MyDisclosures

2021 Supervisor Training

Bill Yates
Vice-Chancellor, Research Protections
2020 Pilot Successes

• 10,792 mandatory disclosers identified
  10,783 disclosures filed
  → 99.9% compliance

• Administrators appreciated automation in the system
  → No need to chase disclosers

• Seamless integration of UPMC and PITT questions
  → No “gaps” between UPMC & Pitt COI

• Electronic transmission of info critical in COVID era
  → No more paper!
Year 1 Lessons Learned

• Delay in rollout due to COVID caused some confusion
  → Standard timetable in 2021

• 1000+ supervisors reviewed disclosures; most received no training on review criteria
  → Addressing through training

• Matching of UPMC & PITT records was not seamless
  → We’ve addressed in 2021

• Supervisor workflow was confusing
  → Addressed in 2021 with the new “supervisor center”
Concerns Following Year 1

• Supervisors’ input -- didn’t understand criteria for reviews
• Faculty and staff confused about what to disclose
• Bigger problem: US govt aggressively pursuing undisclosed engagements, particularly foreign engagements

→ Penalties for institutions
→ Penalties for individuals (including prosecution)
Possible Ramifications

Prominent investigators have been prosecuted for failure to disclose foreign engagements.
Which Foreign Engagements are Scrutinized?

• The US government has particularly scrutinized engagements with:
  → Foreign universities and other academic institutions
  → Foreign government owned companies

• Typically, engagements with foreign-owned multinational companies with a presence in the U.S.A are treated the same as engagements with domestic companies.
  → Examples are GlaxoSmithKline, Roche, Sanofi, Elsevier
What Granting Agencies Expect

Every agency has unique requirements, but the general rules are:

• All research support including resources (personnel, lab space, funding, etc.) must be disclosed

• All components of research outside the U.S. must be disclosed (and typically pre-approved by agency)

• All appointments at other institutions must be disclosed
What Must Be Disclosed in MyDisclosures?

• All outside employment / positions related to PITT professional responsibilities (paid and unpaid)
  → Exceptions for seminars at US Universities, grant reviews for US funding agencies, journal peer review, service for US professional organizations, publications (unless financial threshold exceeded).

• All financial relationships related to PITT professional responsibilities

• All foreign engagement
  → Exception for virtual uncompensated lectures at a foreign university (although export control regulations apply)
Supervisor Responsibilities in Conducting Reviews

- Assure adherence to outside employment policy
  
  \[1 \text{ workday per week for faculty/must be pre-approved}\]

- Assure that all engagements are disclosed to funding agencies and don’t violate export control regulations

- Assure that engagements do not generate a conflict of interest or commitment

- Assure compliance with the University’s Conflict of Interest policies
Supervisor Responsibilities in Conducting Reviews

Conflict of Commitment (COC)

- Outside engagements cannot interfere with PITT responsibilities
- Use of PITT resources for outside engagements limited to “incidental use” (resources already exist, use does not add expense for the University)
- Outside engagement cannot exceed 1 workday/week (excluding nights, weekends, recess periods)
Supervisor Responsibilities in Conducting Reviews

Conflict of Commitment (COC)

- Limited COC policies: consult with Dean if there are concerns about an individual’s conflict of commitment.
- It is advisable to discuss prevalence of outside engagements for faculty with substandard University performance.
Supervisor Responsibilities in Conducting Reviews

Financial Conflict of Interest (FCOI)

• Outside engagements (consulting/board positions, etc.) cannot create or appear to create a FCOI

  ➔ Example: Serving as a board member of consultant for a company that sponsors an investigator’s research

  ➔ Example: Spouse employed by a company that supports an investigator’s research

• If an ongoing, unmanaged FCOI is discovered, notify the COI Office immediately
Supervisor Responsibilities in Conducting Reviews

Financial Conflict of Interest (FCOI)

• New engagements must be reported within 30 days.
• For individuals with PHS funding, discovery of an unreported FCOI requires a retrospective review of research and report to NIH.
Supervisor Responsibilities in Conducting Reviews

