Annual Renewals for Financial Conflict of Interest (COI) Disclosures

- 1. Navigate to ARISE at <u>https://arise.ualberta.ca/</u> 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).

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3. Once in your personal ARISE page, you will see a COI (Conflict of Interest) tab (red arrow), click here. This is where you can see previously disclosed projects and renew any significant financial interests (SFIs). If you don't see a COI tab, please contact nih@ualberta.ca

| ALBERTA | ARISE Alberta Research | Information S | Services | | | Hello, Jay Hunt ▼ |
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| » Dashboard | Home | | | | | |
| Applicant My Roles Applicant Mew Human Study Hew Animal Study Hew FCOI Disclosure New Incident Report New Incident Report Activity Newsfeed | Page for Jay . Inbox - Items appear . General - Link to your Inbox Human Displays all items which re- Human | r Hunt ng in this tai profile manage Animal CC quire action by the study te | offician to move an application to move an application of the second sec | ion form through the i Templates e information. | review process. General | |
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4. Clicking on the COI tab brings you to your Conflict of Interest home page. You should see any previously disclosed projects in the COI section. Click to select the project you wish to renew (red arrow) from the COI Section (top listing). You can also identify projects that require a disclosure by the state of "Disclosure Pending". Do not the Amendments or Renewals sections below (they will not contain the 'Create Renewal' link needed in the following steps).

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5. This opens the project page. Click on the "Create Renewal" button (red arrow) in the left column to start your renewal.

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|----------------------------------|-------------------------------|--|---|--------------------------|---------------|
| Current State | COI00001269 Project Title: | Longitudinal study of gut microbiome | | | |
| | Discloser: | Jay Hunt | RES #: | RES0098989 | |
| Printer Version | Funding Sour | ce: National Institutes of Health (NIH) | Approved Date: | Friday, January 17, 2020 | |
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| 🖶 Create Amendment | DC F | PAA Opened | Hunt, Jay | 1/17/2020 12:34 PM | |
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| | Thanks for y | lo Conflict of Interest our disclosure. Based on your submission, you have no | Reviewer, John financial conflicts of interest, at this | 1/17/2020 12:27 PM | |
| | | Submit Disclosure | Hunt, Jav | 1/17/2020 12:24 PM | |

6. This opens your disclosure. The first page is the 'Acknowledgement of NIH FCOI Training Obligations". This page serves to confirm your training is kept up to date, with available links to training and policies if needed. Confirm your awareness of your responsibilities when holding or participating in NIH funded research by clicking the checkboxes (red arrow) and then click 'Continue' (blue arrow).

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| I acknowled | e and understand that I am responsible for making myself aware of and have reviewed the following relevant University Policies and procedures regarding NIH Conflict of | |
| Finan Rese 2011 | jal Conflict of Interest for NIH and Other Applicable Research Funding Sources Reporting and Assessment Procedure Inch Records Starwardhip Guidance Procedure VIH Regulations NIH Financial Conflict of Interest | |
| In particula | , I confirm that I am aware that: | |
| The e | Xass module that holds the complete initial University of Alberta NIH FCOI training course can be accessed at any time. | |
| All stu | dy team members significantly involved in the design, conduct or analysis of the NIH research need to be identified to the Designated Official (nih@ualberta.ca). | |
| Confli | t of Interest Disclosures must be completed prior to application submission and annually for the life of the project. | |
| Confli | t of Interest disclosures are done retrospectively for the previous year. | |
| Amen | iments to your disclosure must be made within 30 days for changes to your significant financial interests (SFI). | |
| The U | niversity of Alberta's definition for a conflict of interest is "a situation in which there is OR may be perceived to be a divergence between the private financial benefit or | |
| financial inte question who | rest or personal benefit of a person, family member, or an outside party, and that person's obligation to the University, such that an impartial observer might reasonably ther related actions to be taken or decisions made by the person would be influenced by consideration of the person's own interests". | |
| Any in | quiries or additional information can be found on the website or by contacting nih@ualberta.ca. | |
| Non-complia | nce with the policies and procedures described in this Acknowledgement constitutes misconduct and may be handled under the applicable University policies. | |
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7. Project Information: Edit any investigator or project information that has changed since the previous disclosure. Often the Project end date needs to be updated (blue arrow). If no information has changed, or all edits are completed, click 'Continue' (red arrow).

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8. Edit any financial information, and assure any significant financial interest (SFI) statements are reflective of your situation for the previous year (blue arrow). Click 'Continue' to proceed (red arrow).

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9. If applicable, edit any financial information for either your partner or dependents, and assure any statements are reflective of their situation(s) for the previous year (blue arrow). Names are only required if the individual answers 'yes' to any of the SFI statements. Click 'Continue' to proceed (red arrow).



