# CONFLICT OF INTEREST (COI)

**Click Training** 

Research and Economic Development







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## Some Background about Click



The Pre-Award and Compliance System (PACS) is a multi-year collaborative project to implement the online Click Portal



The Click Portal is being implemented to assist principal investigators, students, compliance and research administration staff with administering sponsored programs



UB is leading the implementation of the Click Portal, working in collaboration with our vendor partner, Huron, and the PACS Leadership Team.



## What is COI?

**Conflict of interest (COI)** in research is when financial or personal relationships may compromise — or have the appearance of compromising — an investigator's professional judgment in conducting or reporting research.

It is important that researchers do not have or appear to have a COI related to any of the studies in which they participate.

Federal regulations, state laws and University policies require that researchers submit financial disclosure forms at the time that a proposal is submitted for funding. When a possible COI is disclosed, the case is reviewed by an Institutional Review Board (IRB).

The IRB will coordinate with the PI to manage a potential COI. A COI management plan may be drawn up to ensure that the design, conduct, and reporting of research or other activity is free of bias.



## University at Buffalo's Policy on COI



The University at Buffalo is committed to promoting objectivity in research and maintaining high ethical standards to ensure that the design, conduct, and reporting of research is not biased by the financial interests of individuals acting on behalf of UB.

Investigators must disclose their and their immediate family members significant obligations, significant financial interests, and/or sponsored travel that is related to their institutional responsibilities to provide the reasonable expectation that the design, conduct, or reporting of funded research by UB faculty, students, or staff will not be biased.



## Completing a COI Disclosure Statement

Each Investigators must submit a Disclosure Statement that includes information pertaining to their significant financial interests (SFIs) and any sponsored travel that may be related to their research:

- when submitting a grant application for research
- prior to submitting human subject protocols for review by an Institutional Review Board (IRB)
- annually thereafter
- immediately upon of discovering or acquiring a new SFI.

After the Disclosure Statement is submitted, a review is conducted. If a COI exists, a management of conflicts may be drawn up to continue with the research proposal.



## Click COI Module

The COI Module provides an electronic system for management of research-related conflict of interest disclosures. It ensures the prevention of bias and helps avoid a circumstance in which a researcher's personal interest or relationships might compromise the integrity of research at the University.

If you do not have a Click account, you can request access here: https://www.buffalo.edu/research/research-services/click-implementation.html.

If you do not have access to your annual COI, you can request help here: https://www.buffalo.edu/research/about-us/staff-directory/ris/request-it-help.html

November



UB's annual filing deadline is Nov. 1.







# COI Helpful Tips

- You will begin receiving notifications to complete your annual disclosure about 45 days before it is due.
- The annual disclosure should be updated within 30 days of any financial change that occurs for you or an immediate family member that may impact a study.
- The research certification is done for <u>EACH</u> study submitted to the IRB to attest to your level of conflict of interest with the specific sponsor of the research.
- Failure to submit your annual disclosure or complete the research certification for the individual study will result in a delay in IRB approval
- Even if you have no outside organizations or companies with which you or an immediate family member have a financial relationship you still need to complete the annual disclosure.
- You may be asked to provide additional information as your Disclosure Certification is reviewed.
- If a management plan is required, your agreement to the plan must be documented prior to any funding being released. You are responsible for all its terms, conditions and actions.



## **Two Different Types of Disclosures**

#### Annual and Research Certification COI

#### What's the difference?

- > An annual financial disclosure is submitted once a year through the COI module of CLICK
- > The annual disclosure should be updated whenever you have a change to the one on file
- The research certification is done for <u>EACH</u> study submitted to the IRB to attest to your level of conflict of interest with the specific sponsor of the research

CONFLICT

OF INTERI



#### **Research Certifications**

- > Created in Click when:
  - 1. A new award comes in.
  - 2. A new funded study is submitted to the IRB.
  - 3. A funded study is submitted for continuing review.
  - 4. A new study team member is being added to a funded study.
- A study/award specific way to either update your annual disclosure or certify that no changes need to be made to your annual.
- > Upon award, a research certification is created for the PI, Co-I's and key personnel.
- > For IRB protocols, a research certification is created for the PI and all study team members.
- You will receive an email with a link to the research certification. Should you not receive the email, or it gets deleted, the COI will be found in the COI tab in Click (it will be in your inbox).
- It will include the study or award number as well as the project name, your role and project type.



