Annual Outside Financial Interest Certification – General Information

Information Needed to Complete Your Certification

Managing Individual Disclosures

In SpartaCOI, HOW DO I…?

…Create or Edit My Annual Certification?

…Add a New Disclosure?

…Edit an Existing Disclosure?

…Save a Draft Disclosure/Certification to Finish Later?

…Complete Requested Changes?

…Determine When a Certification/Disclosure Under Review May Be Modified?

…Update a Previously Submitted Certification/Disclosure?

…Work With Previously Reviewed Disclosures?

   Editing Previously Reviewed Disclosures
   Removing Existing Disclosures

…Print My Disclosures?

Supplemental Information

Certification Workspace Tools

My Inbox Workspace Tools

Relationship Questions in Detail

   Officer, Director, Trustee or Policy Manager
   Equity or Ownership in Publicly Traded Organization
   Salary or Other Payment
   Intellectual Property
   Other Financial Interests
   Sponsored Travel

Business and Research Relationships in Detail

Reports

Definitions
**ANNUAL OUTSIDE FINANCIAL INTEREST CERTIFICATION – GENERAL INFORMATION**

As part of the research community, you are required to submit an annual outside financial interest certification form. Your certification is reviewed by the Office of Research Administration’s Conflict of Interest Committee (COI Committee) for potential conflicts of interests. The Annual Outside Financial Interest Certification form is comprised of two parts: Conflict of Interests Training and Education materials and Disclosures.

**NOTE:** An annual certification must be completed even if you have no outside financial interests to disclose

You will receive an email notification from SpartaCOI when the annual certification materials are ready for you to complete. Sign in to SpartaCOI using your CWRU network ID and password to access and complete your certification.

Once you have finished, follow the on-screen instructions to submit your materials to the COI Committee for review. You will be notified by email if additional steps will be needed.

**Information Needed to Complete Your Certification**

Before you log in to begin your certification, gather the following:

- Any consulting agreements you have signed this year
- Receipts from travel paid for by outside companies
- Any stock option agreements
- Your stock portfolio summary
- Your current IRS 1040 and 1099 forms
Managing Individual Disclosures

A disclosure is a record of any financial relationship or interest you or a member of your family hold with a company or organization external to Case Western Reserve University. You, as the discloser, must complete a separate disclosure form for each organization in which you or your family hold an outside financial interest. However, multiple occurrences of financial interest within a single organization may be reported using a single disclosure form (e.g., you are on the Board of Trustees of an organization for which a family member receives a financial benefit from Intellectual Property).

Whether a particular disclosure meets criteria for additional review (i.e., is ‘significant’) is determined systematically. Significant disclosures undergo review by the Office of Research Administration’s Conflict of Interest Committee. You will receive an email after submitting your certification indicating what – if any – next steps will be needed.

All disclosures will need to be entered into the SpartaCOI system the first time you create an annual certification. Once entered, the system will retain a record of your disclosures for review and use in future certifications. Changes or additions to your disclosure records must be recorded in the SpartaCOI system within 30 days as they occur during the year.

IN SPARTACOI, HOW DO I…?
…Create or Edit My Annual Certification?

NOTE: All new SpartaCOI users are required to document within SpartaCOI all disclosures completed prior to the implementation of the new system. Once disclosures have been added to SpartaCOI, they will carry over year-to-year as needed.

1. Sign in to SpartaCOI using your CWRU network ID and password
2. Under “My Current Actions,” click [Edit My Certification]

NOTE: If “My Current Actions” displays anything other than the Edit My Certification button, contact the Office of Research Administration’s Conflict of Interest Committee before continuing.
3. Review the Introduction and CWRU Policy on Conflict of Interests. A link to the CWRU Policy on Conflict of Interests is provided for your convenience. Click Continue to proceed to your certification form.
4. Review the Training and Education materials provided. When finished, confirm that you have read and understood the Training and Education materials.
5. Review the types of interests that must be disclosed.
6. Indicate whether or not you and/or a family member have any interest with one or more outside organization or company that must be disclosed, then click Continue.

**NOTE:**
Selecting No will take you to the Additional Information page of the form (step #8).
Selecting Yes will take you to the Disclosure Details page of the form (step #7 below).

