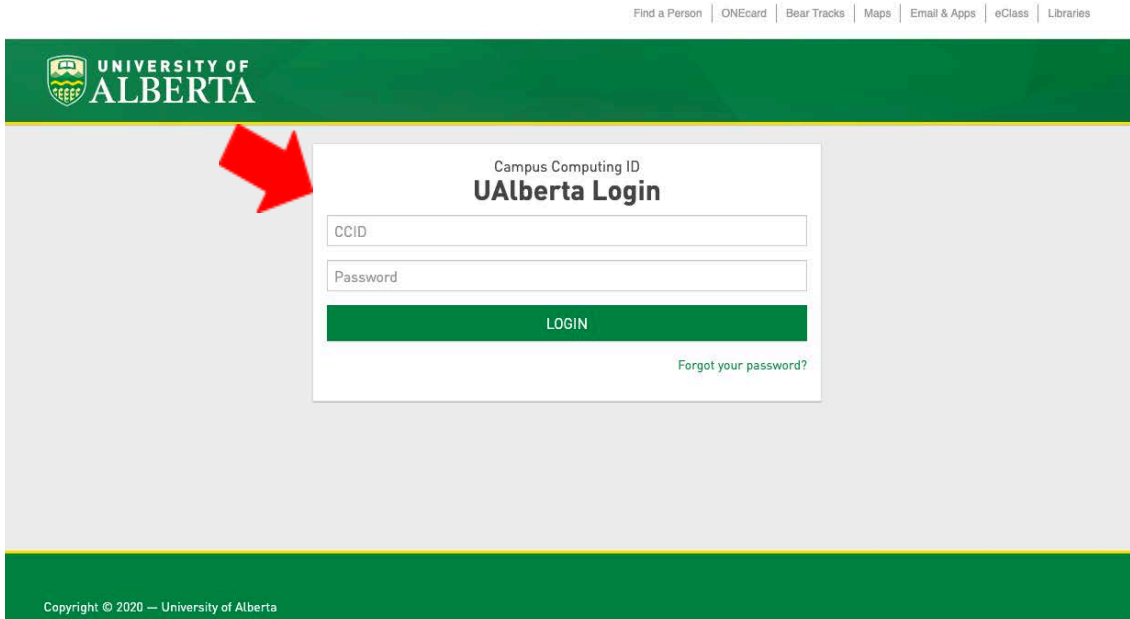
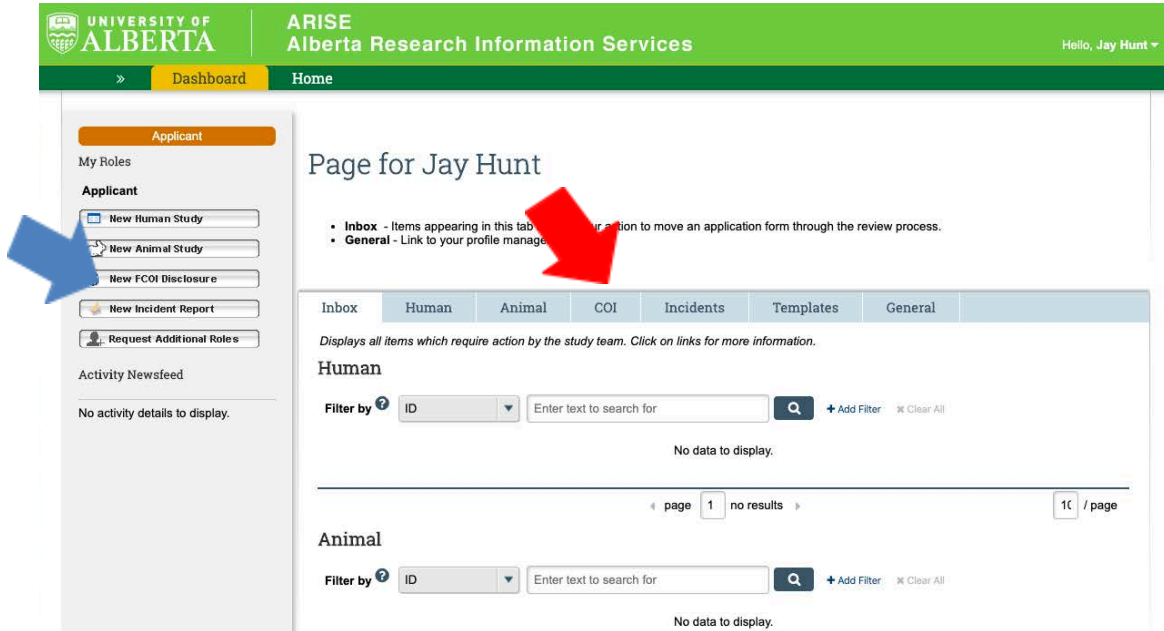