Foreign Engagement

• All foreign engagements must be disclosed, including:
  ➔ Teaching or lecturing at foreign institutions (*except single uncompensated lectures*)
  ➔ Appointments at foreign institutions (*new question in 2021*)
  ➔ Research funding through foreign institutions (*new question in 2021*)
Supervisor Responsibilities in Conducting Reviews

Foreign Engagement

• All foreign engagements must be disclosed, including:
  → Mentoring students at foreign institutions
  → Service on committees or governing boards for foreign institutions
  → Travel sponsored or reimbursed by a foreign institution
  → Organizing meetings for foreign institutions
Must be Disclosed for Foreign Institutions

- Organizing a Meeting
- Honorarium for a Lecture
- Teaching a Course
- Committees or Governing Boards
- Sponsored or Reimbursed Travel
- Salary Support
New Questions in *MyDisclosures* to Remind Faculty about Requirements

• **New:** Do you have *academic appointments* or positions with universities or academic institutions *outside PITT* (or affiliates such as UPMC)?

• **New:** Do you receive any *research funding or support* that is not administered through PITT (or affiliates such as UPMC)?
Supervisor Responsibilities in Conducting Reviews

Foreign Engagement

• If foreign engagements are disclosed, supervisors should advise disclosers:
  ➔ To become familiar with funding agency requirements
  ➔ To inform funding agency about all “other support” for research
Supervisor Responsibilities in Conducting Reviews

Foreign Engagement

• If foreign engagements are disclosed, supervisors should advise disclosers:
  
  ➔ To inform funding agency about all “foreign components” of research
  
  ➔ To secure a data use agreement if needed to transmit findings elsewhere
Data Use Agreement

Definition and Purpose

A Data Use Agreement (DUA) is a contractual document used for the transfer of data that has been developed by nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use. Often, this data is a necessary component of a research project and it may or may not be human subject data from a clinical trial, or a Limited Data Set as defined in HIPAA. Universities will want to ensure that DUA terms protect confidentiality when necessary, but permit appropriate publication and sharing of research results in accordance with University policies, applicable laws and regulations, and federal requirements. DUAs are similar to confidentiality agreements in that they restrict the use and disclosure of the data set, and, in some cases, a CDA format may be used as a starting point to build a DUA appropriate for the transfer of data.

Our University is a state-related entity that receives a large proportion of its research funding from the U.S. federal government. In order to ensure that DUAs meet University policies as well as the requirements of funding agencies, the University’s Office of Sponsored Programs will review and institutionally endorse DUAs to ensure compliance with appropriate policies and regulations.

https://www.osp.pitt.edu/ccc-data-use-agreements
Information Required by Granting Agencies

• For information, see: https://www.osp.pitt.edu/management-disclosures-funding-agencies
Export Control Restrictions

• Export control regulations are federal laws that prohibit the unlicensed export of certain technology or information for reasons of national security or protections of trade.

• PITT's Office of Trade Compliance aids investigators in complying with export control regulations.

Web: export.pitt.edu
MyDisclosures

Improvements in 2021
Disclosures are Simpler in 2021

- All previously entered data will be in the system; disclosers just need to edit entries.

### 1. Disclosures under review:

<table>
<thead>
<tr>
<th>View/Edit</th>
<th>Organization</th>
<th>Relationships</th>
<th>Disclosure Types</th>
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<th>Total Days</th>
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### 2. Previously reviewed disclosures: (click 'Modify' to enable editing)

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Disclosures are Simpler in 2021

• Removed entries transition to “pending removal” state until supervisor approves the disclosure.

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<td>2</td>
<td>6/26/2020 7:14 AM</td>
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New in 2021: Supervisor Center

**SUPERVISOR GUIDANCE**

- Step-by-Step Guides to Submitting Reviews
- Supervisor Checklist
- Supervisor Training
- Request to Add or Remove a Mandatory Discloser

**Action Items**

- All items in this section require your review.

1. Disclosures in "Department Review" must be reviewed individually
2. Disclosures in "No Interests Disclosed" can be batch reviewed.

