

SOP#: RPS-14

Submission of the Personal Financial Holdings Form to the Institute/Center Deputy Ethics Counselor

Version #: 2.0

Next Review Date: 07/2022

Approved Date: 07/2020

Review Interval Period: Biennial

NCI Clinical Director Signature:

POLICY

Assessment of financial conflict of interest is required for all clinical research protocols that may lead to the financial benefit or loss of any individual or entity. All staff involved in a research study are required to disclose financial and other conflicts of interest per NIH policy

PURPOSE

To identify the process for submitting the Personal Financial Holdings (PFH) form via iRIS to the Deputy Ethics Counselor (DEC) for review. This process is performed by the Protocol Support Office (PSO) manager assigned to the protocol.

RESOURCE

NIH Office of Intramural Research Policies [website](#)

Active HRPP Policies (SOPs)

- SOP 21 - *Conflict of Interest Requirements for Researchers and Research Staff*

PROCEDURES

STEP 1: Preparation Prior to Submitting Personal Financial Holdings (PFH) Form

- Review NIH SOP 21 noted above prior to submission of the PFH form to the Institute Deputy Ethics Counselor (DEC) office of the protocol Principal Investigator (PI) or NIH Ethics Office (NEO), if applicable.
- Confirm with the PI if the protocol is “covered” under this SOP.
- Confirm with the PI the “covered” Key Study Personnel (KSP) that will be participating in the protocol.
- Send the Conflict of Interest (COI) guide to all individuals serving as KSP on the protocol via the study correspondence in iRIS or email (if via email, save the email in the study working file).
- Send the COI Certification document NIH SOP 21, Appendix E: “Conflict of Interest (COI) for NIH Employees Who Do Not File Financial Disclosure Forms 717 or 450” to Key Study Personnel who are serving in covered roles but do not file financial disclosure forms. This form is generally used for staff with a classification of “Fellow” in NIH Enterprise Directory (NED).

- Send the COI Certification document NIH SOP 21 Appendix F: “Conflict of Interest (COI) Certification for Non-Federal Employees” to non-NIH employees serving in covered roles on the protocol. Note that on this form all individuals MUST sign the top signature line. Any individuals who are employees of an institution which has its own COI policy should also sign the second line.
- Non-NIH federal employees (e.g., FDA, Walter Reed) do not need to sign a COI form, as they are cleared by their own agency.

STEP 2: Personal Financial Holdings Submission for Initial Review

- Complete the required fields in the study application in iRIS.
- Complete the “DEC Clearance Submission Form” in iRIS. This is the iRIS name for the Personal Financial Holdings Form.
- Attach the KSP list, the study application and the COI certification forms, if applicable.
- Submit the form for DEC review. The DEC form does not require PI signature for submission.
- You will receive the DEC Clearance back via iRIS from the DEC. Attach this document to the IRB submission in iRIS and update the “Initial Review Submission Form” with the DEC approval date.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.

STEP 3: Personal Financial Holdings Submission for Amendments

- Any amendment involving the addition of or modification to any covered personnel on a covered protocol, a change in role of an individual from a non-covered to a covered role, any changes related to the use of commercial products, or any change to an IND/IDE requires the submission of the PFH to the DEC for review. Confirm changes with the PI.

Note: If you are only removing a KSP, a DEC review is not required.

- Send the COI guide to new individuals being added as KSP on the protocol via the study correspondence in iRIS or email (if via email, save the email in the study working file).
- Obtain COI Certification, if applicable, from new KSP who do not file financial disclosure forms and/or from non-NIH employees serving in covered roles, as described above in Step 1.
- Attach the KSP list, the study application and the certification forms, if applicable.
- If you are submitting a PFH to the DEC for a combined Continuing Review (CR) and amendment, you will need to:
 - Create a new DEC clearance form in iRIS.
 - Click on “add investigator” to navigate to the screen where you indicate the individuals you are adding/removing
 - Include the individuals you are adding/removing
- Submit the form for DEC review. The DEC form does not require PI signature for submission.

- You will receive the DEC Clearance back via iRIS from the DEC. Attach this document to the IRB submission in iRIS.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.

STEP 4: Personal Financial Holdings Submission for Continuing Review (CR)

- Submit the DEC Clearance request at the same time as the request for CR information is sent to the study team, as DEC clearance could delay CR approval.
- Check that current KSP list matches the list of Key Study Personnel in iRIS.

Note: If you need to remove someone in order for the DEC to be cleared (e.g., staff member is no longer at the institution), you will need to submit a concurrent amendment to the KSP. Review the amended KSP list with the PI. Also, remember to check the box for “CR/Amendment/KSP” on the type of action on the DEC Clearance submission form.

- Complete DEC Clearance submission form in iRIS and include copy of KSP list and the study application
- Submit the form for DEC review. The DEC form does not require PI signature for submission.
- You will receive the DEC Clearance back via iRIS from the DEC. Attach this document to the IRB submission in iRIS and update the “Progress Report Form” with the DEC approval date.

Note: All actions must have DEC clearance, if applicable, included at the time of submission to the IRB.