## **Before you Start**

Before you submit a certification, gather the following information:

- Any consulting agreements you have signed this year
- Receipts from travel paid by outside companies
- Any stock option agreements
- Your stock portfolio summary
- Your IRS 1040 and/or 1099 forms

This information will help you to complete the form.





# **NAVIGATION** Click COI Module





University at Buffalo The State University of New York			
Login Required	] I for some accounts in 2023. <u>More &gt;</u>	For UB Personnel: U UBitname and passy access the Click COI	Jse your <b>vord</b> to system.
▲ UBITName ■ Password	Log In	If you don't know your name / password or y to reset your passwor	ou need d, please
<ul> <li>I don't know my password</li> <li>Find my UBITName</li> <li>Help</li> </ul>		or 645-3542 for help.	<u>ffalo.edu</u>



## **My Inbox**

Each time you log into the **Click Portal**, you will be taken to your **Inbox**. This area of the portal contains a list of all submissions that currently require you to take an action.

**My Inbox** is divided into two tabbed pages:

- **Compliance Tasks** This tab contains a list of your IRB, IACUC, and Safety submissions that currently require you to take an action.
- SPO Tasks This tab contains a list of your Grants, Agreements, and COI Disclosures that currently require you to take an action.

a Huron solution					Rebecca Simms (p	i)(demo)   My Inbox   Logoff
Home Agreements COI Facil	ities Grants IACU	JC IRB Safety				
Page for Rebecca Simps (pi)(demo)						Components
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	5 items		<pre> q page 1 </pre>	of 1 👂		25 / page



# Sorting and Filtering

The listings within **My Inbox** can be sorted by using the **Filter by** option. This option will allow you to search by **ID** number, **Name**, **Date Created**, **Date Modified**, or **State**.

My Ir	ıbox					
Filte	r 🕄 🛛 ID	<ul> <li>Enter text to search for</li> </ul>	Go	+ Add Filter	🗙 Clear All	
D		Name		Date Created	■ Date     Modified	State Coordinate
	00030511	Annual Disclosure Certification for Principal Investigator (pi1) 2019-2020		9/22/2019 12:29 PM	11/15/2019 3:27 PM	Draft
🖹 DO	00030082	Annual Disclosure Certification for Principal		9/13/2019 12:43 PM	9/13/2019 12:43 PM	Draft



### **My Disclosures**

You may navigate directly to the COI module by clicking the COI tab in the navigation menu at the top of the

en.	University at Buffalo The State University of Ne	v York							Hello, Principal Investigator (pi1
	» My Inbox	Awards Cou	urses Agreements	COI	Grants	IACUC	IRB	Safety	
	COI Meetings C	OI Reports							
	COI								
	COI Meetings	All Certifications	Administrative Review	Under Management	Plan				
	COI Reports	Filter by ? ID    Enter text to search for   Clear All  Clear All							
	View My Certification	ID 🔺	Name			First Name	Last Name	Туре	Status
		DC00031785 Up	odate to Principal Investigator	pi1)'s disclosures 3.30.2	2020	Principal	Investigator (pi1)	Disclosure Update	Administrative Review
	My Disclosures	1 items			∢ page 1	of 1 🕨			10 / page
L	Meetings								
	Reports								

The My Disclosures area is divided into three tabs:

- All Certifications All of your disclosure certifications, regardless of state.
- Administrative-Review All of your COI annual disclosure certifications currently under review.
- Under Management Plan All of your disclosures that are currently under a Management Plan.





University at Buffalo The State University	of New York								Hello, Principal Investigator (pi1) 🔻
» My Inbox	Awards	Courses	Agreements	COI	Grants	IACUC	IRB	Safety	
COI Meetings	COI Reports								
COI									
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	DC0003178	5 Update to Pri	ncipal Investigator (pi	1)'s disclosures 3.3	0.2020	Principal	Investigator (pi1)	Disclosure Update	Administrative Review
My Disclosures	1 items				∢ page [1	of 1 🕨			10 / page
Meetings									
Reports									
COI Discloser Quick Reference	l.								



To open a submission, click on its **Name**. When you open a submission, you will be brought to its **Workspace**.



You can return to **My Inbox** at any time by clicking the **My Inbox** tab in the navigation menu at the top of the screen.





## **Certification Workspace**

**1. Header** – Links to your profile and lets you log off

- **2. Top navigation menu** Links to the different modules within the **Click Portal**
- **3. Activities** Actions that can be taken based on a submission's current **State** and your assigned role within the module
- **4. Disclosures tab** Instructional notes for the Discloser, and a list of disclosures made previously (if applicable).
- **5. Shortcuts** Quick links to other frequently used areas of the module
- 6. **History tab** Actions taken previously on this submission.