7. Review any existing disclosures displayed on the Disclosure Details page.
   a. **If an existing outside interest needs to be updated:** click the [Edit] button next to the disclosure you want to update. (See the “Edit an Existing Disclosure” section for details.)
   b. **If an outside interest is no longer active:** click the [X] button to the right of the corresponding disclosure. (See the “Removing Existing Disclosures” section for details.)
   c. **If you have a new outside interest to report:** click the “Add Disclosure” button (see the “Add a New Disclosure” section for details.)
   d. **When all disclosures have been reviewed/added/edited/removed:** click Continue.
8. Enter any additional information and/or upload any related documents you want to include with your certification and click Continue.
9. Review the bulleted statements at the top of the Annual Certification – Assurance and Certification page and check the box to confirm that you understand and agree with the statements.

**NOTE:** if you click Finish without checking the confirmation box, your disclosure certification will remain unsubmitted.

10. Review any information displayed under “Disclosures Under Review” and “Reviewed Disclosures” for accuracy. Follow the instructions at the bottom of the page to submit.
your certification OR to save your data and return to complete your certification at a later date.

11. Once you have checked the confirmation box and clicked Finish, your certification will be entered into the system and the status will change from Draft to one of the following states:
   a. Disclosure Certification Reviewed: No Outside Financial Interests (if you and/or a family member have no interests with any outside organization or company to disclose)
   b. Disclosure Certification Reviewed: No Action Required (if you have reported an outside interest, but it does not meet criteria that would require further administrative review)
   c. Administrative Review (if one or more of your disclosures meet the predefined criteria that requires further administrative review)

12. You will receive an email verifying the status of your certification and what (if any) next steps will be taken.

…Add a New Disclosure?

1. From the Annual Certification – Disclosure Details page, click the Add Disclosure button.
2. Begin typing the name of organization with which you have a relationship in the “Select the external organization this disclosure is for” box; click the name of the organization when it appears to select it.
   a. If the name of organization does not appear, click the Select button to search using advanced options
   b. If name still does not appear, type it into the “If you are unable to find the organization…” text box provided
   c. If organization does not exist in the SpartaCOI database, you will be asked to provide a one sentence description of the organization’s purpose (e.g., what it does)
3. When the organization name has been entered, click OK
4. Disclosure General Information Page: complete the information requested as follows. When all information has been entered, click Continue.
   a. What type of organization is this?: Choose the organization type from options provided
b. **Please select the type(s) of financial relationship you have with the external organization:** Choose the type of financial relationship(s) you and/or a family member have with this organization from the options provided. You may select more than one type if appropriate.

c. **What is the total aggregate value (in US dollars) of compensation for your combined service with this organization for all the roles checked above?:** Select the range from the drop-down list within which the total amount of compensation provided to you would fall. If the relationship with the organization does not involve monetary compensation (for example, you hold a patent filed with this organization), choose “0”.

5. Enter details about each of the relationship types selected on the General Information page, including whether the relationship is held by yourself, a family member or both. For more information, see [Relationship Questions in Detail](#).

6. Describe the business and research relationship(s) between yourself and the selected organization. For more information, see [Business and Research Relationships in Detail](#).

7. Review **Disclosure Summary** to verify that the individual values listed match the information entered on the “Equity or Ownership” and/or “Sponsored Travel” details pages, and the Total Value range listed matches the information entered on the General Information page. Click **Finish** to submit the disclosure for the selected organization, or click **Back** to make changes.

8. Verify that the completed disclosure is now listed under the **Disclosures Under Review** section of the Annual Certification – Disclosure Details page.

---

**...Edit an Existing Disclosure?**

1. From the Annual Certification – Disclosure Details page, click the **Edit** button next to the disclosure you want to update.

2. Update the information on the Disclosure – General Information page; click **Continue**.

3. If you have updated the type of financial relationship you have with the organization, verify that the correct individual details pages are presented. Edit information on the individual details pages as needed.

4. Review the Disclosure Summary to verify that any updated dollar/percentage values display correctly. Click **Finish** to submit the disclosure for the selected organization, or click **Back** to make changes.
5. Verify that the disclosure listing under the **Disclosures Under Review** section of the Annual Certification – Disclosure Details page reflects the edited information.

