

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.

Courtesy | MIT



MIT RESEARCHER ARRESTED
FEDERAL PROSECUTORS ACCUSE GANG CHEN OF GRANT FRAUD

CBSN
BOSTON

FORECASTS

SPORTS

LOTTERY

HEADLINES

FORECASTS

37°

1:11 PM

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 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 support's 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

<https://www.osp.pitt.edu/ccc-data-use-agreements>

Office of Sponsored Programs

[Home](#)[Funding](#)[Faculty Resources](#)[References](#)[Forms](#)[Clinical and Corporate Contract Services](#) / [Negotiations](#) / [Data Use Agreements](#)

Data Use Agreements

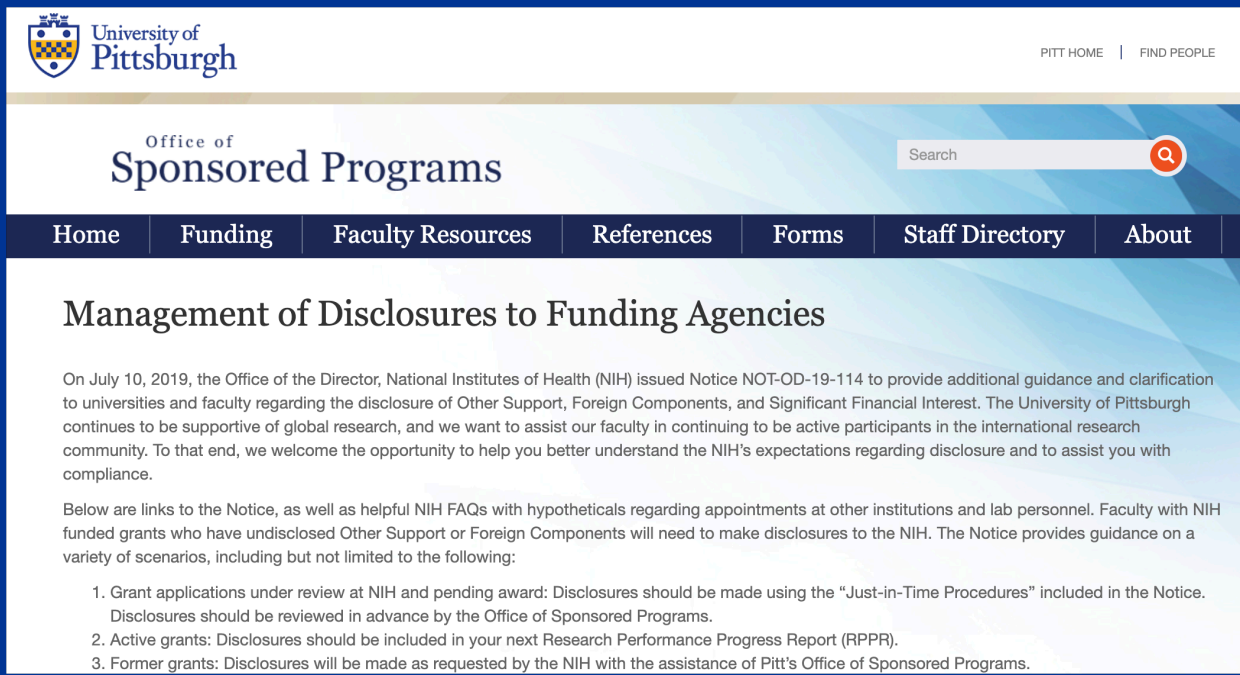
Definition and Purpose

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.

Information Required by Granting Agencies

- For information, see: <https://www.osp.pitt.edu/management-disclosures-funding-agencies>



The screenshot shows the website of the University of Pittsburgh Office of Sponsored Programs. The header includes the University of Pittsburgh logo and the text 'University of Pittsburgh' on the left, and 'PITT HOME | FIND PEOPLE' on the right. Below the header is a navigation bar with the following links: Home, Funding, Faculty Resources, References, Forms, Staff Directory, and About. The main content area is titled 'Management of Disclosures to Funding Agencies'. The text on the page states: 'On July 10, 2019, the Office of the Director, National Institutes of Health (NIH) issued Notice NOT-OD-19-114 to provide additional guidance and clarification to universities and faculty regarding the disclosure of Other Support, Foreign Components, and Significant Financial Interest. The University of Pittsburgh continues to be supportive of global research, and we want to assist our faculty in continuing to be active participants in the international research community. To that end, we welcome the opportunity to help you better understand the NIH's expectations regarding disclosure and to assist you with compliance. Below are links to the Notice, as well as helpful NIH FAQs with hypotheticals regarding appointments at other institutions and lab personnel. Faculty with NIH funded grants who have undisclosed Other Support or Foreign Components will need to make disclosures to the NIH. The Notice provides guidance on a variety of scenarios, including but not limited to the following: 1. Grant applications under review at NIH and pending award: Disclosures should be made using the "Just-in-Time Procedures" included in the Notice. Disclosures should be reviewed in advance by the Office of Sponsored Programs. 2. Active grants: Disclosures should be included in your next Research Performance Progress Report (RPPR). 3. Former grants: Disclosures will be made as requested by the NIH with the assistance of Pitt's Office of Sponsored Programs.'