**Select All Batchable Items:**

- Batch-Approve Selected
- No Interests Disclosed
- Certifications

**Filter by**

- ID
- Name
- Enter text to search for

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<th>Name</th>
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<td>DC00027813</td>
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<td>2/22/2021 3:37 PM</td>
<td>Review Complete: Preparing Correspondence</td>
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4 items
Completing a Supervisor Review

Supervisor Center

In Process Items: All items awaiting action from the discler or the COI Division.

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<tr>
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Completing a Supervisor Review

Supervisor Center

SUPERVISOR GUIDANCE

- Step-by-Step Guides to Submitting Reviews
- Supervisor Checklist
- Supervisor Training
- Request to Add or Remove a Mandatory Discloser

Reviewed Items- All items you approved.

Filter by ID | Name | Enter text to search for | Add Filter | Clear All

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<tr>
<th>ID</th>
<th>Name</th>
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1 items
Completing a Supervisor Review

## Supervisor Center

### Supervisor Guidance
- Step-by-Step Guides to Submitting Reviews
- Supervisor Checklist
- Supervisor Training
- Request to Add or Remove a Mandatory Discloser

<table>
<thead>
<tr>
<th>Action Items</th>
<th>In Process Items</th>
<th>Reviewed Items</th>
<th>Secondary Supervisor Items</th>
</tr>
</thead>
</table>

**Secondary Supervisor Items** - All items on which you are listed as Secondary Supervisor in "No Interests Disclosed" or "Review Complete", for which you **do not** need to take any action.

Filter by ID

Enter text to search for

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Completing a Supervisor Review

Type: Disclosure Update | ID: DC00027813
Discloser: Casey Holderfield | Supervisor: Billy Yates

Secondary Reviews

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<th>Person</th>
<th>Reqd</th>
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<th>Comments</th>
<th>Docs</th>
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<tbody>
<tr>
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</table>

There are no items to display

These reviews must be completed before the Department review can be finalized. Department reviewers can contact the secondary reviewer by using the "Notify Secondary Reviewers" activity on the left.

Your COI disclosure has been submitted and is currently under review.

Management plan:
Snapshot:
Date submitted: 2/8/2021

Needs review: Yes
MY DISCLOSURES
Completing a Supervisor Review

Record and Complete Department Review

Please record your review of the disclosure certification and your conclusion.

1. * Departmental Determination:
   - Approve
   - Approve with Comments
   - Disapprove
   - Request Assistance from COI Office

2. Related Attachments:

   There are no items to display

Request Changes by Department

When you submit this form, the discloser will be notified that changes are required to the disclosure certification application before you will approve it. Use the box below to add instructions or indicate the changes which you require.

1. * Comments about the changes:

2. Attachments:

   There are no items to display
Completing a Supervisor Review

Secondary Reviews

The secondary review(s) must be completed before the Primary Supervisor review can be finalized. Primary Supervisor can contact the secondary reviewer by using the "Notify Secondary Reviewers" activity on the left.

- Person
- Req'd
- Accepted
- Comments
- Docs

There are no items to display.

Summary

Your COI disclosure has been submitted and is currently under review.

Management plan:

- Snapshot:
- Date submitted: 2/24/2021
- Needs review: Yes

No data to display.

DISCLOSER ADDL. INFO

Outside Employment

- Not
- OCI
- University Relationships
- Party to University Transaction
- No
- No
- No
Completing a Supervisor Review

Type: Disclosure Update | ID: DC00026520

Discloser: Christopher Gerard | Supervisor: Kelly Dornin Koss

Secondary Reviews

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<th>Comments</th>
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<tr>
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These reviews must be completed before the Department review can be finalized. Department reviewers can contact the secondary reviewer by using the "Notify Secondary Reviewers" activity on the left.

Your COI disclosure has been submitted and is currently under review.

Management plan:
Snapshot:
Date submitted: 1/25/2021
Needs review: Yes
Completing a Supervisor Review

Submit Secondary Review

1. * Select the review you are submitting:

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<tr>
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<td>Department Review</td>
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</table>

2. * Do you accept the disclosure as submitted?

- Yes  - No  Clear

3. Comments:

4. Supporting Documents:

   + Add

   Name

   There are no items to display
Help is Available to Supervisors

Email: mydisclosures@pitt.edu