**…Save a Draft Disclosure/Certification to Finish Later?**

Until a certification is submitted for review, all information is editable. If you don’t have all the necessary information needed to complete a disclosure/certification, you can choose to save your progress and submit the form at a later time.

1. Click the Exit link at the top or bottom of any of the Annual Certification or Disclosure screens.
   a. If there is new, unsaved information on the page, you will be asked whether or not you want to save that information before exiting.

   **NOTE:** Whenever you click **Continue** to advance to the next page in the Annual Certification or in a Disclosure, the system automatically saves any information entered on that page.

2. To return to a saved, unsubmitted certification: Log in to SpartaCOI and click the **Edit My Certification** button.
3. To return to a saved, in-progress disclosure: Navigate to the disclosure details page of your certification and click the **Edit** button next to the corresponding disclosure.

**…Complete Requested Changes?**

You will receive a notification by email if reviewers request changes to your disclosure prior to final approval.

1. Log in to SpartaCOI
2. Find the name of your disclosure certification and click to open
3. From the disclosure certification workspace, click **Edit**
4. Make requested changes to disclosures per the email notification received
5. When done, save and exit
6. In the certification workspace, click **Submit Changes**
…Determine When a Certification/Disclosure Under Review May Be Modified?

- A certification or disclosure that is under review but in a state where you can modify it: an Edit button will be displayed under My Current Actions
- A certification or disclosure that is under review and cannot be modified: a View Disclosures button will be displayed under My Current Actions
…Update a Previously Submitted Certification/Disclosure?

If you need to amend your certification after it has been submitted for review, you can request that it be returned to a Draft state for correction.

1. Log in to SpartaCOI and click the COI link (located to the left of the Home link at the top of the screen)
2. Under the All Certifications tab, click the name of the certification you need to amend.
4. A notification will be sent to the Office of Research Administration’s Conflict of Interest Committee (COI Committee) with your request to return your certification to a Draft state for correction.
5. The COI Committee will review your certification and either:
   a. Return your certification to a Draft state and notify you that the certification may now be updated
   b. Request that you submit a separate Update to your existing disclosures. An Update to existing disclosures is completed in the same manner as the annual certification, but exists in the system as a separate document.

…Work With Previously Reviewed Disclosures?

All disclosures (including those reported prior to the implementation of SpartaCOI) will need to be entered into the SpartaCOI system the first time you create an annual certification. Once entered, the system will retain a record of your disclosures for review and use in future certifications. Disclosures submitted during prior certification cycles are listed on the Disclosure Details page under section 2: Previously Reviewed Disclosures.

Editing Previously Reviewed Disclosures

If the nature of your relationship changes with an organization, you must update your disclosures to reflect those changes. All of your disclosures are displayed on the Disclosure Details form.

NOTE: Changes or additions to your disclosure records must be recorded in the SpartaCOI system within 30 days as they occur during the year.

Once you modify a previously reviewed disclosure, it becomes part of the current certification process and is subject to review.
Removing Existing Disclosures

When you no longer have any payments or equity with an organization, you can deactivate the disclosure associated with it by clicking the button on the list of existing disclosures.

When you deactivate a disclosure, it is not immediately removed from the system. An Office of Research Administration analyst must approve the deactivation before it is removed from your set of disclosures. Until then, the disclosure will continue to display with a “Pending Removal” label in the Remove column, but will not be included when the system calculates the significant financial interest status of your certification.

…Print My Disclosures?

Click the Printer Version button in the workspace to create a read-only version of all your disclosure certification forms suitable for printing.

1. Sign in to SpartaCOI
2. Click COI
3. Click the name of the disclosure you would like to print
4. Click Printer Version
5. Click Print and follow system prompts to print or save a copy.
SUPPLEMENTAL INFORMATION

Certification Workspace Tools

1. **Current State**: Displays the current state/status of a COI Certification/Update

2. **Edit**: Click here to add or update information when selected certification is in an editable state. If certification is NOT in an editable state, this button will say View

3. **History**: Displays a summary of actions that have occurred as the certification moves through the creation and review process

4. **Attachments**: Any documentation you’ve attached to your certification and/or any disclosures can be accessed here.

