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## A. Definitions

### 1. Who is an “Investigator”? Is it only the Principal Investigator?

No. An Investigator is the principal investigator (PI) or project director (PD) *and* any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding. The PI/PD, upon consideration of the individual’s role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct or reporting of the research.

All senior/key personnel, as identified in the proposal, progress report, or any other report submitted to PHS by UCLA, would be considered to be Investigators. In addition, other individuals who are not senior/key personnel but who the Principal Investigator determines have responsibility for the design, conduct or reporting of the research should be identified as Investigators.

Collaborators, consultants, and service providers (other than subrecipients or subgrantees) are not typically independently responsible for the design, conduct or reporting of the research, and as such do not meet the definition of “Investigator.” However, if the PI determines that one of these contributors does meet the definition, that collaborator, consultant or service provider will be subject to the PHS regulations.

### 2. What is the Public Health Service (PHS)?

PHS is a subdivision of the U.S. Department of Health and Human Services. It includes the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and a number of other agencies that make research awards.

See [http://rpc.research.ucla.edu/RPC/Documents/PHS\\_Agency\\_List.pdf](http://rpc.research.ucla.edu/RPC/Documents/PHS_Agency_List.pdf) for a list of PHS units.

### 3. What are “institutional responsibilities?”

For the purposes of this regulation, UC has defined “Institutional responsibilities” as teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California performed in the course and scope of the Investigator’s UC appointment/employment.

### 4. What is a “Significant Financial Interest (SFI)?”

An SFI is anything of monetary value, whether or not the value is readily ascertainable, that meets the PHS thresholds **and** that reasonably appears to be related to or is in the same field of expertise as the Investigator’s Institutional Responsibilities.

### 5. What is a “Financial Conflict of Interest (FCOI)?”

An FCOI is a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the PHS research activity.

## B. Applicability

### 1. Do these regulations apply to all awards issued by PHS agencies?

They apply to all PHS research grants, cooperative agreements, and contracts with the exception of Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications. The regulations explicitly apply to research grants, career development grants, center grants, individual fellowships, infrastructure awards, institutional training grants, program projects, research resources awards, conference grants and all NIH "S" awards, such as NIH S06 (Minority Biomedical Research Support) awards.

Awards from other federal agencies are not subject to these regulations. However, some non-governmental agencies such as the American Cancer Society and the American Heart Association require review under the PHS regulations. See [http://rpc.research.ucla.edu/RPC/Documents/PHS\\_Agency\\_List.pdf](http://rpc.research.ucla.edu/RPC/Documents/PHS_Agency_List.pdf) for a list of other research sponsors that have adopted the PHS regulations.

### 2. Do the regulations apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members) or to consultants?

Maybe. If the Principal Investigator determines the project participants meet the definition of an "Investigator" in A.1 above, the PHS regulations apply.

### 3. Are post-doctoral scholars and graduate students receiving funding from PHS subject to the regulations?

Yes. If a postdoctoral scholar or a graduate student is supported by an individual fellowship award, such as an NIH F31 or F32, or from an institutional training grant, such as an NIH T32, the regulations apply. If funding comes from another type of research award and the principal investigator of the project has determined that the postdoctoral scholar or graduate student is responsible for the design, conduct, or reporting of the research, then the definition of "Investigator" is met, so the regulations apply.

## C. Disclosure

### 1. Who is required to disclose financial interests?

All Investigators who are planning to participate in, or are participating in, PHS-funded research, are required to disclose their SFIs, and except for travel, must include the SFI of the Investigator's spouse or registered domestic partner and dependent children.

Collaborators from other institutions who are considered Investigators and who will be conducting research under a subaward issued by UCLA will be expected to comply with the policies and procedures of the institution at which they are employed.

Collaborators who will be conducting research under an Independent Consultant Agreement issued by UCLA and who the Principal Investigator identifies as Investigators must disclose their SFIs to UCLA using eDGE (see Item 3 below). Given the usual responsibilities of Independent Consultants, it is not anticipated such individuals typically will be considered Investigators.

## 2. What should be disclosed?

Investigators are required to disclose all Significant Financial Interests (SFIs) – that is, anything of monetary value that:

- Meets the PHS thresholds (see C.5 below); **and**
- Reasonably appears to be related to or is in the same field of expertise as the Investigator's institutional responsibilities (defined in A.3 above).