10. Non-Travel SFIs: If you indicated holding a non-travel related SFI on any disclosure page (either for yourself, your spouse/partner or any dependents), you will be required to edit/disclose the details. Click on the 'Add' button (red arrow) to add a new financial interest that appeared in the previous year. This will bring up a new pop-up window. (see step 11). To edit a previously disclosed SFI, click on the name of the entity (blue arrow). This will also bring up a new pop-up window (see step 11).

If you do not need to edit any of the information, click 'Continue' and skip to step 12. If you did not have any SFIs, you will not see these pages and can skip to step 15.

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| | Sunnyside Pharmaceutical Inc | Investigator | \$10,000 - \$19,999 | stock and ownership inte | erest | | 0 |
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| | | | a commercial or for-prom e | sing (the substance is the c, part | | o mit Deagnaide Cintairy | |
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11. Pop-up non-travel SFI entries: For previously entered SFIs, update any information that has changed in the previous year (blue arrow). Once updated, click OK (red arrow). For new entries, complete the required fields, and click OK (red arrow). After you have entered all applicable SFIs, or if you have no SFIs to disclose, click 'Continue' (green arrow) on the Non-Travel SFI page (same as step 10).

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12. Travel SFIs: If you indicated holding a travel related SFI on any disclosure page (either for yourself, your spouse/partner or any dependents), you will be required to edit/disclose the details. Click on the 'Add' button (red arrow) to add a new financial interest that appeared in the previous year. This will bring up a new pop-up window. (see step 13). To edit a previously disclosed SFI, click on the name of the entity (blue arrow). This will also bring up a new pop-up window (see step 13).

If you do not need to edit any of the information, click 'Continue' and skip to step 14.

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| 3.2 17 | ivel Significant Financial | Interests | | | | | | |
| | - | | | | | | | |
| | + Add | | | | | | | |
| | Name of Entity | Owner of SFI | Purpose of Travel | Destination | Trip Start Date | Trip End Date | Total Value | |
| | Pfizer Canada | Investigator | Conference | Seattle WA | Sunday, August 16, 2020 | Thursday, August 20, 2020 | \$5,500.00 | |
| | | | | | | | | |
| | | | | | | | | |
| | ificant Financial I | nterest: | | | | | | |
| | Can include: | it reasonably appears | to be related to the Investig | ator's Institutional re | sponsibilities. | | | |
| | Publicly traded | antity: renumeration and | or equity aggregate greater tha | n \$5,000 CAD in previo | us 12 months | | | |
| | Intellectual prop Reimbursed or t | erty: aggregate income f sponsored travel; aggreg | rom payor greater than \$5,000 ate greater than \$5,000 CAD p | CAD in previous 12 mo CAD in previous 12 mo er entity in previous 12 | nths nths months *exclusions for U.S. governn | n-on company) nent, U.S. post-secondary institutions, an | d/or U.S. health science centres | |
| | Aggregate incon Aggregate sum | te from seminars, lecturi greater than \$5,000 CAE | es, service on advisory/review p) for the previous 12 months for | oanels/boards when gre r a combination of multi | ater than \$5,000 CAD per entity for I ple SFIs of the above types when fro | the previous 12 months (same U.S. exclu m a single entity | isions as above) | |
| | Note: Aggregate = su | m of SFIs of Investiga | tor + Spouse/Partner + Dep | endent Child(ren) | | | | |
| | Salary or other r | emuneration from the In | stitution | | | | | |
| | Intellectual prop Income from inv | erty assigned to the Insti estments (e.g., mutual fo | tution inds) where the Investigator do | es not control the inves | tment decisions | | | |
| | U.S. post-secon | dary institution, or U.S. h | ealth science center | us when it aggregates | ress uner po,000 GAD from the end | in the previous 12 months, or 2) any a | enount nom a 0.3. government, | |

13. Pop-up travel SFI entries: For previously entered SFIs, update any information that has changed in the previous year (blue arrow). Once updated, click OK (red arrow). For new entries, complete the required fields, and click OK (red arrow). After you have entered all applicable SFIs, or if you have no SFIs to disclose, click 'Continue' (green arrow) on the Travel SFI page (same table as step 12).

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| 3.2 Trave | i Significant Financial Intere | 1 | Travel S | SFI for Investigator | | |
| 3.2 | * Travel SFIs: + Add | | 1.0 | * Name of entity (sponsor or organization): | | |
| | Name of Entity O | | | Prizer Canada | - 1 | |
| | Pfizer Canada Im | | 2.0 | * Holder of SFI entity: Investigator | | |
| | | | 3.0 | * Purpose of Travel: Conference | | |
| | Significant Financial Interes | : | | | _ | |
| | A financial interest that reas | > | 4.0 | * Destination: | _ | |
| | Can include: | | | | _ | |
| | Publicly traded entity: n Non-publicly traded ent | t. | 5.0 | * Trip start date: | _ | |
| | Intellectual property: ag Reimbursed or sponsor | 9 | | Sunday, August 16, 2020 | _ | |
| | Aggregate sum greater | 2 | 6.0 | * Trip end date: | _ | |
| | Note: Aggregate = sum of S | F | | Thursday, August 20, 2020 | - 1 | |
| | Exclusions: Salary or other remune Intellectual property as: Income from investmen | e h | 7.0 | Total monetary value (CAD) – include airfare, meals, transfers, hotels, etc. | | |
| | Income from seminars, U.S. post-secondary in | le t | | \$5,500.00 | - 1 | |
| | Ownership interest in the ownership interest in the ownership interest. | e | | Value cannot be determined | | |
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14. 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. If you did not have any SFIs to disclose, you will not see this page. Click 'Continue' (red arrow) when complete.