5. **Comments**: Comments added throughout your certification and/or any disclosures can be viewed here.

Page 11 of 19
**Printer Version:** Click here to create a copy of your COI disclosure ready for printing

**Log Comment:** Click here to enter general comments about your certification and/or disclosures. Comments entered can be viewed on the **Comments** tab.

**My Disclosures:** Displays a list of your individual disclosures currently included in the SpartaCOI system.

---

**My Inbox Workspace Tools**

**My Current Actions:** Displays what actions are currently available to you

**Shortcuts:** Links to useful documents and features within the SPARA COI system.

**My Inbox:** List of Certifications and Updates to Disclosures that require some type of editing or response from you.
**Relationship Questions in Detail**

You must enter additional details about each of the relationship types selected on the General Information page (see Add a New Disclosure), including whether the relationship is held by yourself, a family member or both. The information required for each type of relationship is listed below.

**Officer, Director, Trustee or Policy Manager**

1. Disclose specific fiduciary relationship(s)
2. Choose one or more from the following,
   - Board of Directors
   - Trustee
   - Officer
   - Policy-Influencing Manager
   - Other Fiduciary Role
3. If “Other”, describe in space provided
4. Disclose who holds the relationship
5. Choose from self, family member or both

**Equity or Ownership in Publicly Traded Organization**

1. Disclose specific type of interest(s)
2. Choose one or more from the following,
   - Stock
   - Stock Option
   - Other Interest
3. If “Other”, describe in space provided
4. Enter the total value of position(s)
5. Disclose who holds the interest
6. Choose from self, family member or both

**Salary or Other Payment**

1. Disclose specific type(s) of salary or payments
2. Choose one or more from the following,
   - Salary
   - Honoraria / Speaking Fees
   - Consulting / Advisory Fees
   - Expert Witness Fees
   - Paid Authorship or Editorial Fees
   - Other Remuneration
3. If “Other”, describe in space provided
4. Disclose who receives the salary / payment
5. Choose from self, family member or both

**Intellectual Property**

1. Disclose specific type(s) of Intellectual Property
2. Choose one or more from the following,
   - Licensed Technologies
   - Patent Owned/Held by Individual
   - Royalties
   - Fixed Payment
   - Copyrights
   - Other Intellectual Property
3. If “Other”, describe in space provided
4. Disclose who holds the Intellectual Property
5. Choose from self, family member or both

**Other Financial Interests**

1. Disclose specific type(s) of other financial interests
2. Choose one or more from the following,
   - Vendor Relationship
   - Acceptance of Gift(s)
   - Acceptance of Favor(s)
   - Other Financial Interests
3. If “Other”, describe in space provided
4. Disclose who holds the interest
5. Choose from self, family member or both
Sponsored Travel

Complete disclosures for sponsored travel related to NIH/DHHS research only.

1. Estimate the value of sponsored or reimbursed travel, including airfare, lodging, meals, entertainment and per diem
2. Click Add to provide a destination, duration and purpose for each sponsored trip

Business and Research Relationships in Detail

Research Relationships

1. Describe specific research relationships between selected organization, yourself and the university
2. Choose from the following:
   - This organization sponsors my research
   - This organization supports my research (e.g., provides biologics, devices, drugs, equipment, technical expertise or other services)
   - This organization manufactures products used in my research
   - This organization has intellectual property rights or holds a license that will be utilized, developed, or studied in my research
   - This organization is a Research Collaborator (e.g., sub-recipient, Small Business Innovation Research [SBIR], Small Business Technology Research [STTR])
   - I have no research relationship with this organization

Business Relationships

1. Describe specific business relationships between selected organization, yourself and the university
2. Choose from the following:
   - I make purchasing decisions with this organization for the university
   - I make purchasing decisions with a competitor of this organization involved in my research
   - I have a business relationship with this organization
I have a business relationship with a competitor of this organization involved in my research

I have no business, purchasing and/or vendor relationship with this organization

Reports

A variety of pre-formatted reports are provided based on available data. Access to reporting data varies by system role.

