

Office of the Vice Provost for Research

Special Disclosure Process for PHS-funded Projects—How to submit a PHS Financial Interests and Travel Statement (PHS-FITS)

Prior to participating in research that will be funded by the Public Health Service (PHS), Penn’s FCOI Policy requires Investigators (the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research) to submit a PHS – FITS to their Schools.

PHS-FITS Overview. You are being asked to complete a disclosure of Significant Financial Interests (SFIs) and Travel in PHS-FITS because you have been identified as an Investigator for one or more proposals funded or to be funded by the PHS. PHS-FITS can be accessed at is:








<https://phsfits.apps.upenn.edu/phsFits/jsp/fast2.do?fastStart=investigator&bhcp=1>

You must also complete a separate Grant Relatedness Assessment for each PHS award and each PHS proposal that likely will be funded in the near future.

All Investigators must submit disclosures in PHS-FITS, even if they have no SFIs or Travel to report.

Before you log in to PHS-FITS, you should have information available about your extramural activities and investments for the past 12 months that derive from your professional standing or field of discipline at Penn. These may include equity interests, payments for consulting or other services, IP interests and fiduciary responsibilities. You should also have information available about reimbursed travel and travel that was paid on your behalf for the past 12 months.

Technology Tips. Icons and buttons used in this program

	Allows you to add additional entries
<input type="checkbox"/> None	Select this box, if applicable
	Edit
	Delete
	Financial Interest elimination date calendar
	Validation error. Click or hover over for specific action required.
	Show questions and answers
	Hide questions and answers

FIRST TIME USERS:

Process for Submission of SFIs. When you log in to PHS-FITS, you are at the Financial Interests page which asks about your SFIs, regardless of their relatedness to a particular PHS grant.

Read the “Do Include” and “Do Not Include” bullet points.

Questions 1-4 all require a response. Click the box next to “None” if applicable.

Question 1 (Equity + Payments from public companies) - Only list a company if the combination of payments + equity is > \$5,000. You do not have to disclose every stock - only stock in companies that you know conduct or plan to conduct business related to your field of discipline (Example – If you are a dermatologist and you hold stock in X Company which you know makes a drug for a skin disorder, you should disclose. If you hold stock in a utility company, you need not disclose).

Question 2 (Payments from outside entities) - List any entities not listed under Question 1 from which you receive payments > \$5,000. You may have disclosed such relationships in your School's annual extramural report and typically would have received a 1099 from each entity.

Question 3 (Equity in private companies) - You only must disclose equity held in your own name and not your inventor's share of the equity pool held by Penn per the University's Patent Policy.

Question 4 (IP not assigned to Penn) - Do not provide \$ received – just describe the IP.

Save your answers by clicking "Submit/Certify" or clear your answers and start over by clicking "Clear."

Process for Submission of Travel. You are required to list travel within the past 12 months regardless of its value, and even if you have not reported any SFIs under the Financial Interests page. If you have no travel to report, click "None. (I have no reimbursed or sponsored travel to report.)"

Read the "Do Not List" bullet points.

You may aggregate travel if sponsored by the same entity for the same purpose and same destination. Otherwise, each trip must be entered on its own line.

For Destination, you do not need to list travel within the Philadelphia metropolitan area.

Save your answers by clicking "Submit/Certify" or clear your answers and start over by clicking "Clear."

You will be asked whether you wish to complete a Grant Relatedness Assessment for any PHS award that is funded or will be funded in the near future. Otherwise, you may log out of PHS-FITS.

Process for Submission of Grant Relatedness Assessments

You must submit a separate Grant Relatedness Assessment for each PHS award and each PHS proposal that likely will be funded in the near future. You do not need to submit a Grant Relatedness Assessment on proposals that are unlikely to be funded (but you still must have an up to date disclosure of your SFIs and Travel at the time of proposal submission). You only need to submit one Grant Relatedness Assessment for each grant which only requires updating for a change in circumstances (see Update Requirements, below).

Enter your 8-digit ORS Institution # and click "Find." The information for this grant will populate and 5 questions will appear. If you do not know the correct institution number, check with your Business Administrator.

Answer questions 1-5 as they apply to a particular grant. All questions require a response.

Questions 1-2 (related to entities listed under the Financial Interests page) - By clicking Yes to questions 1 or 2, you can view the entities you identified.

Question 3 (Fiduciary role) - You may identify a company, even if not listed under the Financial Interests page.

Question 4 (IP not assigned to Penn) - Only check Yes if you received any payments during the last 12 months.

Question 5 (Clinical Trial IP) - Check Yes if this research is a Clinical Trial (any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes) and you are an inventor or otherwise have a

financial interest in the IP that is a focus of this research, regardless of whether it has been licensed and even if owned by Penn.

You may “Save as Draft” and complete at another time. Otherwise, certify your answers by clicking “Submit/Certify.” You will now see a “submission date” for this grant in the list of grants.

If you wish to submit Grant Relatedness Assessments for additional grants, click “New Grant” highlighted in yellow. Otherwise, you may log out.

RETURN USERS: When you log in, you are at the Financial Interests tab.

