

## **Guidance: COI Disclosures**

**Note for IRB Submissions: Starting Monday, December 5, 2022, please have study team members complete COI disclosures via Cayuse.**

**\*\*\* Prior approval for use of hard copy disclosures form is required. Please forward appropriate justification to OSR for funded projects ([conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)), and IRB for unfunded projects ([chairboffice@challiance.org](mailto:chairboffice@challiance.org)) to receive approval for use of hard copy disclosure forms. \*\*\***

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### **Questions**

Please direct any questions regarding research-based disclosures as follows:

- Funded Research-based disclosures or annual disclosures:
  - Contact: [conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)
- Unfunded Research-based disclosures:
  - Contact: [chairboffice@challiance.org](mailto:chairboffice@challiance.org),
  - Michelle Ewahi [mewahi@challiance.org](mailto:mewahi@challiance.org), and
  - Mercedes Hasan [ahasan@challiance.org](mailto:ahasan@challiance.org)

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## Cayuse Outside Interests/COI Instructions/Reference

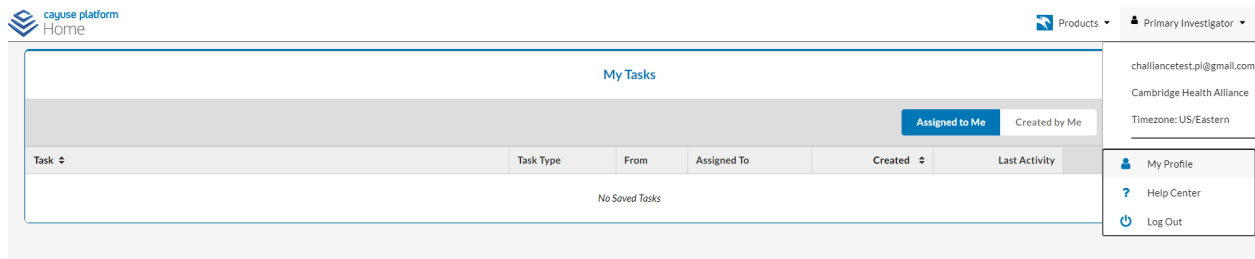
### Step by Step Instructions:

#### Submitting a Research-Based disclosure via Cayuse Outside Interests/COI

Please make an account with the [Cayuse Help Center](#) to review other helpful documents and videos regarding the submission process and how to use Cayuse IRB/Human Ethics & COI/Outside Interests.

