Welcome to the UCLA electronic disclosure gateway (eDGE). This system was created to facilitate UCLA’s compliance with the U.S. Public Health Service (PHS) regulations on Promoting Objectivity in Research – which are their conflict of interest rules. Under these rules, the Principal Investigator of an award from NIH or many other PHS agencies and everyone else who will share responsibility for the design, conduct or reporting of the project must disclose all personal (or individual) financial interests that meet the PHS definition. Some other non-PHS sponsors also require review under these regulations. References to PHS below include all sponsors that specifically require review under the PHS regulations.

The same people who are required to disclose their financial interests must also complete a training session prior to participating in research related to any PHS-funded project. By completing this briefing module you will fulfill this obligation. You will find additional PHS, UC and UCLA resources by clicking on the links throughout this module. UCLA Policy 926, “PHS Regulations on Objectivity of Research,” implements the 2011 PHS regulations. Under this policy, you must disclose financial interests that fall within the reporting categories and meet thresholds that PHS defines as “Significant Financial Interests” (SFIs), as further delineated below.

SFIs must be disclosed through eDGE at least annually, and must also be updated within 30 days of acquiring or discovering a new SFI. Staff of the UCLA Office of Research Policy & Compliance (RPC) will conduct a preliminary review of all disclosed SFIs to determine whether any of them appear to be related to your proposed research – that is, whether the SFI could be affected by the research or whether the SFI is in an entity whose financial interests could be affected by the research. RPC staff may confer with you to gather more information or clarification, and may collect additional details from other campus units, such as the Office of Intellectual
Property if UC patented inventions or copyrighted software are involved in the research design.

Related SFIs will be reviewed a second time, usually by the campus Conflict of Interest Review Committee (CIRC). This review is conducted to determine if an SFI that is related to the PHS research constitutes a Financial Conflict of Interest (FCOI); that is, whether the SFI could reasonably appear to directly and significantly affect the design, conduct or reporting of the research. If an FCOI does exist, the CIRC will develop a plan designed to eliminate, reduce or manage the FCOI. You may be asked to help in developing the plan, and you will be required to review it and confirm its acceptability. RPC staff will then provide all necessary reports to PHS and, as necessary, will respond to public requests for information.

As a UCLA Investigator, you have a number of responsibilities related to the disclosure of your SFIs.

You should know how SFIs are defined. A financial interest is anything of monetary value, whether that value can be easily determined or not, that is held by you. Except for travel, financial interests held by your spouse or registered domestic partner, and dependent children must also be included in your disclosure. Under the PHS definitions, a financial interest becomes significant when it:

1. reasonably appears to be related to or is in the same field of expertise as your institutional responsibilities – which include the teaching/education, research, outreach, clinical services, and University and public service you perform in the course and scope of your UCLA appointment, AND
2. meets any of the following reporting categories and thresholds:

- Income received from a publicly-traded entity during the 12 months prior to disclosure which, when combined with the value of any equity interest you hold in the entity, exceeds $5,000.

- Income received from a non-publicly traded entity during the 12 months prior to disclosure that exceeds $5,000 OR any amount of equity interest you hold in that entity.

- Income received from an entity, other than UC, for intellectual property rights and interests during the 12 months prior to disclosure that exceeds $5,000. This could include royalties for books, or license fees for software or technology you may have invented before you came to UCLA.

- The occurrence of travel paid for or reimbursed on your behalf by a for-profit or non-profit entity, including professional organizations and foreign universities.

• You should keep in mind that SFIs do not include:

  1. Mutual funds or other investment vehicles such as retirement funds as long as you do not directly control the investment decisions.

  2. Payments made to you by UC for salary, stipends, royalties, honoraria, reimbursement of expenses or any other remuneration received from the University.

  3. 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.
4. Travel costs paid for or reimbursed 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.

• Your SFI disclosure must be current before UCLA submits any new or renewal applications to PHS on which you plan to participate. However, review by RPC staff will not begin until Just-in-Time or similar notification is received from the sponsor.

• If an FCOI has been previously reported to PHS under any ongoing awards, your SFI disclosure must be current and review by the RPC staff must be completed before the annual progress report is submitted. For all other ongoing awards, your SFI disclosure must be current and review by the RPC staff must be completed prior to the awards are accepted or no-cost time extensions are approved.

• You may be required to complete additional training, your research funding may be withheld, or other UC or sponsor enforcement mechanisms may be implemented if you failed to disclose as detailed in UCLA Policy 926 and this training, or because you failed to comply with a plan put in place to manage your FCOI.

If you are the Principal Investigator on a proposal you will be expected to complete an Extramural Proposal Approval and Submission Summary (“EPASS”) form with each proposal for funding. Within Section 7 of the EPASS are questions about the sponsor. When you check the first box indicating the sponsor is PHS, you will be asked whether there are others who share responsibility for the design, conduct or reporting of the project. If there are, you will be asked to provide their names. This information will be used by UCLA staff reviewing and submitting the proposal, and to ensure that you and all other Investigators have submitted disclosures within the past 12 months. The information will also be shared with RPC staff so they know which disclosures will need review.

We realize that the PHS regulations, and therefore the UC and UCLA policies that implement the regulations, may seem burdensome. Through development of the web-
based disclosure system, smart forms and this training we have tried to make compliance as simple as possible.

As an Investigator you will be in compliance if you:

- Complete this briefing at least every four years and on other occasions if specifically notified by RPC staff.

- Complete the annual certification in eDGE: 1) if you have no financial interests that meet the SFI definition, you still must go into the system to certify that you have “no significant financial interests” and follow the submission instructions; or 2) if you have previously reported financial interests, you must update your disclosures at least annually by revising those with any changed information or deleting those that are older than 12 months and therefore no longer need to be a part of your certification.

- Update your disclosure by reporting any new SFIs within 30 days of acquiring or discovering the interest throughout the period during which you are participating in any PHS-funded project.

- Provide any additional information requested by RPC staff or the CIRC as they review your disclosure.

- If an FCOI management plan is created, acknowledge your acceptance of the plan promptly so RPC staff can submit the required report to PHS. This must be done before any pending funding is released so that spending can begin.

- If an FCOI management plan is in place, abide by its terms and conditions since there are federal sanctions for non-compliance. As UCLA is responsible for monitoring compliance with the plan, please respond promptly to all requests for information.