Click on the link that you is emailed to you, and it should take you directly to your certification.

If you do not have the link, In the COI tab, Click on Create My Certification.

If you have already started but not submitted your Disclosure, this button will read Edit My Certification.

or View My Certification if it has already been Submitted for review.

## **Getting Started**





## **COI SmartForm**

	X My Inbox	Awards	Courses	Agreeme	nts COI	Grants	IACUC	IRB	Safety		Hello, Princ	ipal Investigator (pi1) ▼
To open the COI SmartForm from the Certification <b>Workspace</b> , click on the <b>Edit</b> button.	Draft My Current Actions Edit Printer Version Submit Disclosures Col Discloser Quick Reference COl Advanced Reports Reference	Type: Annual Certification Date Created: 9/22/2019 Disclosures Histor Notes to Discloser This institution is commit complexity of our society Principal investigators sh sponsored program, whe To prepare for completing any consulting agre receipts from travel any stock option ag your stock portfolio your IRS 1040 and any agreements yo any paid or unpaid To get started: Click on My Disclosures	ted to ensuring its our various relation our various relation outdensure that a ther or not involvin g this form, you ma exements (foreign on (foreign or domess preements (foreign on vor 1099 forms. u have signed with position (foreign on the "Edit" buttor	1 faculty an open i ons with each oth ny staff, student ig research, mus ay want to collect r domestic) you l tic) paid by outsi or domestic) or domestic) or domestic) any foreign or or r domestic) in to the left, uno	and productive environment her and with outside insitutio s, or other employees who p st complete an annual disclo t the following documents: have signed this year ide companies domestic entity der "My Current Actions".	in which to conduct teac ns, along with the height articipate in the design, ( sure form. Disclosures n	Discloser: Principal In thing, patient care, and tened national and gov conduct, or reporting of nust also be updated w	vestigator (pi1)   Phor I research. The institut remmental sensitivity t f research, complete a vithin 30 days when in	e: ion's concern with co o such matters. COI disclosure form erests change.	onflict of inter	est reflects the /, anyone engag	ever-increasing Jed in any
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		Organization	Publicly Traded?	Relationship	s Disclosure Types					Significan	t? Total Value	Last Updated
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		Dow Chemical Corporation		Self	Consulting, advisory, or sp	eaking compensation				yes	\$350,000.00	11/27/2019 11:20 AM







On the SmartForm page, you will see:

- 1. Required fields (\*)
- 2. Field help (0)
- 3. Navigation bar





The **Continue** and **Back** buttons will move you forward or back one page in the forms

The navigation bar allows you to perform the following actions:

- •Save Saves your work for the current page
- •Exit Exits the forms and returns you to the Workspace
- •Hide/Show Errors Performs a check on every page within the forms to ensure that all required fields have been completed
- •Print Prints the current page
- •Jump to: Allows you to see and navigate to all pages within the forms



## What to Disclose

Indicate if there are any business or financial relationships that you or an immediate family member had in the previous 12 months, or with which you or an immediate family member anticipate within this calendar year.

\* Are there any outside organizations or companies (foreign and domestic) with which you or an immediate family member have a relationship? 🚱 • Yes O No <u>Clear</u>

If you have answered **No** to this question, you will skip to the Assurance and Certification page.

If you have answered **Yes**, you will continue to the <u>Disclosure Details</u> page.



Click the Add Disclosure button



Click the 3 dots to open the Organization database

Search for the organization with which you have a relationship, and click the **Go** button

If you are unable to locate the **Organization** within the database, use the blank field provided to enter its **Name**.

Continue to SmartForm to answer questions and disclose details about the relationship.