Cayuse Website: <https://challiance.app.cayuse.com/>

1. Select the down arrow next to your name in the upper right corner and select My Profile.

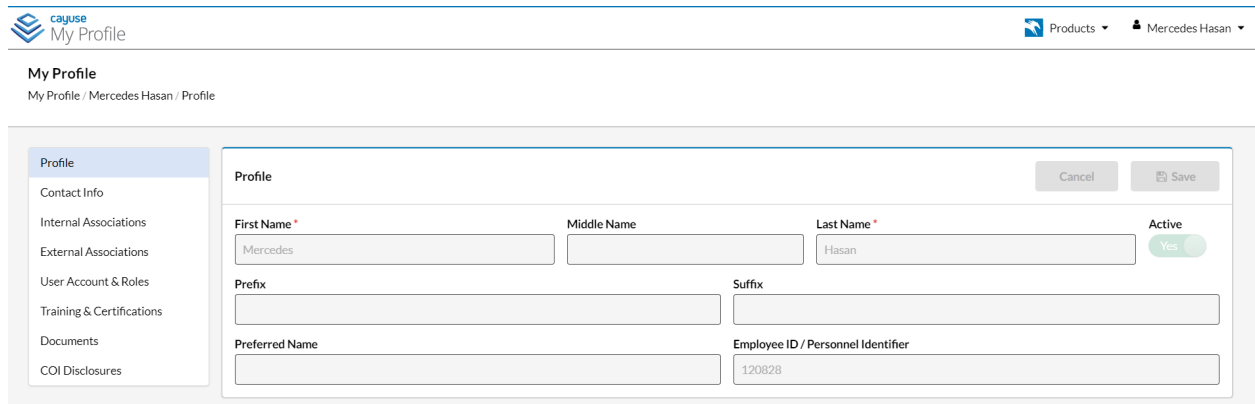


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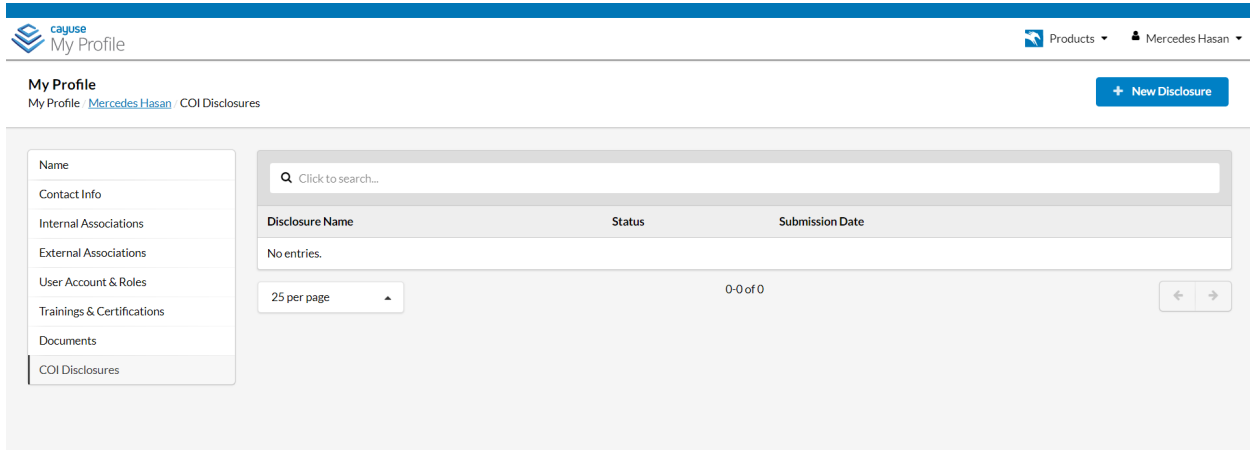
2. In My Profile in the menu on the left select COI Disclosure

\*if you do not see “COI Disclosures” as an option:

- Contact OSR for annual disclosures or funded research projects/IRB applications ([conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)).
- Contact the IRB Office (Mercedes Hasan [ahasan@challiance.org](mailto:ahasan@challiance.org)/Michelle Ewahi [mewahi@challiance.org](mailto:mewahi@challiance.org)) for research based disclosures for unfunded IRB applications.

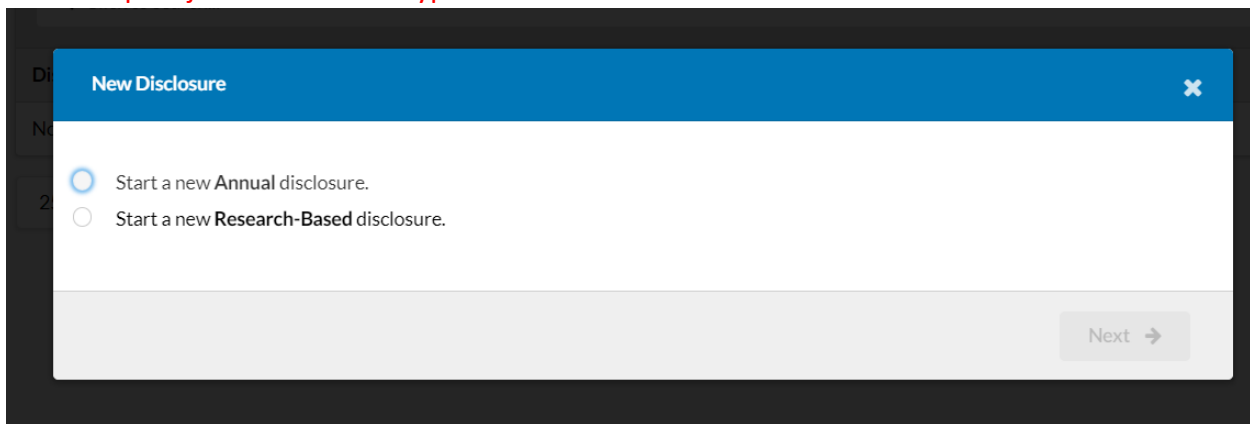


3. Select the blue New Disclosure button in the upper right corner.



4. You then will be prompted to Start a new Annual disclosure or a new Research - Based disclosure.

- Select Research-Based disclosure, and ensure the proper IRB # is included with your submission, or you may be required to resubmit. The IRB # will allow the IRB office to link your disclosure to the specific IRB protocol.
- If you have nothing to report, in the question do you have any outside activities to report just select No or type No.