If you wish to complete a Grant Relatedness Assessment for a specific awarded grant or one that is likely to be funded in the near future, you must first re-certify or update your Financial Interests for the past 12 months and click “Submit/Certify.” Next, you must re-certify or update your Travel (under the Sponsored Travel tab) to reflect the past 12 months and click “Submit/Certify.” Then click the Grant Relatedness tab.

To delete a financial interest, click on the “FI elimination date” calendar icon. Do not delete any currently held equity or any entity from which you received payments within the past 12 months.

What happens after submission of my Grant Relatedness Assessment? You will receive an email from your School’s FCOI officer if additional information or action is required, if you must submit a more specific disclosure to the Office of the Vice Provost for Research in FIDES, or if no further action is required.

Update Requirements.

New SFIs. You must update your SFIs within 30 days of discovering or acquiring a new SFI not previously reported in PHS-FITS. You also must update all your Grant Relatedness Assessments for all awarded grants to assess possible relatedness of each grant to this new SFI.

Change in Relatedness. If a previously reported SFI that was unrelated to one or more grants becomes related, you must update your Grants Relatedness Assessment(s) for the relevant grant(s). For example, if you reported payments from GSK that were unrelated to any grant and now GSK is providing a study drug for one grant, you must update your Grant Relatedness Assessment for that grant.

New PHS proposals / awards (including transfer of a grant from another institution to Penn). You must update / re-certify your SFIs and Travel and then complete a Grant Relatedness Assessment for every PHS award or proposal likely to be funded in the near future.

Annual Certification of SFIs and Travel in PHS-FITS

If you are an Investigator participating in PHS-funded research, you must annually recertify the accuracy of your Financial Interests and Travel in PHS-FITS. You must do this regardless of when you last disclosed and even if you have no financial interests or travel to report. **You do not need to recertify any Grant Relatedness Assessments unless you add a new Financial Interest** (See #8 below).

If you receive a notice that your annual certification is due, please log in to PHS-FITS at

<https://phsfits.apps.upenn.edu/phsFits/jsp/fast2.do?fastStart=investigator&bhcp=1>

Once you have logged in, please follow the directions below.

1) Click on the Financial Interests tab and review your responses to the 4 questions.

- 2) If there is no change, click Submit/Certify and OK.
- 3) If you have a new financial interest that requires disclosure (see, “Do and Do not include” instructions on the page):
 - a) If you previously checked “None” for that question, uncheck the “None” box and complete the box / boxes next to the “Add More” icon in the space provided.
 - b) If you already have one or more financial interests listed for a question, click on “Add more” and add the new financial interest in the space provided.
- 4) If you wish to eliminate a financial interest, choose the date eliminated using the calendar icon under “FI elimination date.”
- 5) Click “Submit/ Certify” and “OK.”
- 6) Click on the Sponsored Travel tab.
 - a) If you have no new travel that requires reporting (travel within past 12 months not previously listed), click “Submit/Certify” and “OK.”
 - b) If you have new travel to report, uncheck the “None” box (if “None” was previously checked) and enter the travel in the space next to “Add more” or if there is already travel listed, click “Add more” and add new Travel.
 - c) If you want to remove travel that occurred over 12 months ago, click the Edit icon and then change the Trips # and Total days # as appropriate (e.g. 0 / 0 if all trips were greater than 12 months ago). You may also make an entry in the Comments section (e.g. travel > 12 months old).
- 7) Click “Submit/ Certify” and “OK.”

You have completed your annual certification of Financial Interests and Travel. If you have not added a new financial interest, you may log out. **DO NOT CLICK ON THE GRANT RELATEDNESS TAB.**

- 8) **If you have added a new Financial Interest**, you have 2 options:
 - a) Click on the Grant Relatedness tab now to update your Assessment of Relatedness for each of your awarded grants, or
 - b) Wait until you receive an email requesting that you update your Assessment of Relatedness for the grants listed in the email. Then log in to PHS-FITS and click on the Grant Relatedness tab.

Instructions for Updating Grant Relatedness

- Click on the edit icon for the first grant listed in the email.
- Review your responses to the 5 questions as they apply to each of your disclosed financial interests, including the new financial interest.
- If no changes to your responses are required, click Submit/ Certify and OK. Otherwise, make any required changes and then click Submit/ Certify and OK.
- Repeat the above for each grant listed in the email.
- Click logout.

Other event triggers for completion of PHS-FITS:

- At time of IRB protocol submission if PHS-funded if a Grant Relatedness Assessment was not previously submitted for this grant
- Upon being added as an Investigator to an ongoing project
- As required in any communication from the Office of the Vice Provost for Research, your School, or the University

Other things to know about PHS-FITS

- By hovering your mouse over some of the headings, you can see further guidance regarding answering questions.
- To delete an erroneous entry after you have submitted your SFIs, you must click the edit icon next to the erroneous entry and indicate the date eliminated (e.g., the same date as you entered the interest) using the calendar in the FI elimination date column.

Please contact Richard Shellenberger, FCOI Program Coordinator, at (215) 898-3603 or by e-mail at phs@exchange.upenn.edu for any questions.