How to create a new Conflict of Interest (COI) Disclosure – CCI Oncology specific

1. Navigate to ARISE at <https://arise.ualberta.ca/> Please have pop-up blockers disabled.
2. Login to ARISE (red arrow) using your CCID and password (the same as for your @ualberta.ca account).
3. If you have never used the study, you must first provide your certificate of training to nih@ualberta.ca for your FCOI account to be enabled.



4. Once you have provided your certificate of training to nih@ualberta.ca and your FCOI access has been enabled, click on the 'New FCOI Disclosure' button (blue arrow). If you don't see a COI tab (red arrow), please contact nih@ualberta.ca so the Designated Official can register your training in ARISE.



5. This brings you to the first page of your Financial Conflict of Interest Disclosure called the 'Investigator & Project Information' page. Please complete the required fields, and include any other details. For Cross Cancer Institute Investigators, please indicate the following responses:

RES: Oncology, or RES0025292 (COG)

Project/Grant End Date: LEAVE BLANK

Funding Source: NIH

Project Title: NRG Oncology or COG

Lead UoFA PI: Susan Chafe (NRG Oncology) or Sarah McKillop (COG)

UoFA is Lead Institution: Yes

External Contractor: No

Click 'Continue' on the bottom right to save and continue (red arrow).

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Save Print Continue

1.1 Investigator & Project Information

* RSO Project Number (RES):

* Project/Grant End Date:

Faculty:

Department:

* Funding Source:

Funding Source (Other):

* Project Title:

* Lead UoFA Principal Investigator:

* UoFA is Lead Institution?
 Yes No [Clear](#)


* External Contractor (Sub-Grant Out):
 Yes No [Clear](#)

Your role in the project:
 Academic Personnel
 Non-Academic/Trust Personnel
 Trainee
 Other
[Clear](#)

* Do you have a spouse/partner? Spouse/Partner is defined as either a) the person to whom the investigator is lawfully married as evidenced by a legally certified document of marriage, or b) a person whose relationship to the investigator falls under the legal definition of Adult Interdependent Relationship (formerly common-law relationship).
 Yes No [Clear](#)

* Do you have a dependent child(ren)? A dependent child must meet all 4 criteria: 1) Residency: Must live with the investigator for at least 6 months of the year; 2) Relationship: The child, adopted child, single foster child, or a descendant of any of those (such as grandchildren) of the investigator; Step-children and half-siblings also meet this qualification. Siblings and their descendants also qualify; 3) Age: must be under age 19 at the end of the year, unless they are under age 24 and a full-time student. However, any child who is permanently disabled can be claimed as a dependent, regardless of age; 4) Support: The child cannot provide more than half of the money for their own support, i.e. a child whose care is paid for by a trust fund or other source of money would not be eligible.
 Yes No [Clear](#)

Save Print Continue



6. Personal Declaration: Declare any potential conflicts of interest that match the descriptions outlined on this page. Please note that if you indicated that you have a spouse/partner or any dependents, you will be required to complete these statements on their behalf on subsequent pages. Once completed, please click 'Continue' (red arrow).

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2.1 Declarations

2.1 Investigator:
 *I hereby declare that I, Jay Hunt, the Investigator,

<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="button" value="Clear"/>	Received payment(s) from, or held equity in, a publicly traded entity; those payments/equity are related to my institutional responsibilities and have an aggregate value of greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received payment(s) from a non-publicly traded entity; those payments are related to my institutional responsibilities and have an aggregate value of greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Held any equity interest in a non-publicly traded entity (e.g., spin-off company) in the previous 12 months, that entity being related to my institutional responsibilities.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received aggregate income from a payor, for my intellectual property interests related to my institutional responsibilities, greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received aggregate payment(s) or reimbursement(s) for seminars, lectures or service on advisory/review panels/boards, related to my institutional responsibilities and greater than \$5,000 CAD per entity in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Have an aggregate sum greater than \$5,000 CAD for the previous 12 months for a combination of multiple SFIs of the above types when from a single entity.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Have taken sponsored travel (or have been reimbursed for travel) related to my institutional responsibilities, with an aggregate value greater than \$5,000 CAD per entity in the previous 12 months.