University of Pittsburgh

PITT HOME | FIND PEOPLE

Office of Sponsored Programs

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Management of Disclosures to Funding Agencies

On July 10, 2019, the Office of the Director, National Institutes of Health (NIH) issued Notice NOT-OD-19-114 to provide additional guidance and clarification to universities and faculty regarding the disclosure of Other Support, Foreign Components, and Significant Financial Interest. The University of Pittsburgh continues to be supportive of global research, and we want to assist our faculty in continuing to be active participants in the international research community. To that end, we welcome the opportunity to help you better understand the NIH's expectations regarding disclosure and to assist you with compliance.

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Export Control Restrictions



Office of Trade Compliance



Research Sites



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Trade Compliance

The Office of Trade Compliance offers a variety of services to the University of Pittsburgh education and research community.

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:

View/Edit	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
There are no items to display							

2. Previously reviewed disclosures: (click 'Modify' to enable editing)

Modify	View	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
				■ Reimbursed and/or Sponsored Travel				
	View	American Physiological Society	Self	■ Consulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)	\$15,000.00	20	6/26/2020 7:14 AM	
	View	Springer Publishing Company LLC	Self	Reimbursed and/or Sponsored Travel	\$0.00		6/26/2020 7:14 AM	
	View	Americans for Medical Progress	Self	Management, Officer or Board of Directors Positions (e.g.: President, CEO, CTO, CMO, CSO)	\$0.00	2	6/26/2020 7:14 AM	
				■ Reimbursed and/or Sponsored Travel				
	View	Japan Aerospace Exploration Agency	Self	■ Consulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)	\$10,500.00	1	6/26/2020 7:14 AM	

Disclosures are Simpler in 2021

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

1. Disclosures under review:

View/Edit	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
Edit	Japan Aerospace Exploration Agency	Self	<ul style="list-style-type: none">Reimbursed and/or Sponsored TravelConsulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)	\$10,500.00	1	2/8/2021 6:23 PM	Pending Removal

2. Previously reviewed disclosures: (click 'Modify' to enable editing)

Modify	View	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
✎	View	American Physiological Society	Self	<ul style="list-style-type: none">Reimbursed and/or Sponsored TravelConsulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)	\$15,000.00	20	6/26/2020 7:14 AM	✕
✎	View	Springer Publishing Company LLC	Self	Reimbursed and/or Sponsored Travel	\$0.00		6/26/2020 7:14 AM	✕
✎	View	Americans for Medical Progress	Self	Management, Officer or Board of Directors Positions (e.g.: President, CEO, CTO, CMO, CSO)	\$0.00	2	6/26/2020 7:14 AM	✕

New in 2021: Supervisor Center

[My Inbox](#)[Supervisor Center](#)[Disclosures](#)[Subscribe](#) [Help](#)

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

In Process Items

Reviewed Items

Secondary Supervisor Items

Action Items- All items in this section require your review.

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

Select All Batchable Items: ☐

Batch-Approve Selected No Interests Disclosed Certifications

Filter by ?

ID

[+ Add Filter](#)[x Clear All](#)

ID	Name	Date Modified	State	Primary Supervisor	Secondary Supervisor(s)	Batch Approve?
DC00028000	Annual Disclosure Certification for Aaron Paige 2021	2/24/2021 1:37 PM	No Interests Disclosed	Billy Yates		<input type="checkbox"/>
DC00027994	Annual Disclosure Certification for Centa Schumacher 2021	2/25/2021 10:18 AM	No Interests Disclosed	Casey Holderfield	Billy Yates	<input type="checkbox"/>
DC00027813	Update to Casey Holderfield's disclosures 2.8.2021	2/22/2021 3:37 PM	Review Complete: Preparing Correspondence	Billy Yates	Erin Kershaw Angela Coldren	Not Eligible
DC00026520	Update to Christopher Gerard's disclosures 12.17.2020	2/11/2021 9:42 AM	Department Review	Jennifer Woodward	Billy Yates	Not Eligible

4 items

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Completing a Supervisor Review

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Supervisor Center

SUPERVISOR GUIDANCE

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[Action Items](#)[In Process Items](#)[Reviewed Items](#)[Secondary Supervisor Items](#)