**Getting Help**

- Questions about the Cayuse system can be directed to Cayuse Support:
  - <https://support.cayuse.com/hc/en-us/articles/360000452828-Contact-Support>
  - Phone (pacific time): 503-297-2108 ext. 1 or 1-877-689-3661
  - Email: [support@cayuse.com](mailto:support@cayuse.com)
- Cayuse Help Center <https://support.cayuse.com/>
  - This system is not accessible with your CHA credentials/Single Sign On.
  - Please make an account with your CHA email address as username and new password.
  - Product name is "Outside Interests"

## Cayuse User Management

### User Management

Note: Users are managed by CHA, not Cayuse.

- CHA Google Form to request access to Human Ethics/IRB or Outside Interests/COI: <https://forms.gle/LKffnHqnsycvU4EY8>
- User profiles will take 2-3 days to be available within Cayuse.
- You may request user accounts for non-CHA staff.
  - Please indicate that “Guest Access” should be allowed for these staff when requesting their user profile, otherwise these staff will not be able to access Cayuse. If an account needs to be converted to a guest account at a later date, please contact us.
  - You may request user accounts for non-CHA research staff who need access to:
    - i. Submit a COI disclosure via Cayuse for CHA IRB/OSR review.
    - ii. The IRB submission for which they are listed as staff.
  - Guest users will automatically receive an account activation email from Cayuse with a temporary password.
- Email Addresses & CITI Integration - fCOI training viewable within Cayuse
  - Please note that CHA Staff should only use @challiance.org or @icommunityhealth.org email addresses.
  - All full-time CHA staff or staff whose primary appointment is with CHA should update their email address within their CITI profile.
  - There will be a grace period after which this will be required.
- Access to Cayuse is via Single Sign On (SSO)- use your CHA credentials!

### Tips

- All sections with a red asterisk are required; you will not be able to complete your submission until all information is entered.

## Hybrid Paper/Electronic Process

### Hybrid Paper/Electronic Process

**Note: COI Disclosures should be submitted via Cayuse as of Dec 5, 2022**

**\*\*\* Prior approval for use of hard copy disclosures form is required. Please forward appropriate justification to OSR for funded projects ([conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)), and IRB for unfunded projects ([chairboffice@challiance.org](mailto:chairboffice@challiance.org)) to receive approval for use of hard copy disclosure forms. \*\*\***

#### Unfunded Studies

- [COI disclosure form](#) for non-PHS funded or unfunded studies. Please send a copy of the hard-copy disclosure form(s) and updated Study Team Roster to the IRB Office ([CHAIRBOffice@challiance.org](mailto:CHAIRBOffice@challiance.org)).
- Electronic Cayuse Outside Interests/COI disclosures (see guidance starting on Page 3)

#### PHS-Funded Studies

- CHA Policy: [Conflict of Interest in Public Health Service Funded Research \(A-COM-0015\)](#)
- In August 2012 new regulations went into effect regarding research funded by the [US Public Health Service \(PHS\)](#). The regulations require disclosure of significant financial interests by investigators who participate in PHS-funded research either directly or via sub-award.
- All CHA employees, collaborators, or contractors, regardless of title or position, who are responsible for the [design, conduct, or reporting of research activities](#) that are funded by the PHS, and any of its components, including NIH, Agency for Healthcare Research and Quality (AHRQ), and Centers for Disease Control (CDC), funding by means of a grant or cooperative agreement are subject to these regulations.

#### *Process:*

1. Complete the required fCOI training.
  - Option 1: Log into [citiprogram.org](http://citiprogram.org), affiliate with CHA, enroll in the Conflict of Interest course and complete the three required modules.
  - Option 2: NIH fCOI training. A copy of each training transcript should be sent to OSR along with the Study Team Roster.
2. fCOI disclosure forms:
  - [fCOI disclosure form](#) for PHS-funded studies. Please send a copy of the hard-copy disclosure form(s) and updated Study Team Roster to (1) OSR

