



Purpose: An established business process around Financial Conflict of Interest (fCOI) is necessary in order to ensure compliance with revised [NIH fCOI guidelines](#) and the [University's fCOI policy](#). Because financial conflicts of interest may corrode the school and the University's reputation and thus erode confidence in the University and diminish its trustworthiness and stature, the school must ensure that faculty are made aware of such conflicts and are dutiful in reporting them. Reported conflicts must receive scrupulous attention and management.

Guidelines & Considerations:

- a) **Annual Certification:** All persons holding faculty and academic appointments at the school are responsible for filing an annual disclosure and certification of their financial interests and related outside activities. This process is administered by the [Office of Faculty Affairs](#). Investigators are also advised to review the [HSPH Implementation Plan for the Harvard University Policy on Individual Financial Conflict of Interest for Persons Holding Faculty and Teaching Appointments](#).
- b) **Requirements at Proposal Stage:** Each Investigator who is planning to participate in PHS+ funded research as well as faculty and academic appointees for non-PHS+ funded research *must* disclose to SPH's designated official their significant financial interests (and those of their spouse and dependent children) no later than the date of submission of the Institution's proposal for funded research.
- c) **Requirements at Award Stage:** Prior to expenditure of any funds under a PHS+ sponsored research project, the designated official will determine whether an Investigator has any significant financial interests related to the funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that will specify the actions that have and will be taken to manage such financial conflict of interest. In addition, all Investigators must have completed fCOI training. For non PHS+ sponsored research projects, all faculty and academic appointees must have an updated disclosure on file.

Key Definitions

Investigator means the **project director or principal Investigator** and **any other person**, regardless of title or position, **who is responsible for the design**, conduct, or reporting of research funded or proposed for funding by the NSF or any agency that follows 42 CFR Part 50, Subpart F (see the updated listing at the FDP fCOI link, above). This may include, for example, **collaborators or consultants**.

For the definition of *Significant financial interest*, please refer to the [HSPH Implementation Plan for the Harvard University Policy on Individual Financial Conflict of Interest for Persons Holding Faculty and Teaching Appointments](#).

PHS+ refers to all PHS agencies (NIH, CDC, HRSA, etc.) plus NSF and others that use PHS regulations including American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation and Alliance for Lupus Research. For a complete list, visit this [link](#).



Business Process –Financial Conflict of Interest (fCOI)

Standards of Service:

- *Investigators* must update their annual certifications within 30 days of a new financial interest arising and must complete training prior to engaging in sponsored research.
- Collaborators and subcontractors must report any financial conflicts of interest to SPH prior to signing the subcontract agreement or within 30 days of identification.
- SPH must provide fCOI reports to PHS regarding all financial conflicts of interest of all investigators and subrecipient *Investigators* prior to the expenditure of funds and within 60 days of any subsequently identified fCOI.
- PHS *investigators* **only** must disclose the occurrence of travel related to their institutional responsibilities and paid for by anyone other than government agencies, higher institutions or hospitals within 30 days of travel.

Process Steps

Step	Role	Task/Activity
PROPOSAL STAGE		
1	PI	Identifies funding opportunity and determines which personnel are PHS+ <i>Investigators</i> .
2	GM	Enters proposal into GMAS and populates research team including PHS+ <i>Investigators</i> .
4	Automated (no action)	Generates fCOI approvals for all PHS+ <i>Investigators</i> and HU faculty. HU <i>Investigators and faculty/academic appointees</i> not already in annual fCOI system are automatically added to the system. fCOI status is fed to GMAS.
5	Automated (no action)	An email is sent to <i>Investigators</i> who have already filed their annual report notifying them to update it if applicable. Those who have not filed are notified to complete it. The date of the last filed fCOI disclosure & approval status is exported automatically to GMAS from Annual fCOI system.
6	<i>Investigators</i>	<i>Investigators and faculty/academic appointees</i> on grant update or complete fCOI disclosure in annual system.
7	GM	For non Harvard Personnel listed as <i>Investigators</i> , requests they complete an fCOI form and that they read the training document . Saves completed forms in S drive. OR if non HU <i>investigators</i> are part of a subcontract and they have their own policy (but non FDP), request they complete this form and upload to the GMAS request repository in a COI folder. If they are part of the FDP Clearinghouse , makes a note in the comments section of the request "X institution part of FDP Clearinghouse".
8	GM	Confirms all <i>Investigators/faculty & academic appointees</i> have an updated annual disclosure on file prior to submitting the proposal to SPA for review.
9	SRA	Reviews that all <i>Investigators/faculty & academic appointees</i> on grant have an updated fCOI disclosure on file. If complete, finalizes proposal review.
10	AD	Submits/signs proposal.