Note: Aggregate = sum of SFIs of Investigator + Spouse/Partner + Dependent Child(ren)

Exclusions:

- Salary or other remuneration from the Institution
- Intellectual property assigned to the Institution
- Income from investments (e.g., mutual funds) where the Investigator does not control the investment decisions
- Income from seminars, lectures, service on advisory/review panels/boards when 1) aggregates less than \$5,000 CAD from one entity for the previous 12 months, or 2) any amount from a U.S. government, U.S. post-secondary institution, or U.S. health science center
- Ownership interest in the Institution where the Institution is a commercial or for-profit entity (This situation is rare, please contact the NH Designated Official)

Continue >

7. Partners/Dependents Declaration: If you indicated that you have a spouse/dependents, you will be required to disclose on their behalf. You will only be required to submit their name if they hold a Significant Financial Interest (SFI)/agree to any of the statements listed. Once completed, please click 'Continue' (red arrow).

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2.3 Dependent Child(ren)

2.3 I, Jay Hunt, the Investigator, on behalf of my dependent child(ren), hereby declare that my dependent child(ren)

<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received payment(s) from, or held equity in, a publicly traded entity; those payments/equity are related to the Investigator's institutional responsibilities and have an aggregate value of greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received payment(s) from a non-publicly traded entity; those payments are related to the Investigator's institutional responsibilities and have an aggregate value of greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Held any equity interest in a non-publicly traded entity (e.g., spin-off company) in the previous 12 months, that entity being related to the Investigator's institutional responsibilities.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received aggregate income from a payor, for my intellectual property interests related to the Investigator's institutional responsibilities, greater than \$5,000 CAD in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Received aggregate payment(s) or reimbursement(s) for seminars, lectures or service on advisory/review panels/boards, related to the Investigator's institutional responsibilities and greater than \$5,000 CAD per entity in the previous 12 months.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Have an aggregate sum greater than \$5,000 CAD for the previous 12 months for a combination of multiple SFIs of the above types when from a single entity.
<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="button" value="Clear"/>	Have taken sponsored travel (or have been reimbursed for travel) related to the Investigator's institutional responsibilities, with an aggregate value greater than \$5,000 CAD per entity in the previous 12 months.

Dependent Child(ren) Name(s)

+ Add

First Name	Last Name
There are no items to display	

Note: Aggregate = sum of SFIs of Investigator + Spouse/Partner + Dependent Child(ren)

Exclusions:

- Salary or other remuneration from the Institution
- Intellectual property assigned to the Institution
- Income from investments (e.g., mutual funds) where the Investigator does not control the investment decisions
- Income from seminars, lectures, service on advisory/review panels/boards when 1) aggregates less than \$5,000 CAD from one entity for the previous 12 months, or 2) any amount from a U.S. government, U.S. post-secondary institution, or U.S. health science center
- Ownership interest in the Institution where the Institution is a commercial or for-profit entity (This situation is rare, please contact the NH Designated Official)

Continue >

Note: A similar page will appear if you indicated you have any dependents. Complete this page as above.

8. Non Travel SFIs: If you indicated holding a non-travel related financial interest on any disclosure page (either for yourself, your spouse/partner or any dependents), you will be

required to disclose the details. Click on the 'Add' button (blue arrow) to add a financial interest. This will bring up a new pop-up window (have pop-up blockers disabled). Complete the required information relating to the financial interest. For item #5, please include as detailed a description of the SFI as possible, as this will help to provide context for the Designated Official and speed up the FCOI evaluation process. When finished, click 'OK' if you only need to add one entry, or 'OK and Add Another' to bring up another window to enter another SFI (red arrow). Please note that financial interests related to travel should be disclosed on a later page. **If you, your partner and your dependents do not hold any SFIs, you will not see these pages and can proceed to Step 15 in this guide.**

The screenshot shows a web browser window with the URL 'arise-test.uslberta.ca/ARISE_TEST/sd/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?...' and a page title 'Add UACOI_Type_Non Travel SFI'. The main content area is a form titled 'Non-Travel SFIs for Investigator'. It has several sections:

- 1.0 Name of entity in which I have a significant financial interest:** A text input field containing 'Teva Pharmaceuticals'.
- 2.0 Holder of SFI entity:** A dropdown menu with 'Investigator' selected.
- 3.0 Annual value of significant financial interest (CAD):** Radio buttons for '\$1 - \$4,999', '\$5,000 - \$9,999' (selected), '\$10,000 - \$19,999', '\$20,000 +', and 'Indeterminable'. There is a 'Clear' link below.
- 4.0 If value cannot be readily determined, explain:** A large text area.
- 5.0 Nature of the significant financial interest (stock, ownership interest, salary/fees earned, etc.):** A text input field containing 'stock'.

At the bottom of the form are three buttons: 'OK', 'OK and Add Another', and 'Cancel'. A blue arrow points to the 'Add' button in the left sidebar, and a red arrow points to the 'OK and Add Another' button.

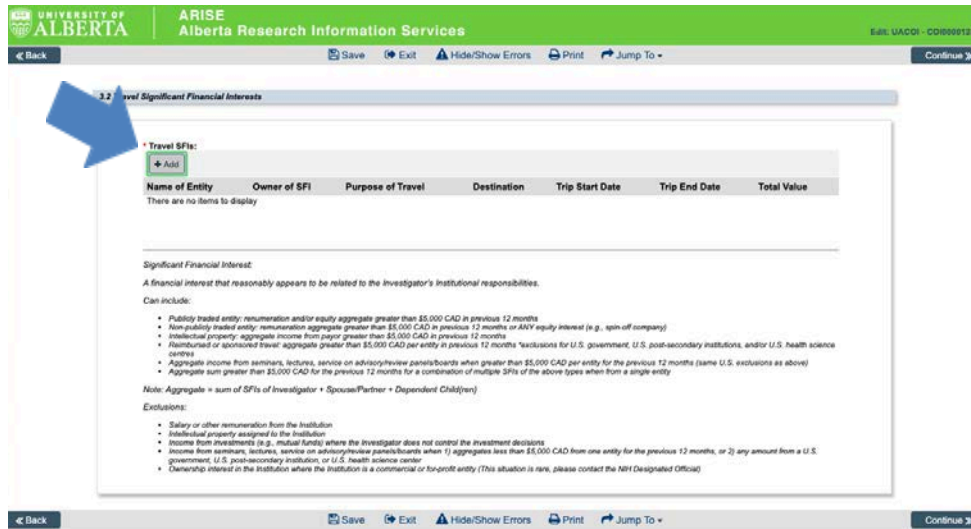
9. Non Travel financial interests appear as a list once entered. You can edit by clicking on the name of the entity, highlighted in blue (blue arrow). You can delete the entry on the far right of the table (green arrow). After entering all non travel SFIs, click 'Continue' to proceed (red arrow).

The screenshot shows the '3.1 Non Travel Significant Financial Interests' page. At the top, there are navigation buttons: 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. The main content area is a table with the following data:

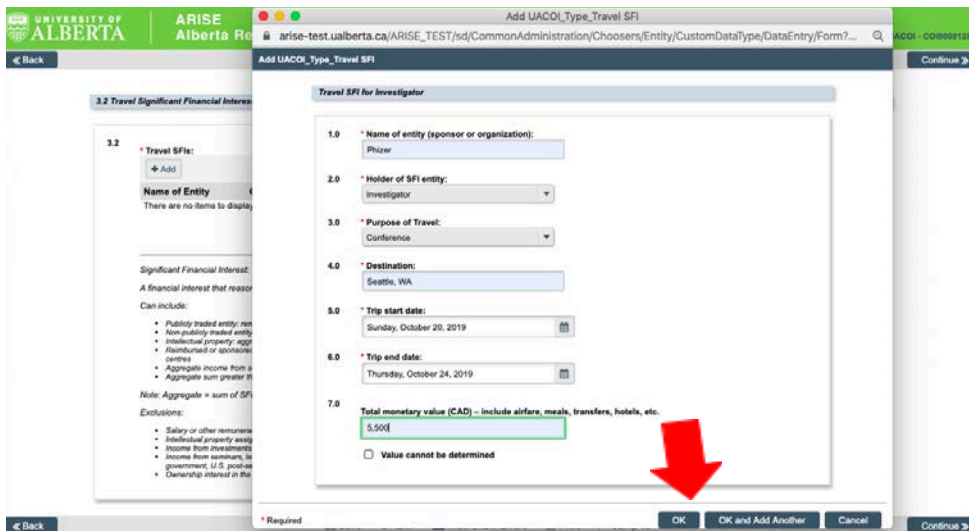
Name of Entity	Owner of SFI	Annual Value	Nature of SFI
Teva Pharmaceuticals	Investigator	\$5,000 - \$9,999	stock