## 3. How do Investigators disclose SFIs at UCLA?

UCLA has developed an electronic system, the electronic Disclosure Gateway (eDGE) (see <http://edge.research.ucla.edu/>), to facilitate disclosure of all SFIs that meet the PHS definition and thresholds. This system is to be used for disclosing SFIs required under the PHS conflict of interest regulations as well as those non-governmental agencies who have adopted the PHS regulations (see [http://rpc.research.ucla.edu/RPC/Documents/PHS\\_Agency\\_List.pdf](http://rpc.research.ucla.edu/RPC/Documents/PHS_Agency_List.pdf)).

## 4. When must Investigators disclose their SFIs?

Investigators are to disclose SFIs at the following times:

- A. Initial disclosures must be made by all Investigators planning to participate in a proposed research project before the application for funding is submitted.
- B. UCLA Investigators (and collaborators who are Investigators under Independent Consultant Agreements) who are engaged in research supported by PHS or other sponsors that have adopted the PHS conflict of interest regulations have an ongoing responsibility to update their disclosures in eDGE throughout the period of research support:
  - Within 30 days of acquiring or discovering any new SFI; and
  - At least annually
- C. New Investigators must complete a disclosure of SFIs before joining an ongoing research project.

## 5. What is the PHS threshold for reporting SFIs?

SFIs are defined as follows under the PHS regulations:

- A. For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months **and** the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

*[Investigators are not required to disclose SFIs in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does*

*not directly control the investment decisions made for these investment vehicles.]*

- B. For a *non-publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds \$5,000, **or** any amount of equity interest, including, but not limited to stock, stock options, or ownership interest in the entity.

*[Investigators are not required to disclose (a) payments made by The UC Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of California; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.]*

- C. *Intellectual property rights and interests*: Income from each organization that exceeds \$5,000 during the 12 months preceding disclosure.

*[Investigators are not required to disclose royalties received from The UC Regents related to patents or copyrights.]*

- D. *Travel*: The occurrence of any sponsored or reimbursed travel, whether payment is made to the Investigator directly, or expenses paid for on behalf of the Investigator by a for-profit or non-profit organization.

*[Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.]*

## **6. What are some examples of SFIs?**

Examples of SFI include:

- A. Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization; or salary received outside of the University of California.
- B. Stock or stock options in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
- C. Receipt of income from any organization other than the UC Regents for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from prior employers and other universities.

- D. Travel reimbursements made to, or on behalf of, the Investigator, regardless of the amount, by a for-profit or nonprofit entity, *excluding* a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center, hospital or research institute.

**7. What if I acquire or discover new financial interests during the course of an award?**

Funded Investigators have an ongoing obligation to disclose SFIs throughout the period of the award and must update disclosures within 30 days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new SFI.

**8. What about payments to or assets held by my spouse or registered domestic partner, or dependent children? Must these financial interests be disclosed?**

Yes. All aggregated income received for services, equity holdings, and income received from intellectual property rights by the Investigator, his/her spouse or registered domestic partner and dependent children must be disclosed if they are related to the Investigator's institutional responsibilities and meet the PHS thresholds.

Travel payments reimbursed by or directly paid by outside entities need be made only for the Investigator.

**9. Do I need to disclose salary or other payments that I receive from the University of California?**

No. Salary, royalties, or other remuneration from The UC Regents does not need to be disclosed.

**10. Do I need to disclose all travel related to my institutional responsibilities?**

Under the PHS regulations, all travel related to the Investigator's institutional responsibilities must be disclosed if it is reimbursed by, or paid directly by a for-profit or nonprofit entity, except for a Federal, state, or local government agency, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education. Included within this exemption from reporting is travel paid for by the US Department of Energy National Laboratories, such as Sandia Labs, Los Alamos, or Lawrence Livermore.

**11. Do I have to disclose all my travel within 30 days of traveling?**

There are two options for disclosing travel:

- You may disclose travel that you anticipate taking in the next 12 months, prospectively in eDGE; or,
- If a trip was not prospectively disclosed, you must disclose it in eDGE within 30 days of the occurrence of the travel.

**12. What information regarding my travel do I need to disclose:**

A. You will be asked to identify:

- The identity of the sponsor/organizer;

- The destination – the city/state;
  - The duration – can be a range such as “1 - 4 days” or “approximately 3 days” or “up to 5 days”; and
  - The purpose of the trip – a short description of the reason for the travel.
- B. If you anticipate that within the next 12 month period you will take multiple trips for the same purpose and the travel expenses will be paid for by the same sponsor/organizer, you can make a single entry. For example, if you expect to travel to quarterly board meetings of the American Hantavirus Society, held in Flagstaff in February, May, August, and November, you can complete a single entry in eDGE that encompasses all four trips. Use the Purpose field to clarify that you are disclosing multiple trips for the same purpose.
- C. If you are unsure of the exact location, but know it is likely to be one of a few places, you can indicate more than one anticipated location on your prospective disclosure.

