policy
- State law may provide guidance
- May include a complete ban, a dollar limit, or other specific mandates
- Less likely to be governed by a management plan

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Physician Payment Sunshine Act

- Requires pharma/device makers to annually report payments or “transfers of value” to physicians and teaching hospitals
- Reporting ownership or investment interests held by physicians or their family members in those entities
- Data included on Open Payments website
- Should have a process for examining/challenging the information on Open Payments

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The screenshot displays the OpenPaymentsData.CMS.gov website. At the top, there is a navigation bar with links for Home, Search Tool, Summary Data, Data Explorer, Download Data, About, and Take Survey, along with a Sign In button. The main content area features a large image of a modern hospital building on the left. To the right of the image, the heading "Search Open Payments" is followed by a descriptive paragraph: "The Open Payments Search Tool is used to search payments made by drug and medical device companies to physicians and teaching hospitals." Below this text is a search input field with a magnifying glass icon and the placeholder text "Search Physician, Teaching Hospital, or Company by Name". Underneath the search field, there is a link for "Or use the Refined Search". At the bottom of the search area, a note states "Open Payments data is from August 2013 to December 2018 - See About page". At the very bottom of the page, there is a section titled "The Facts on Open Payments" with a dropdown menu for the year, currently set to "2018".

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OpenPaymentsData.CMS.gov

Home Search Tool Summary Data Data Explorer Download Data About Take Survey [Sign In](#)

Search for a Entity

⌛ Loading data...

Show Results on a Map [+ Refine Search](#)

Entity Name contains "University of Texas Medical Branch"

No entities matched search criteria provided. [Please refine your search](#) and try again.

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OpenPaymentsData.CMS.gov

Home Search Tool Summary Data Data Explorer Download Data About Take Survey [Sign In](#)

THE UNIVERSITY OF TEXAS MEDICAL BR.

📍 301 University Blvd
Galveston, TX 77555

[Review or dispute your reported data](#)

Filters: [?](#) [Reset Filters](#)

Year: Payment Type: Company Making Payment: Nature of Payment:

General Payments	Research Payments
\$792,691.19 (136 payments)	\$865,569.76 (156 payments)

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- Consequences of COI noncompliance
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Types of COI Noncompliance

- *Noncompliance*: Failure to comply with relevant regulations, policies, and institutional mandates or decisions (Have a process/policy)
- Employee: "I didn't know I needed to do that."
- Employees need to be aware and understand the relevant regulations and institutional policies (Training is important!)
- Types of noncompliance can be (1) non-serious, (2) non-continuing, (3) serious, and (4) continuing/ongoing

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Types of COI Noncompliance

- **Research COI Policies:**

- Failure to complete annual disclosure(s)
- Leaving off entities from a disclosure
- Failure to complete training requirements
- Failure to comply with a management plan
- Noncompliance related to an institutional decision; COI Committee; IRB; institutional official

Types of COI Noncompliance

- **Non-Research/Individual COI Policies:**

- Failure to complete annual disclosure(s)
- Prohibited Speaker's Bureau activity
- Outside clinical activity that conflicts with policy
- Collaboration with a foreign entity without prior approval
- Failure to comply with a management plan
- Noncompliance related to an institutional decision; COI Committee

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Consequences of COI Noncompliance

- Negative media publicity
- Adverse action by a governmental agency
- Stark law
- Anti-kickback statute
- A perception that the COI program is weak and ineffectual

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Memorial Sloan Kettering Leaders Violated Conflict-of-Interest Rules, Report Finds



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An Institution's Culture of Compliance

- Is based on climate (i.e., the practices and procedures followed; signals employees receive re: which behaviors are rewarded and valued)
- Institutions with strong compliance cultures outperform weaker cultures in both financial and nonfinancial goals
- Institutions with strong cultures of compliance:
 - ~88% of observed misconduct is reported (vs. ~41% in weak cultures)
 - 2.1 times higher employee engagement equates to ~12% higher productivity

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An Institution's Culture of Compliance

- A compliant culture is “built in” – not added on
- Culture of Compliance concept evolved in the financial sector following the 2008-2009 economic crisis; gained momentum in university settings in about 2015
- Embeds compliance into daily workflows, creates structure and clarifies expectations for individual behaviors across organizations
 - Goes beyond yearly, mandated training

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Institutional Comfort with COI Noncompliance

- Is your institution acceptable of more risk?
- Is your institution risk averse?
- Have discussions with stakeholders & institutional leadership
- Relay consequences of COI noncompliance
- Present draft noncompliance framework; make adjustments as needed

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Event characterization and risk assessment relies on four primary questions