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| | 3.3 SFI 0 | commentary | | | | | | | |
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15. 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 (red arrows). Then click 'Continue'. These consents must be collected for every disclosure.

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| 4.1 Consent | or Collection and Disclosu | re of Personal Inform | ation (for co | ompliance with the Province | of Alberta Fre | eedom of Information and Protection of Pri | vacy [FOIPP] Act). |
| -c In | onsent for collection of per dicate your agreement with the | sonal information: e statement by checki | ng the box | | | | |
| |] I understand that the perso | nal information provid | ed herein is d | collected under the authority o | Section 33(c) | of Alberta's Freedom of Information and Prot | ection of |
| Pr m de | wacy Act for authorized purpo ay be disclosed to academic a tails on the use and disclosur | oses including adminis and administrative unit e of this information, p | tration of em s according t lease contac | ployment and research record o University policy, and report t the Designated Official at 78 | s and will be p ng requiremen 0-289-4890. | rotected under Part 2 of that Act. Personal inf tts to NIH or other funding sources, as require | ormation d. For |
| 2. In | onsent for disclosure of pe dicate your agreement with th | rsonal information: e statements by check | king the corre | sponding boxes | | | |
| |) I voluntarily authorize the l | Iniversity's Designated | d Official to di | sclose all information relating | to the presenc | e or absence of any significant financial intere | sts (SFIs) |
| di (h As | closed herein, to National Inst tps://policiesonline.ualberta.c sessment-Procedure.pdf) an | stitutes of Health (NIH) a/PoliciesProcedures/ d 45 CFR Part 94. | for the purp Procedures/I | ose of compliance with the Un Financial-Conflict-of-Interest-fo | ted States reg r-NIH-and-Oth | ulations 42 CFR Part 50 Subpart F er-Applicable-Research-Funding-Sources-Re | porting-and- |
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| VC CC | luntarily authorize the Univer llected on this form pertaining | sity's Designated Offic to that Financial Con | ial to declare flict of Interes | such information to the NIH/C at on a public website or release | ther Funding S e it in respons | Sponsor, as applicable, and to post any or all e to a written request, pursuant to the Proced | nformation ure. |
| | I understand that as UofA/ | AHS employee with fu | nding via the | se entities, PIs and their study | staff are not re | equired to sign or disclose information for othe | r |
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| <u>1</u> | is permission will exist from t | he time this record is a | submitted to t | he end-date of the award plus | 3 years. | | |

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

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| 5.1 Acknowledgement Regard | ing Revocation of Consent to Disc | lose | | | | |
| I acknowledge of Health (NIH). In s acknowledge that the | that, at any time, I may notify the De uch event, or in any other event that e University of Alberta must notify the | signated Official my consent (or t applicable fundi | that I no longer wish t he consent of my spound | apply and/or se/partner or d Funding Spon | work on a research project funded by Nal ependent child[ren]) for disclosure is revo sor, or in the case of a sub-contract in, th | ional Institutes oked, I e prime |
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| Concepto may be source | lod at any time by an indication in wa | iting to the Deal | apated Official | | | |

17. Pre-submission page: Once you complete the renewal entry, you arrive at the renewal page. 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, where you may communicate with the Designated Official through the ARISE system, if you choose.

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| irrent State | COI00001269_R | EN2 | | | | |
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| Edit Disclosure | Discloser: | Jay Hunt | | RES #: | RES0098989 | |
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| Official | • | | | | | |
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18. 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' (red arrow) to submit.

| ALBERTA | ARISE Alberta P | Execute "Submit" on COl00001269_REN2 | Hello, Jay Hunt + |
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| Current State Pre Submission C Edit Disclosure Printer Version C View Differences Activities C Submit C Copy Disclosure C Copy Disclosure | COl0000124 Project Title Discloser: Funding So History | Submit Please confirm your submission of your Financial Conflict of Interest Disclosure and Consent for NIH funded research. Click OK to submit. Click Cancel to return to your record. Additional Comments: OK Cancel OK Cancel | |

19. Submitted Renewal disclosures: The disclosure is submitted because you can see 'In Review' in orange on the left and the history log tab displays 'Submit Disclosure' 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.

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End of Instructions