Below the table, there is a section for 'Significant Financial Interest' with a list of inclusions and exclusions. A blue arrow points to the entity name in the table, a green arrow points to a delete icon on the right side of the table row, and a red arrow points to the 'Continue' button at the bottom right.

10. Travel SFIs: If you indicated holding a travel related financial interest on any disclosure page (either for yourself, your spouse/partner or any dependents), you will be required to disclose the details. Click on the 'Add' button to add a financial interest (blue arrow). This will bring up a new pop-up window.



11. Pop-up travel SFI entries: Complete the required information relating to the financial interest. Trip start and end dates should be entered using the calendar on the right side of the field. Navigate and select the date within the calendar. When finished, click 'OK' if you only need to add one entry, or 'OK and Add Another' to bring up another window (red arrow).



12. Similar to the non travel entries, Travel financial interests appear as a list once entered. You can edit by clicking on the name of the entity, highlighted in blue (blue arrow). You can delete the entry on the far right of the table (green arrow). When finished entering your travel SFIs, click 'Continue' to proceed (red arrow).

3.2 Travel Significant Financial Interests

3.2 * Travel SFI(s):

[+ Add](#)

Name of Entity	Owner of SFI	Purpose of Travel	Destination	Trip Start Date	Trip End Date	Total Value
Investigator	Investigator	Conference	Seattle, WA	Sunday, October 20, 2019	Thursday, October 24, 2019	\$5,800.00

Significant Financial Interest:
A financial interest that reasonably appears to be related to the investigator's institutional responsibilities.

Can include:

- Publicly traded entity remuneration and/or equity aggregate greater than \$5,000 CAD in previous 12 months
- Nonpublicly traded entity remuneration aggregate greater than \$5,000 CAD in previous 12 months or ANY equity interest (e.g., spin-off company)
- Intellectual property aggregate income from payor greater than \$5,000 CAD in previous 12 months
- Nonemployment or sponsored travel aggregate greater than \$5,000 CAD per entity in previous 12 months *exclusions for U.S. government, U.S. post-secondary institutions, and/or U.S. health science centres
- Aggregate income from seminars, lectures, service on advisory/review panels/boards when greater than \$5,000 CAD per entity for the previous 12 months (same U.S. inclusions as above)
- Aggregate sum greater than \$5,000 CAD for the previous 12 months for a combination of multiple SFIs of the above types when from a single entity

Note: Aggregate = sum of SFIs of investigator + Spouse/Partner + Dependent Child(ren)

Exclusions:

- Salary or other remuneration from the institution
- Intellectual property assigned to the institution
- Income from investments (e.g., mutual funds) where the investigator does not control the investment decisions
- Income from seminars, lectures, service on advisory/review panels/boards when 1) aggregates less than \$5,000 CAD from one entity for the previous 12 months, or 2) any amount from a U.S. government, U.S. post-secondary institution, or U.S. health science center
- Ownership interest in the institution where the institution is a commercial or for-profit entity (This situation is rare, please contact the NHI Designated Official)

13. The SFI Commentary page asks you questions relating to the SFIs you have listed. This provides context and information on which to evaluate your SFIs in relation to the specific proposed funding project. As stressed in the training, a SFI that is related to your proposed funding will result in a tailored, practical plan to manage the financial interest while allowing research to proceed, created by both the individual and the Designated Official. Complete and then click 'Continue' (red arrow).

3.3 SFI Commentary

1.0 * You indicated 'yes' to one or more of the previous significant financial interests (SFI) for the investigator, partner or dependents). For each of the SFI(s) you have identified, could the financial interest be related to this specific proposed/awarded study? Please provide relevant details.

Teva Pharmaceutical stock is unrelated to my direct research and the proposed project does not use any Teva products.