Edit Printer Version Disclosures History	Certification Disclosure
	Certification Disclosure
Submit Disclosures Research Certification Instructions	
You must recertify that all of your financial disclosures are up-to-date in the system because of your involvement in the following research project(s): Research Project ID: MODCR00000123 Research Project Name: Test	
My Disclosures Research Project Role: Principal Investigator Research Project Type: IRB	
Meetings         Remember that you must disclose any financial interests that could be reasonably construed as related to the design, conduct, recruitment, or enrollment of subjects in the above research.           Reports         Image: Construct of the subject of the	
COI Discloser Quick Reference Notes to Discloser	
COI Advanced Reports Reference This institution is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. The institution's concern With conflict of interest reflects the ever-increasing complexity of our society, our various relations with each other and with outside instantiand governmental sensitivity to such matters.	
Principal investigators should ensure that any staff, students, or other employees who participate in the design, conduct, or reporting of You Are Here: Research Initiated Certificati form. Additionally, anyone engaged in any sponsored program, whether or not involving research, must complete an annual disclosure updated during the year whenever interests change.	Save   Exit   Hide/Show Errors   Print   Jump To: Assurance and Certification -
Select the "edit" button and continue through the Smart Form pages to review the information that was populated from your annual. You can make any changes to your disclosure at this time if needed.	pecca Simms (pi)(030) : Assurance and Certification         Ind the Financial Conflicts of Interest Policy.         if my knowledge true and complete and does not misstate any facts.         by my campus.         ed Management Plan as required per the Federal Regulations to manage, reduce, or eliminate existing conflicts of interest or obligations related to my littlons contained in any Management Plan.         Disclosure Type(s)       Total Value         Equity (shares / options / private ownership) in external company       \$25,000.00         Disclosure Type(s)       Total Value         tion at a later time: DO NOT check the confirmation box and click "Enish"       Total Value         ion for review: DO check the confirmation box and click "Enish"       "         ion for review: DO check the confirmation box and click "Enish"       "         id confirm that I understand and agree with the above statements.       "



## Disclosure Summary

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Compensation Type	Dollar Value						- 1
Stock Equity	\$35,000.00						- 1
Options Equity							- 1

It is a good idea to review the summary for accuracy. After you have finished reviewing your **Disclosure(s)**, click the **Finish** button to save your work and move to the next pages within the **SmartForms** 



## **Disclosure Details**



The Disclosure Details page will now list the new Disclosure that you have created.

- To make any changes to that **Disclosure**, click the **Edit** button to its left.
- To create an additional Disclosure, click the Add Disclosure button.

If you have created **Disclosures** in the past that have already been reviewed by the **COI Committee**, they will be listed here.

- If you need to make any changes to a previous **Disclosure**, click the **Modify** button to its left.
- If the relationship for that **Disclosure** is no active, click the **Remove** option

Click the Continue button to save your work and move to the next page within the SmartForms



#### Submitting Disclosure for Review - 2 Steps

1. Click Submit Disclosures under My Current Actions.

The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

- If an error appears, update any required fields that were missed. Save your changes, Exit the SmartForms, and then click the Submit button again.
- If there are no errors, a statement will appear in the window.
- 2. Read the statement and then place a checkmark next to the sentence at the bottom of the window.

Click **OK** to submit the **Disclosure(s)** for review.



## Finishing Submission Step 1

<u>IMPORTANT</u> .	Ň			arrograms/se	a nooms, Displayr ag			e.entry.Entry[	Hello	o, Principal Inve	stigator (	(pi3) 🔻
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## Finishing Submission Step 2

#### VERY IMPORTANT:

You must check this box and click Finish in order to successfully submit. If you do not click this button, it will save the proposal as a draft to be edited later but can not be submitted until it is checked.

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Institutional Responsibilities	I agree to coor reduce, or eli conditions co	any additional mormation as requested by my campus, operate in the development of any needed <i>Management</i> minate existing conflicts of interest or obligations related intained in any <i>Management Plan</i> .	t <i>Plan</i> as require ↓ Go to forms menu ♣ Print ▼
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What to Disclose			
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	*** <u>BEFORE</u>	YOU FINISH***	
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# After you Submit

Check to ensure that the following things have occurred:

- The Status Bar in the upper-left corner of the Workspace has now changed from Draft to Administrative Review.
- Today's date will appear as the **Date Submitted** on the **Summary** tab.
- On the **History** tab, the most recent action is **Disclosures Submitted**.



## What To Expect After Submitting

- Submitting your disclosure(s) initiates a series of activities that may include:
  - Review by a COI Administrator
  - Optional ancillary review by individuals, departments, and other organizations
  - Communication of the reviewers' decision to the discloser
- Any of these may lead to a request for you to take further action, such as providing clarifications regarding the disclosure
- Whenever you need to act, you will be notified by a member of the Compliance Team by e-mail, and the certification appears in My Inbox when you log in to the Click Portal





- For policy questions regarding COI:
  - Office of Research Compliance, Kyle Mann, klmann@buffalo.edu
- For questions regarding Click:
  - Tracie Groves, traciegr@buffalo.edu
- For assistance with UBITNames and Passwords:
  - Electronic Research Administration, <u>support@research.buffalo.edu</u>

