CONFLICT OF INTEREST (COI)

Click Training
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

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 **EACH** 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 EACH study submitted to the IRB to attest to your level of conflict of interest with the specific sponsor of the research
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.
For UB Personnel: Use your UBitname and password to access the Click COI system.

If you don't know your name / password or you need to reset your password, please contact UB CIT at support@research.buffalo.edu or 645-3542 for help.
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.
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 Disclosures

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

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.
COI Home Page
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.
To open the COI SmartForm from the Certification Workspace, click on the Edit button.
Disclosure Update for Principal Investigator (pil): Institutional Responsibilities

The following questions apply to all activities.

1. Do you write orders and/or prescribe items or services for patients who visit this institution? 
   - Yes
   - No

2. Do you influence or decide which vendor or manufacturer or service provider, supplier are chosen for purchase, lease, use or acquisition of any items or services at this institution? 
   - Yes
   - No

   If Yes, please describe your role in the decision-making or in influencing decisions:

3. Are you involved in any regulatory or policy activities on behalf of this institution? 
   - Yes
   - No

On the SmartForm page, you will see:
1. Required fields (*)
2. Field help (?)
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  ☐ No  Clear

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 Disclosure Details 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.
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.
Disclosure Summary

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.
VERY IMPORTANT:

You MUST save and exit the certification and the click on Submit Disclosures on the main COI workspace page in order to finalize the submission.
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.

**BEFORE YOU FINISH**

To save your disclosure certification for completion at a later time: DO NOT check the confirmation box and click "Finish"

To finalize and submit your disclosure certification for review: DO check the confirmation box and click "Finish"
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
Questions?

• 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,
    support@research.buffalo.edu