Business Process –Financial Conflict of Interest (fCOI)

AWARD STAGE		
11	OPS	Receives notice from sponsor in response to request for funding. If not funded, update request status to not funded and end here. If funded, logs notice of award.
12	Automated (no action)	Department Administrator role in GMAS receives a to-do and e-mail when the award notice is logged notifying them that the research team needs to be confirmed.
13	GM	Verifies research team in GMAS accurately reflects <i>Investigators</i> on project and confirms TBD <i>Investigators</i> if applicable.
14	GM	Confirm research team via request home screen in GMAS using <Confirm research team> button. Hit button and then it will allow you to edit.
15	Automated (no action)	New HU <i>Investigators/faculty & academic appointees</i> automatically added to annual fCOI reporting system and notified via email to complete disclosure. Existing <i>Investigators/faculty & academic appointees</i> e-mailed to update their disclosures.
16	<i>Investigators</i>	Enters or updates disclosures.
17	Automated (no action)	GMAS updated with fCOI approval statuses based on annual fCOI system. Sends e-mail or report to SPH DIO with approvals in “needs review” status. NOTE: for non competing continuations, SRA must request review be done because e-mails will not be generated automatically from GMAS.
18	SPH DIO	Reviews fCOI reports with status “needs review” alongside grant info in GMAS (including non Harvard <i>investigators</i> if applicable).
19	SPH DIO	If no conflict is determined, flips fCOI report status to “No Conflict” in annual system. If conflict is determined, discusses with <i>Investigator</i> ways to eliminate, reduce or manage conflict.
20	SPH DIO	Notifies sponsor of conflict and actions taken to reduce, eliminate, or manage.
21	SPH DIO	Flips fCOI report status to “Eliminated”, “Reduced”, or “Managed” and logs notes and management plan in annual system.
22	Automated (no action)	Status of most recent fCOI disclosure exported automatically to GMAS from Annual system.
23	SRA	Reviews approvals prior to award setup. Ensures <i>Investigators</i> have completed training by checking training list on shared drive.
24	SRA	Proceeds to account setup/agreement with sponsor signed.
25	SRA	For subcontractors that do not have their own fCOI policy, ensure subagreement contains appropriate fCOI language.
POST AWARD		
26	GM	During the course of the project, updates GMAS research team with any new <i>Investigators</i> that join project and ensures disclosures are complete and any fCOI managed prior to commencement of work on the project. Research team is edited from the Segment Home <Research Staff> section.



Harvard School of Public Health

08/25/16

Research Administration

08/24/12

Business Process –Financial Conflict of Interest (fCOI)

Revised:

Effective:

27	Investigators	During the course of the project, PHS <i>investigators</i> only must disclose the occurrence of travel related to their institutional responsibilities and paid for by anyone other than government agencies, higher institutions or hospitals. The disclosure is completed within a module of the annual fCOI reporting system and must be done within 30 days of travel. Travel disclosures must be done prior to proposal submission and then regularly as needed after that. Threshold of \$5,000 per calendar year per entity.
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Business Process –Financial Conflict of Interest (fCOI)

Language in GMAS fCOI e-mails:

Trigger	Sent to	Subject	Body of Text
Generation of COI approval for FCOI participant research team member	Research team member	Action Required: Submit/Update Conflict of Interest Disclosure for Proposal Submission	<p>You have been added to the research team for project <X>. the PI of this project is <X>. Please go to the <link for 'Financial Conflict of Interest System'> to a) review and update your disclosure or b) create and submit your annual disclosure. If you have already submitted your Financial Conflict of Interest disclosure and have no updates to make, no additional action is needed for this project. University policy and/or federal regulation require that you complete a financial interest disclosure prior to submitting a proposal for sponsored funding and at least annually. You must update that disclosure within 30 days of acquiring any new significant financial interest and you should immediately disclose to your School's designated institutional official if you believe that a new or previously disclosed financial interest may conflict with your proposed research. If you receive funding subject to the 2011 PHS Regulations, you must also disclose the occurrence of any sponsored/reimbursed travel not reimbursed through the University or by another U.S.-based higher education institution or by the federal, state, or local government. If you have any questions or concerns please contact your School's "Designated Institutional Official" <link> for guidance.</p> <p>Failure to complete a disclosure of your financial interests in a timely manner may delay or prevent submission.</p>
Generation of COI approval for non-FCOI participant research team member with HUID	Research team member	Action Required: Submit/Update Conflict of Interest Disclosure for Proposal Submission	<p>You have been added to the research team for project: <X>, the PI of this project is <X>. Please submit (if you have not already uploaded/submitted with proposal to a SPA representative) your Conflict of Interest Disclosure Statement. If you have already submitted your Financial Conflict of Interest disclosure and have no updates to make, no additional action is needed for this project.</p> <p>HMS Investigators</p> <p>If your project is submitted through HMS, you must upload/submit your COI Disclosure Statement to SPA which requires you to go to the Outside Activity Reporting System (link) and update or report your outside activities and go to CITI <link> and complete the required training* (if grant proposal is subject to PHS regulations). Failure to complete 1) the COI Disclosure Statement (including updating the Outside Activity System with new financial interests including the occurrence of sponsored/reimbursed travel) and 2) the required training (for grants subject to PHS only) in a timely manner will hold up funding. *Training only needs to be completed once every four years or immediately if 1) the institution</p>



Business Process –Financial Conflict of Interest (fCOI)

			<p>changes the policies in such a way that changes your reporting obligations, 2) you are new to the institution, or 3) you are not in compliance with the PHS regulations or a management plan promulgated under those regulations.</p> <p>All other Investigators Submit your disclosures in accordance with your School's submission process. If you are not aware of the process to submit your disclosure, please contact your Central Sponsored Administrator or Designated Institutional Officer" (link)</p> <p>Policy University policy and/or federal regulation require that you complete a financial interest disclosure prior to submitting a proposal for sponsored funding and at least annually. You must update that disclosure within 30 days of acquiring any new significant financial interest and you should immediately disclose to your School's designated institutional official if you believe that a new or previously disclosed financial interest may conflict with your proposed research. If you receive funding subject to the 2011 PHS Regulations, you must also disclose the occurrence of any sponsored/reimbursed travel not reimbursed through the University or by another U.S.-based higher education institution or by the federal, state, or local government.</p> <p>Failure to complete a disclosure of your financial interests in a timely manner may delay or prevent submission</p>
<p>Research team is confirmed and research team member is an FCOI participant with COI approval status = No Disclosure</p>	<p>Research team member</p>	<p>Action Required: Submit Conflict of Interest Disclosure to Prevent Delay in Funding</p>	<p>You are on the research team for <X >, the PI of this project is <X >, which and it has been awarded. Before Harvard can accept this award, you must enter a disclosure of financial interests at <insert link titled 'Financial Conflict of Interest system' pointing to FCOI system>. School DIO must review and assign an appropriate status prior to an account string being established.</p> <p>Failure to complete a disclosure will prevent account setup and allowability of costs.</p> <p>University policy and/or federal regulation require that you complete a financial interest disclosure prior to submitting a proposal for sponsored funding and at least annually. You must update that disclosure within 30 days of acquiring any new significant financial interest and you should immediately disclose to your School's designated institutional official if you believe that a new or previously disclosed financial interest may conflict with your proposed research. If you receive funding subject to the 2011 PHS Regulations, you must also disclose the occurrence of any sponsored/reimbursed travel not reimbursed through the University or by another U.S.-</p>