1. Is the event serious or non-serious?

Serious events:

Acts or omissions that result in non-compliance with federal regulations or institutional policies as determined by the COI committee or institutional COI official

Acts for which there is a strong possibility that the objectivity and the integrity of the research has been compromised

Non-serious events:

Incidents such as unintentional mistakes or misunderstandings

Event characterization and risk assessment relies on four primary questions

1. Is the event serious or non-serious?

2. Is the event continuing or non-continuing?

Continuing events:

A pattern of repeated noncompliant acts, omissions, or behaviors that indicates a deficiency in the ability or willingness of the employee to comply with federal regulations, institutional policy, or determination of the COI committee or institutional COI official

A pattern of conduct for which there is a strong possibility that the research will be materially and adversely affected

Non-continuing events:

Isolated occurrences

Event characterization and risk assessment relies on four primary questions

1. Is the event serious or non-serious?
2. Is the event continuing or non-continuing?
3. Is the institutional risk low, medium, or high?

Low risk:

Little to no impact to research or institutional reputation

Medium risk:

A direct impact to research/ institution with possible harm

High risk:

Materially affect or impact research/ institution or reputation with serious and/or immediate risk of harm

Event characterization and risk assessment relies on four primary questions

1. Is the event serious or non-serious?
2. Is the event continuing or non-continuing?
3. Is the institutional risk low, medium, or high?
4. What modifying factors (i.e., mitigating or escalating factors) are present?

Mitigating factors include:

Accidental/ unintentional violation

First-time occurrence

Self-disclosure

Escalating factors include:

Intentional or malicious conduct

Multiple violations

PHS-funded research

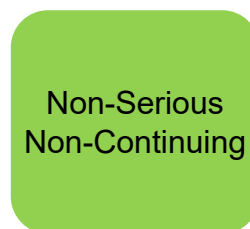
Event Assessment

1. Serious vs. Non-Serious
2. Continuing vs. Non-Continuing
3. Institutional Risk
4. Modifying Factors



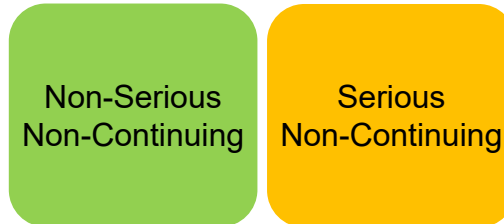
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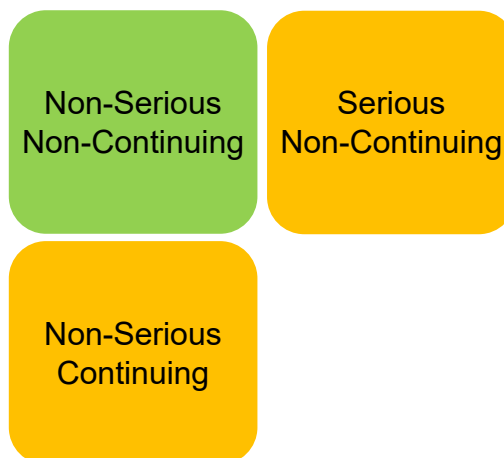
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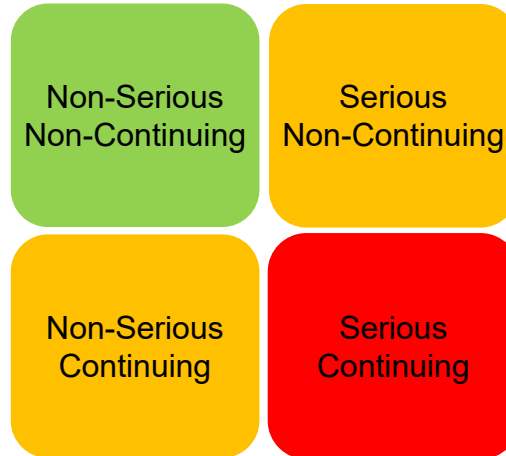
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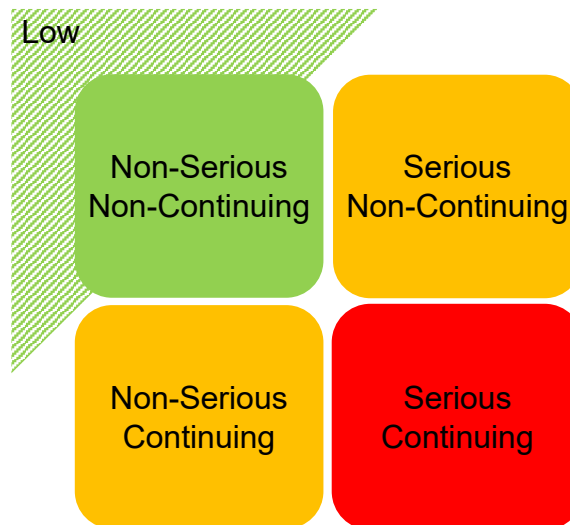
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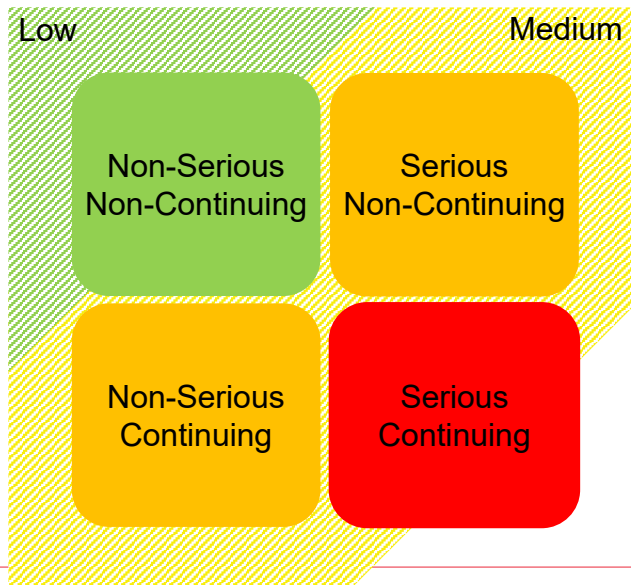
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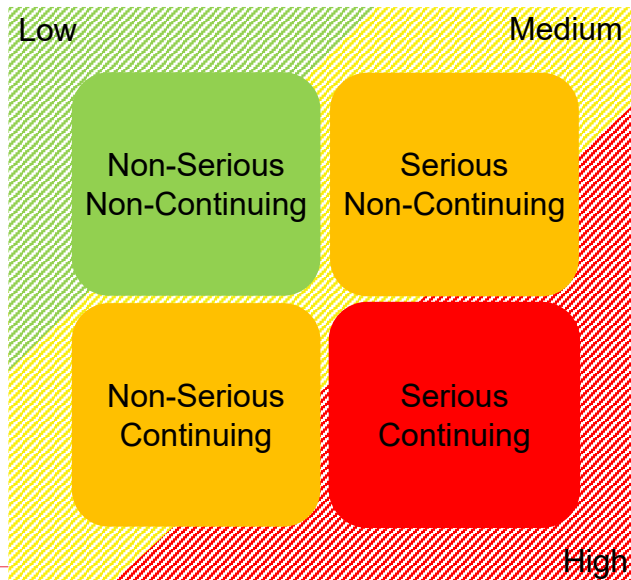


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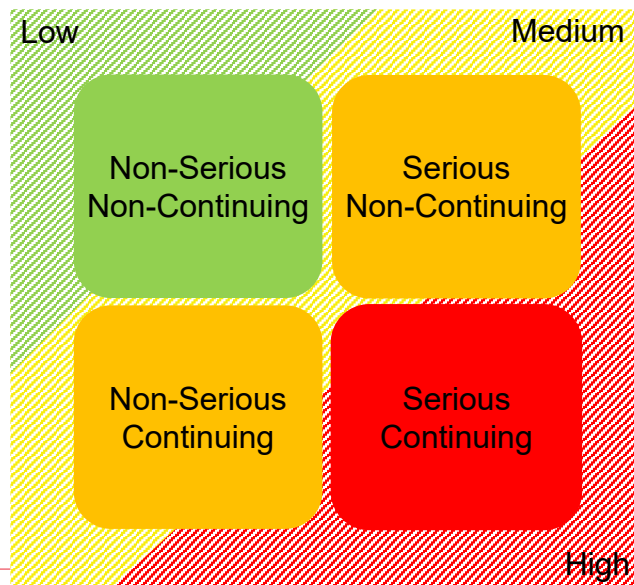


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Event Assessment

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4. Modifying Factors



Examples: Mitigating and Escalating Factors

Mitigating Factors

Mistake / Unintentional
First occurrence
Lack of education
Cooperation with inquiry
Self disclosure

Escalating Factors

Intentional / Malicious
Pattern of repeated noncompliance
Violation despite education
Failure to cooperate with inquiry
Attempt to hid from discovery

A final word about a policy...

- What's in your current policy?
- Noncompliance may result in "...sanctions up to and including termination."
- COI Noncompliance-specific institutional policy
- Policies to look at: Penn State, Cornell, Washington Univ./St. Louis

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Questions

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