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

Filter by ⓘ

ID

[+ Add Filter](#)[✕ Clear All](#)

ID	Name	State	Last State Change	Primary Supervisor	Secondary Supervisor(s)
DC00027812	Annual Disclosure Certification for Allison Caffas 2021	Draft	2/5/2021 2:42 PM	Billy Yates	
DC00027814	Annual Disclosure Certification for Michael Tommarello 2021	Draft	2/8/2021 9:04 AM	Billy Yates	
DC00000010	Update to Allison Caffas's disclosures 2.24.2020	Draft	2/24/2020 10:32 AM	Billy Yates	
DC00026797	Update to Billy Yates's disclosures 1.27.2021	Administrative Review	2/22/2021 3:36 PM	Billy Yates	
DC00028003	Update to COI Discloser's disclosures 2.24.2021	Draft	2/24/2021 4:26 PM	Billy Yates	

5 items

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Completing a Supervisor Review

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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](#)[In Process Items](#)[Reviewed Items](#)[Secondary Supervisor Items](#)

Reviewed Items- All items you approved.

Filter by ?

ID

[+ Add Filter](#)[✕ Clear All](#)

ID

▲ Name

State

Last State Change

Primary Supervisor

Secondary Supervisor(s)

DC00027815

Annual Disclosure Certification for Casey Holderfield 2021

Review Complete

2/24/2021 2:54 PM

Billy Yates

Erin Kershaw
Angela Coldren

1 items

[◀](#) page 1 of 1 [▶](#)

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Completing a Supervisor Review



My Inbox

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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

In Process Items

Reviewed Items

Secondary Supervisor Items

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



[+ Add Filter](#)

[✕ Clear All](#)

No data to display.

◀ page 1 no results ▶

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Completing a Supervisor Review

Department Review

NEXT STEPS

View Disclosures

Printer Version

✓ Record and Complete Department Review

↩ Request Changes by Department

👤 Manage Secondary Reviews

📢 Notify Secondary Reviewers

👤 Reassign Primary Supervisor

(UPITT COI - Disclosure Certification - In Progress)

Type: Disclosure Update | ID: DC00027813

Discloser: [Casey Holderfield](#) | Supervisor: Billy Yates

Draft

→

In Review

→

Under Mgmt Plan

→

Complete

Secondary Reviews

Person	Reqd	Accepted	Comments	Docs
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.

Summary

History

Disclosures

Private Review Information

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

Management plan:

Snapshot:

Date submitted: 2/8/2021

Needs review: Yes

MY DISCLOSURES

Export

Completing a Supervisor Review

Record and Complete Department 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

[Clear](#)

2. Related Attachments:

+ Add

Name

There are no items to display

OK

Cancel

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:

+ Add

Name

Description

There are no items to display

OK

Cancel

Completing a Supervisor Review

No Interests Disclosed

NEXT STEPS

View Disclosures

Printer Version

☒ Approve - No Interests Disclosed

☒ Send to my Inbox - further review required

☐ Send Notification to Reviewers

☐ Reassign Primary Supervisor

Type: Annual Certification | ID: DC00028000

Discloser: Aaron Paige | Supervisor: Billy Yates

Draft

In Review

Under Mgmt Plan

Complete

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	Reqd	Accepted	Comments	Docs
There are no items to display				

Summary

History

Disclosures

Private Review Information

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

Management plan:

Snapshot:

Date submitted: 2/24/2021

Needs review: Yes

MY DISCLOSURES


Export

No data to display.

DISCLOSER ADDL INFO

Outside Employment

No		
OCI	University Relationships	Party to University Transaction
No	No	No

 University of
Pittsburgh

Completing a Supervisor Review

Department Review

NEXT STEPS

View Disclosures

Printer Version

☒ Submit Secondary Review

(UPITT COI - Disclosure Certification - In Process)

Type: Disclosure Update | ID: DC00026520

Discloser: [Christopher Gerard](#) | Supervisor: Kelly Dornin Koss

Draft

In Review

Under Mgmt Plan

Complete

Secondary Reviews

Person	Reqd	Accepted	Comments	Docs
View Billy Yates	yes			

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.

Summary

History

Disclosures

Private Review Information

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:

Organization	Person	Review Type	Required
<input type="checkbox"/>	Billy Yates	Department Review	yes

2. * Do you accept the disclosure as submitted?

☐ Yes ☐ No [Clear](#)

3. Comments:

4. Supporting Documents:

Add

Name
There are no items to display

OK

Cancel

Help is Available to Supervisors

Email:
mydisclosures@pitt.edu

Record and Complete Department 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

[Clear](#)

2. Related Attachments:

+ Add

Name

There are no items to display

OK

Cancel