Business Process –Financial Conflict of Interest (fCOI)

			based higher education institution or by the federal, state, or local government.
Research team is confirmed and research team member is an FCOI participant with COI approval status != No Disclosure	Research team member	Action Required: Review Conflict of Interest Disclosure	<p>You are on the research team for <X>, the PI of this project is <X>, and it has been awarded.</p> <p>If there are any changes needed to your previously submitted Financial Conflict of Interest disclosure in the <insert link titled 'Financial Conflict of Interest system' pointing to FCOI system> please submit a modification to the report immediately. If you have already submitted your Financial Conflict of Interest disclosure and have no updates to make, no additional action is needed for this project. School DIO must review and assign an appropriate status prior to an account string being established. University policy and/or federal regulation require that you update your disclosure within 30 days of acquiring any new significant financial interest and you should immediately disclose to your School's designated institutional official if you believe that a new or previously disclosed financial interest may conflict with your research. If you receive funding subject to the 2011 PHS Regulations, you must also disclose the occurrence of any sponsored/reimbursed travel not reimbursed through the University or by another U.S.-based higher education institution or by the federal, state, or local government.</p> <p>Failure to complete a disclosure will prevent account setup and allowability of costs.</p>
Research team is confirmed and research team member is not an FCOI participant with a HUID	Research team member	Action Required: Submit/Update Conflict of Interest Disclosure	<p>You are on the research team for <insert project name>, the PI of this project is <insert PI first name last name>, and it has been awarded.</p> <p>Before Harvard can accept this award, you must update or file your Conflict of Interest disclosures / Outside Activity Report. If you have already submitted your Financial Conflict of Interest disclosure and have no updates to make, no additional action is needed for this project.</p> <p>HMS Investigators</p> <p>If your project is being managed through HMS, you are required to update your Outside Activity Report <http://ecommons.med.harvard.edu/gopage.asp?aoa.asp> with any new significant financial interests including the occurrence of any sponsored/reimbursed travel if the award is subject to PHS regulations.</p> <p>All other Investigators</p> <p>Submit your disclosures in accordance with your School's submission process. If you are not aware of the process to submit your disclosure, please contact your Central Sponsored Administrator or Designated Institutional Officer.</p> <p>Policy</p>



Business Process –Financial Conflict of Interest (fCOI)

			<p>University policy and/or federal regulation require that you update your disclosure within 30 days of acquiring any new significant financial interest and you should immediately disclose to your School’s designated institutional official if you believe that a new or previously disclosed financial interest may conflict with your research. If you receive funding subject to the 2011 PHS Regulations, you must also disclose the occurrence of any sponsored/reimbursed travel not reimbursed through the University or by another U.S.-based higher education institution or by the federal, state, or local government.</p> <p>Failure to complete a disclosure will prevent account setup and allowability of costs.</p>
<p>Research team is confirmed and any research team members have an approval status = Needs Review</p>	<p>COI Administrator</p>	<p>Action Required: Review COI Disclosure(s) for <ProjectTitle></p>	<p>Harvard has received notice that <X > has been awarded. Please review the disclosures of the following research team members. <List Research Team Member Name for research team members whose COI Approvals are in "Needs Review" status></p> <p>Failure to complete a review will prevent account setup and allowability of costs.</p>
<p>Notice has been logged associated to IR, IR prior, CR, CR prior and segment status = pending</p>	<p>Department Administrator</p>	<p>Action Required: Confirm Research Team for <ProjectTitle></p>	<p>A notice has been logged for project <X> . The Project ID is <X> and the PI is <X>. Please confirm the Research Team is accurate. The Research Team should include all individuals who are responsible for the design, conduct, or reporting of the proposed research.</p>