**13. Do prospective travel disclosures need to be updated if there are changes to the travel?**

If the purpose of the travel or the sponsor/organizer of the travel changes, or if there are *substantive* changes to the destination or the duration, you will need to go into eDGE and create a new entry with updated information. In the Purpose section, you should indicate that this new entry supersedes the earlier prospective entry.

**14. What happens if my financial interests change during the award period such that I no longer have any SFIs?**

You can update your information in eDGE when the change occurs, or you can wait to update it at the time of your next annual disclosure.

**15. I am an Investigator in an NIH-supported clinical trial network. My network has developed a study-wide policy for the trial that requires me to disclose my SFIs to my network’s steering committee/operations office on an annual basis. Do I also need to disclose my SFIs to UCLA?**

Yes. You need to disclose your SFIs in eDGE, since reporting your SFIs to a steering committee or other entity overseeing an NIH-supported clinical trial network will not fulfill your responsibilities to UCLA.

**16. Is income from all non-profit institutions excluded from the definition of SFI?**

No, the only exclusions are income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a US institution of higher education, or an academic teaching hospital, medical center, or research institute that is affiliated with a US institution of higher education. Income from all other sources is included in the definition of Significant Financial Interest and must be disclosed in eDGE.

**17. Do Investigators need to disclose SFIs received from foreign institutions?**

Yes. Exclusions for higher education or governmental agencies apply only to U.S. institutions.

Foreign investments are covered financial interests under the regulation, if the investments satisfy the SFI definition and threshold. The Investigator must disclose SFIs (and those of the Investigator's spouse or registered domestic partner, and dependent children) in eDGE.

**18. Am I required to disclose interests in mutual funds?**

No. Mutual funds and other investment vehicles such as retirement funds do not need to be disclosed as long as the Investigator does not directly control the investment decisions.

**19. What about stock and stock options?**

Stock option assets are to be reported in eDGE by the time an application for funding is submitted, and then reported annually or as new stocks are obtained, in the same manner as all other assets.

**20. Does the Investigator have to keep up with day-to-day changes in value of publicly traded stock or other similar interests with fluctuating value?**

No. Generally, the annual disclosure requirement will be sufficient to allow the Investigator to disclose updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

**21. Is an Investigator who is part of a health sciences compensation plan required to disclose payment for consulting in excess of \$5,000 from an outside entity when the payment is made directly to the UCLA compensation plan?**

Yes. The remuneration must be disclosed regardless of whether it was received by the Investigator and then turned over to a UCLA compensation plan or paid directly to the plan by the outside entity.

**D. Management of Disclosures**

**1. Who will review my disclosures?**

An initial review of all disclosures will be made by the staff of the UCLA Research Policy & Compliance office (RPC) to determine if any SFI is related to the PHS research project. If it is determined that an SFI is related, a second review will be conducted by the UCLA Conflict of Interest Review Committee (CIRC) or the RPC to determine whether the SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS project and would then constitute a Financial Conflict of Interest (FCOI) that needs to be eliminated, reduced or managed.

**2. Wouldn't it be much easier if the Investigator determined whether an SFI is related to the PHS-funded research project?**

It would be easier, but the PHS regulations require UCLA to make that determination.

**3. What happens if it is determined that an FCOI exists?**

When UCLA has determined that an FCOI exists, a management plan will be developed to specify the way in which the FCOI will be monitored until completion of the project. The management plan must be agreed to by the Investigator and information about the plan will be sent to PHS by RPC.

**4. When does information about the FCOI management plan need to be sent to PHS?**

The UCLA RPC must send initial reports of FCOI to PHS prior to UCLA's expenditure of any funds provided under a PHS project. When identified conflicts of interest are eliminated before research funds are expended, UCLA is not required to submit a report to PHS.

Additional FCOI reports must be submitted to PHS by RPC:

- A. Throughout the lifetime of an award when progress reports are submitted, or at the time that an award is extended (either through extension notification or a PHS prior approval request). When during the course of an ongoing PHS project an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
- B. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS project.
- C. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing PHS project.

**5. What happens if I forget to disclose a SFI in a timely manner? (Updated)**

If during the course of an ongoing PHS project, the Investigator discovers an SFI that was not disclosed in a timely manner or previously reviewed, UCLA will review the SFI within 60 days to determine whether it is related to a PHS project and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI is not identified or managed in a timely manner UCLA must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS project. The purpose of this retrospective review is to determine if the ongoing PHS project was biased in its design, conduct or reporting.

Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that UCLA will take to manage the identified FCOI.