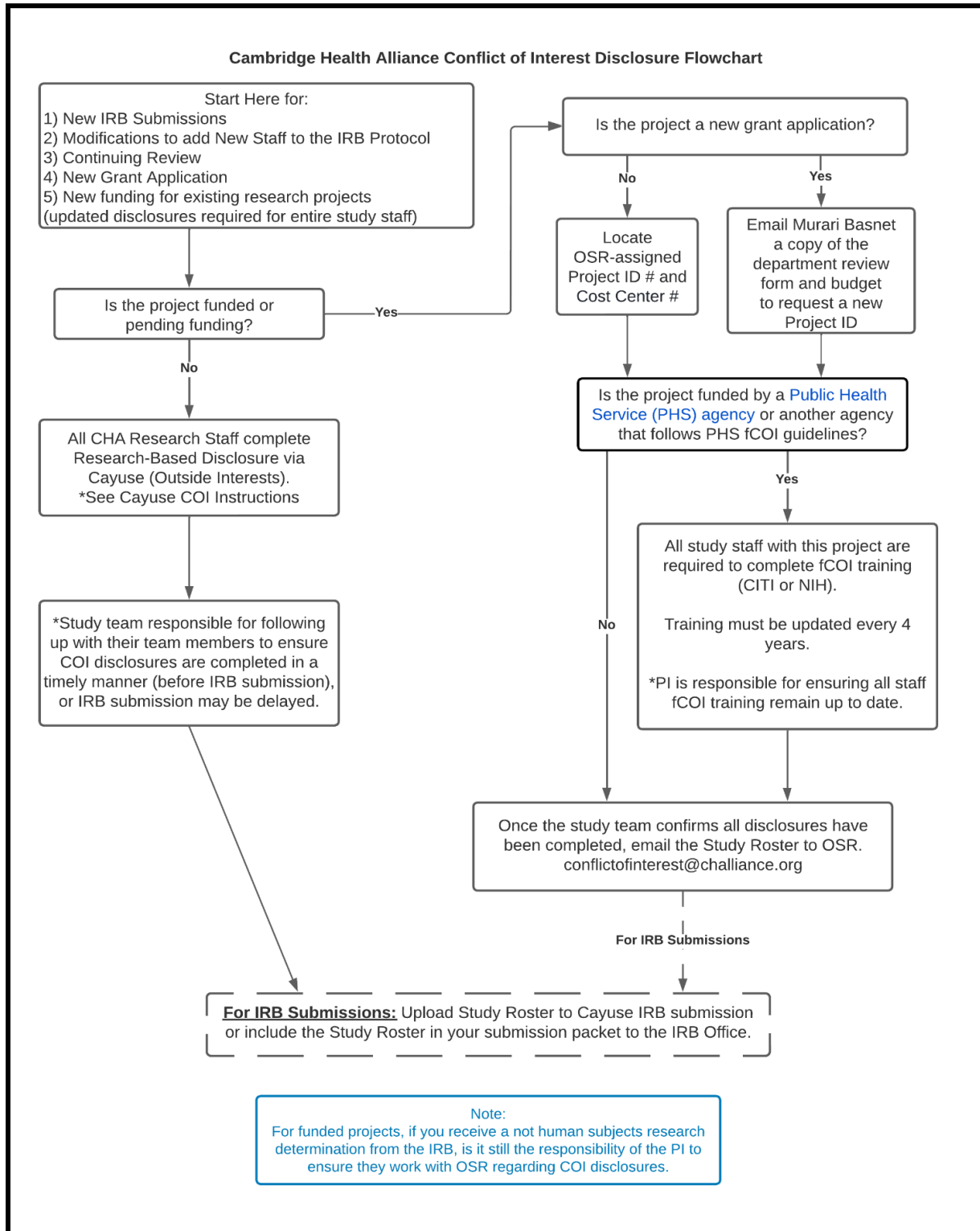
[conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)) and (2) the IRB Office  
([CHAIRBOffice@challiance.org](mailto:CHAIRBOffice@challiance.org)).

- Electronic Cayuse Outside Interests/COI disclosures (see guidance starting on Page 3)
3. Jorge/OSR will review all disclosures, and notify the IRB Office when this process is complete.

**Other Funded Studies (that DO NOT follow PHS fCOI requirements)**

1. COI disclosure forms:
  - [COI disclosure form](#) for non-PHS funded or unfunded studies. Please send a copy of the hard-copy disclosure form(s) and updated Study Team Roster to (1) OSR ([conflictofinterest@challiance.org](mailto:conflictofinterest@challiance.org)) and (2) the IRB Office ([CHAIRBOffice@challiance.org](mailto:CHAIRBOffice@challiance.org)).
  - Electronic Cayuse Outside Interests/COI disclosures (see guidance starting on Page 3)
2. Jorge/OSR will review all disclosures, and notify the IRB Office when this process is complete.

Flowchart: CHA COI Process



### Flowchart: Multi-site studies where an IRB Reliance Agreement is Utilized