Pfizer sponsored a scholarship which funded my travel to an international conference. It has no relation to the current proposed research.

2.0 * For the same SFI(s) you have identified above, is the financial interest an entity whose financial future could be affected (either positively or negatively) by this specific proposed/awarded study? Please provide relevant details.

None would be directly affected by the results of my research.

14. Consent: According to Alberta's Freedom of Information and protection of Privacy (FOIP) Act, Investigators must consent for the collection and disclosure of personal information. Indicate your agreement with the statements by clicking on the check boxes. Then click 'Continue' (red arrow).

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4.1 Consent for Collection and Disclosure of Personal Information (for compliance with the Province of Alberta Freedom of Information and Protection of Privacy (FOIP) Act).

1.0 *Consent for collection of personal information:
Indicate your agreement with the statement by checking the box

I understand that the personal information provided herein is collected under the authority of Section 33(c) of Alberta's Freedom of Information and Protection of Privacy Act for authorized purposes including administration of employment and research records and will be protected under Part 2 of that Act. Personal information may be disclosed to academic and administrative units according to University policy, and reporting requirements to NIH or other funding sources, as required. For details on the use and disclosure of this information, please contact the Designated Official at 780-289-4800.

2.0 *Consent for disclosure of personal information:
Indicate your agreement with the statements by checking the corresponding boxes

I voluntarily authorize the University's Designated Official to disclose all information relating to the presence or absence of any significant financial interests (SFIs) disclosed herein, to American Cancer Society (ACS) for the purpose of compliance with the United States regulations 42 CFR Part 50 Subpart F (<https://www.fda.gov/oc/ohrt/PolicyProcedures/Procedures/FinancialConflictOfInterestforNIHandOtherApplicableResearchFundingSourcesReportingandAssessmentProcedure.pdf>) and 45 CFR Part 94.

I voluntarily authorize the Designated Official to disclose the information herein to any personnel of the University as deemed necessary by the Designated Official in order for that Designated Official to assess, in accordance with the Procedure, whether any Significant Financial Interests (SFIs) disclosed herein constitutes a Financial Conflict of Interest (FOCI).

In the event that the Designated Official determines that any Significant Financial Interest that I have disclosed herein constitutes a Financial Conflict of Interest, I voluntarily authorize the University's Designated Official to declare such information to the NIH/Other Funding Sponsor, as applicable, and to post any or all information collected on this form pertaining to that Financial Conflict of Interest on a public website or release it in response to a written request, pursuant to the Procedure.

I understand that as UofA/NIH employee with funding via these entities, PIs and their study staff are not required to sign or disclose information for other institutions. If this is done, it is done under the free will of the PI/study staff to sign/disclose as per the other institution's requirements

This permission will exist from the time this record is submitted to the end-date of the award plus 3 years.

Continue

15. Revocation of Consent: Investigators can revoke consent at any point and are required to acknowledge this responsibility by clicking on the check boxes. Then click 'Continue' (red arrow).

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5.1 Acknowledgement Regarding Revocation of Consent to Disclose

1.0 I acknowledge that, at any time, I may notify the Designated Official that I no longer wish to apply and/or work on a research project funded by American Cancer Society (ACS). In such event, or in any other event that my consent (or the consent of my spouse/partner or dependent child(ren)) for disclosure is revoked, I acknowledge that the University of Alberta must notify the applicable funding agency (NIH, Other Funding Sponsor, or in the case of a sub-contract in, the prime recipient) that I am no longer compliant with the funding agency's requirements. I acknowledge that, as a result of such noncompliance, I could be subject to:

- i. Penalties imposed by the funding agency at their discretion (an example of a penalty includes but is not limited to: revoking permissions for the investigator to apply for any further research project funding from that funding agency and/or other funding agencies);
- ii. Requests by the funding agency that I pay back all funds that have been paid by the funding agency to the University; and/or
- iii. Refusal by the funding agency to send any further funds to the University for the research project.