1. Sign in to SpartaCOI
2. Click COI
3. Click COI Reports or choose Reports from the “Shortcuts” menu
4. Choose the report that most closely matches your data requirements
5. Filter and sort as needed. See table below for details
6. Click Export in upper-right of data table
7. Download link is provided when processing is complete
8. Click OK to return to COI Reports menu

Definitions

All CWRU COI Policies and Definitions

Common Conflict of Interests Definitions and Examples

Clinical affiliates

CWRU’s affiliate/partner hospitals:

- University Hospitals Case Medical Center (UHCMC),
- Cleveland Clinic,
- MetroHealth Medical Center (MHMC), and
- Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC)

Discloser
Disclosure
A record of any financial relationship or interest you or a member of your family hold with a company or organization external to Case Western Reserve University

Equity
Any stock, stock option or other ownership interest in an outside entity

Exclusions
Activities in which individuals may engage without disclosure

Faculty
Denotes Board of Trustees-appointed full, associate, or assistant professor; senior instructor or instructor

Family Member
Defined as yourself, your spouse/domestic partner, dependent children, and any other dependent person living in the same household.

Institutional / University Responsibilities
Professional responsibilities conducted on behalf of the University

Intellectual Property (IP) Rights and Interests
Any intellectual property rights and interests (except those intellectual property rights assigned to the institution) and agreements to share in royalties related to such rights. Disclosable intellectual property rights and interests are as follows:

- Licensed technology (patented or unpatented),
- Fixed payments (upfront fees, milestones, annual fees),
- Royalties,
- Copyrights, and
- Patents owned by investigator (not owned by institution)

Investigator
For purposes of financial interest disclosure, any personnel listed on any sponsored project (research, administrative, training, fellowship or assessment projects) through
CWRU, and/or an investigator conducting research at CWRU or one of its clinical affiliates.

No Actionable Conflict of Interests
Individuals who have an outside interest that is not significant, or is found to be unrelated to University research or responsibilities, will not require further action regarding their outside interest. Such individuals’ annual outside interest review will be marked as "Disclosure Certification Reviewed: No Action Required."

Officer or Director
For purposes of outside financial interest disclosure, the "officer or director" holds a board membership or other officer position involving advisory or fiduciary duties with any outside entity whether compensated or not.

Outside Entity
For purposes of financial interest disclosure, an "outside entity" is any corporation, partnership, proprietorship, firm, association, organization, or other entity outside the University and its clinical affiliates (but excluding federal, state or local government agencies). A person from whom a discloser has received disclosable remuneration or other financial interest is also an "entity" by this definition.

Outside Financial Interest
Anything of monetary value, whether or not the value is readily ascertainable.

Population Required To Disclose
Any individual pertaining to one or more of the following populations is required to disclose per CWRU COI policy: Faculty, Investigators and Senior Staff. See Common Conflict of Interests Definitions and Examples for additional details.

Reimbursed or Sponsored Travel
Investigators must disclose the occurrence of any reimbursed or sponsored travel related to an individual’s institutional responsibilities. "Sponsored" travel is travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available.

Routine Follow-up
Routine follow-up is review that is intended to assist the investigator and the University in fulfilling the CWRU policy as well as NIH regulations—to identify and manage any financial conflicts of interest with research. The Conflict of Interests Committee staff will work with the investigator to summarize their financial interests and related University responsibilities for the COIC. Where the COIC determines there could be the appearance of a conflict, the Committee works with the investigator to manage the conflict.

Salary
Disclosable salary and remuneration is salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Senior Staff
University officer, senior official or staff member. "Senior officials" required to complete the form comprise the Provost, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, Chief of Staff, vice presidents for Development, University Relations, and Diversity, Inclusion and Equal Opportunity, and any other person that the President designates. Staff with purchasing / vendor responsibilities are required to complete the form (as designated by salary grade and purchasing limit), and any other employees at the request of their supervisors.

Significant Financial Interest ("SFI")
In a research context, an SFI is a financial interest of the Investigator and/or of the Investigator’s family member that reasonably appears to be related to the Investigator’s institutional responsibilities. When outside multiple financial interests for the same outside entity or source are disclosed, the information will be reviewed in aggregate for significance.

More Help
For more information, email the COIC staff at caseoic@case.edu, or call 216-368-5963. If you leave a voicemail, please spell your name and provide your email address.