If bias was found during the retrospective review, UCLA will promptly notify PHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines UCLA's plans to eliminate or mitigate the effect of the bias.

Additionally, if PHS determines that a project designed to evaluate the safety or effectiveness of a drug, medical device or treatment was not managed or reported by UCLA, then UCLA must include in the management plan the requirement that the Investigator shall disclose the financial conflict of interest in each public presentation or in the results of the research and to request an addendum to previously published presentations.

## E. Using eDGE

### 1. Where is the logon button?

The Logon button is located at the upper right side of the initial screen, in small typeface.

### 2. Should I submit my disclosure even if I don't have all my information collected?

The disclosure should be submitted only when all information is included. If, after entering into eDGE, you realize you cannot complete the disclosure at that sitting, you can exit (without clicking the Finish buttons) and the information will be saved for completion at a later date. If after submittal you realize changes are needed, contact the RPC Help Desk at [rpchelp@research.ucla.edu](mailto:rpchelp@research.ucla.edu) or x68546 so the submittal can be returned to you for editing rather than submitting additional disclosures.

### 3. How do I submit the completed disclosure?

Submittal of the disclosure requires clicking TWO Finish buttons – a check box after the final sentence on the last screen AND the button at the lower right side of that same screen. Clicking just one button will not submit the disclosure.

## F. Other

### 1. Will information about my SFIs be available to others? (Updated)

Information provided in your disclosure may be released or transmitted to other appropriate UC or UCLA units.

Additionally, the information may be released or transmitted to PHS or other research sponsors that have adopted the PHS conflict of interest regulations, upon request.

PHS regulations require that UCLA respond within 5 business days to any public request for information about those SFIs held by key personnel which UCLA has determined constitute an FCOI. These requests will be handled by RPC. The information released will include, at a minimum, the Investigator's name, title and role within the project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate value of the SFI.

Under the California Public Records Act, other information may be made available to the public upon request. These requests are handled routinely by the UCLA Office of Records Management and Information Practices.

### 2. How long are SFI records to be kept?

Records of financial disclosures, RPC /CIRC determinations and recommendations, and University actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects do not need to be retained.

**3. If collaborators (e.g., subawardees, subcontractors or consortium members) are participating on a research project, does the PI have to monitor their disclosures?**

Collaborators from other institutions who meet the definition of Investigator (see definition in Section 1.A.) and who will be conducting research under a subaward from UCLA, are expected to comply with the policies and procedures of the institution at which they are employed. The subaward document that UCLA issues to the other institution will include language requiring the institution to have established a system compliant with the PHS regulations. If the institution fails to comply, UCLA has the option of terminating the subaward.

Although not likely to occur frequently, if the collaborator will be conducting research under an Independent Consultant Agreement issued by UCLA and the PI has determined that individual is an Investigator, he/she must disclose in eEDGE. Instructions for eEDGE access by non-UCLA employees/appointees can be found at: <http://edge.research.ucla.edu/> under How to Access the System.

**4. When do Investigators have to take training?**

Every Investigator must complete training prior to engaging in PHS-funded research, and at least every four years. Additionally if an Investigator does not comply with UCLA's Policy 926 "Public Health Service Regulations on Objectivity in Research" or with a management plan, he/she may be asked to repeat the training.

For Investigators who are already conducting PHS research, training must be completed by the time additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, through approval of a no-cost time extension, or prior to acceptance of a PHS Notice of Award issued subsequent to August 24, 2012, whichever comes first.

**5. Where do I find the training?**

The UCLA Briefing Module has been embedded into the disclosure process. It will appear the first time you log into eEDGE. Once you have read through the Briefing Module and acknowledged your completion you will be able to begin entering your first annual disclosure. During subsequent logons you will not see the briefing module until you are required to retake it.

For reference purposes, however, the same Briefing Module is posted to the eEDGE website under Quick Reference Guides & Training Materials [<http://edge.research.ucla.edu/>].

**6. It appears that disclosures I must complete under the State of California law are similar to those I have to respond to for PHS. Can one disclosure satisfy both sets of requirements?**

Unfortunately, no. The State of California requirements ask different questions and define disclosure categories differently.

**7. Where can I find additional information?**

See the UCLA Office of Research Policy and Compliance (RPC) home page (<http://rpc.research.ucla.edu>).

Also see the information posted by the UC Office of the President (<http://www.ucop.edu/research/policies/integrity.html#coi>).

Information specific to NIH grants and cooperative agreements is available on the Financial Conflict of Interest Page of the NIH Office of Extramural Research home page (<http://grants.nih.gov/grants/policy/coi/index.htm>). Many of the UCLA FAQs have been adapted from those posted by NIH.