2.0 I acknowledge that, in the event that such notification to the applicable funding agency is made, the University of Alberta is in no way responsible for:

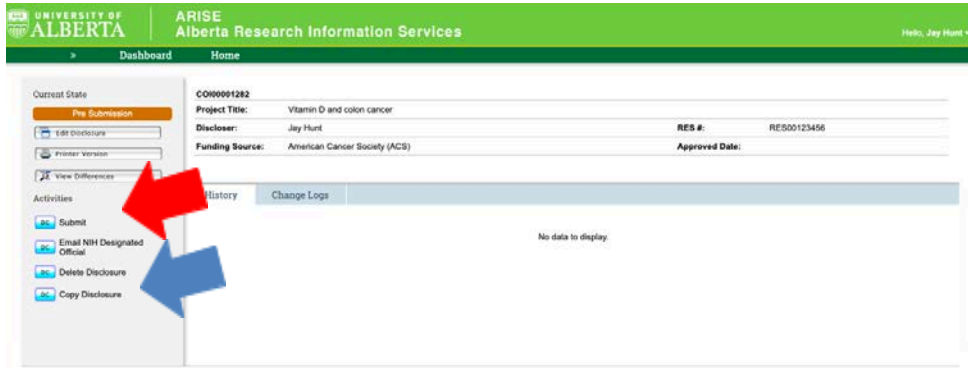
- i. Reimbursement of funds to the funding agency;
- ii. Reimbursement of committed or non-cancelable costs of my research project that arise because there is no further funding coming from the funding agency; and/or any penalties that may be assessed at the discretion of the funding agency.

3.0 I understand that this voluntary disclosure means that this procedure, and accepting funding, is optional. Failing to abide by the funding agreement requirements, the UofA procedure and the 2011 NIH Regulations from the underlying funding source may result in loss of funding or withholding final disbursement of funds.

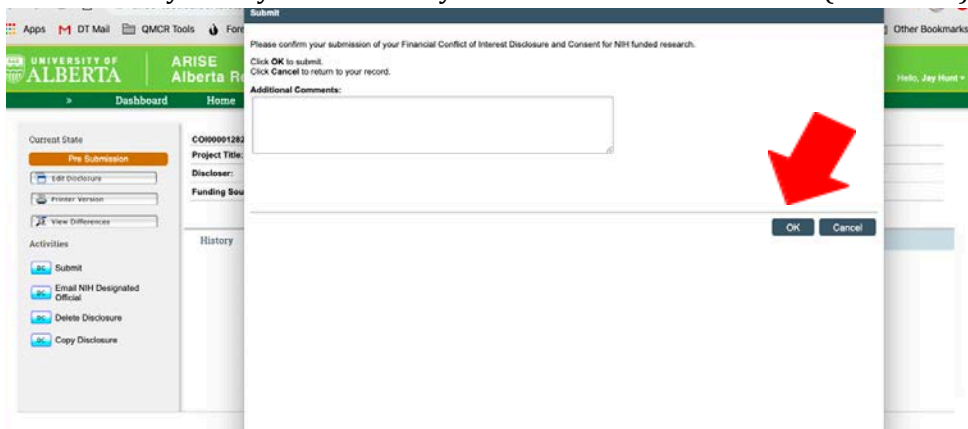
Consents may be revoked at any time by so indicating in writing to the Designated Official.

Continue

16. Pre-submission page: Once you complete the disclosure, you arrive on the newly created page for your project. Here you can see the project title, the RES number, the funding source and other information. You can also see in the left column that the disclosure for this project is in 'Pre-submission'(orange). **In order to submit this disclosure to the NIH Designated Official, click 'Submit' (red arrow).** Also note the blue arrow, for multiple disclosures. You can copy a disclosure and then edit the project information to keep multiple SFIs on different project disclosures (see the "How to copy a COI" Tipsheet).



17. Submission Pop-up: A pop-up window that appears that provides the option to include any details that you may feel necessary and then click 'OK' to submit (red arrow).



18. Submitted disclosures: The disclosure is submitted because you can see 'In Review' in orange on the left (green arrow) and the history log tab displays 'Submit Disclosure' (red arrow) as an activity that has occurred, including a date, time and author. If you need to communicate further with the NIH Designated Official, you can click on the 'Email NIH Designated Official' in the left column (blue arrow).

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Dashboard Home

Current State: **In Review** | CO00001282

Project Title: Vitamin D and colon cancer
Discloser: Jay Hunt
Funding Source: American Cancer Society
RES #: RE600123456
Approved Date:

View Disclosure
Printer Version
View Differences

Activities

Change Log

Activity	Author	Activity Date
Submit Disclosure	Hunt, Jay	1/24/2020 4:01 PM

The new disclosure is created and submitted.