



## Financial Conflict of Interest (FCOI) Disclosure and Training Requirements Standard Operating Procedures

All investigators who plan to apply for funding (directly or flowing thru another institution) from any external sponsor must complete the Summary Financial Interest Disclosure form at the time of the proposal submission. The Public Health Service (PHS) of the US Department of Health and Human Services (including the National Institutes of Health (NIH)) has specific regulations regarding financial conflict of interest (FCOI) disclosures and training which are outlined below. All investigators are required to file disclosures. Investigator is broadly defined as 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, and may include students, postdocs, collaborators, and research associates affiliated with the project. The UMass Lowell FCOI form (revised 8-9-17) incorporates requirements from all external sponsors into one form.

The University of Massachusetts PHS FCOI policy (also known as the UMass Policy for Promoting Objectivity in Biomedical Research) and the "Summary Disclosure of Financial Interests for All Sponsored Projects" form can be found on the UML Office of Institutional Compliance website.

### PHS FCOI Policy:

[https://www.uml.edu/docs/UMA%20Policy%20for%20Promoting%20Objectivity%20in%20Biomed%20Research4-6-12\\_tcm18-109520.pdf](https://www.uml.edu/docs/UMA%20Policy%20for%20Promoting%20Objectivity%20in%20Biomed%20Research4-6-12_tcm18-109520.pdf)

### Process to Initiate, Submit, and Track Disclosures:

#### *At Proposal Stage*

1. The Office of Research Administration (ORA) will send to the Principle Investigator (PI) the Summary Financial Interest Disclosure Form and alert them of the disclosure requirements for proposals submitted to external sponsors. Disclosure requirements apply to all investigators associated with the proposal, and it is the responsibility of the PI to distribute the Disclosure form to all other investigators on the proposal. The form is sent using Echosign. FCOI training must be noted and up to date for all PHS agencies and related sponsors (renewed every 4 years). The last training completion date is the date to be added to the form. The online training is available at [www.citiprogram.org](http://www.citiprogram.org). Affiliate yourself with University of Massachusetts Lowell, create a username and password, add the module to your profile, and complete the training.
2. For investigators who have a potential FCOI, the box should be checked 'yes' on the Summary Disclosure Form. When the form is returned to ORA prior to proposal submission, ORA will check for any 'Yes' responses and forward the disclosure form to the Director of the Office of Institutional Compliance (OIC). The OIC Director will then send the Investigator's Detailed Disclosure Form to those persons who indicate they have a potential conflict. The Detailed Disclosure form should be completed and returned to OIC prior to proposal submission so potential financial conflicts of interest are on file at the time of the award. In some cases, the Conflicts Committee may need to review the COI and a management plan may be required.
3. Each investigator should maintain a copy of their own FCOI Forms for audit purposes. It is the responsibility of the Principle Investigator (PI) to assure that all investigators on the award have submitted a completed FCOI Form to ORA prior to proposal submission.
4. The disclosure form has check boxes to indicate the type of external sponsor. Different external sponsors have different thresholds for financial conflicts of interest determinations and disclosures are evaluated based on the sponsor requirements.
5. The types of activities to disclose include financial interests that could pose a potential conflict and loss of objectivity when conducting the research or if travel reimbursements have been

received over the prior 12 months from organizations (except for federal, state, or local government agencies). Please note that the reporting thresholds are different for various sponsors.

#### *At Award Stage*

1. When ORA is notified of an award, the Grants & Contracts Administrators will notify OIC of the award and OIC reviews the FCOI disclosure information to determine whether there is a disclosure that could result in a conflict of interest.
2. OIC will evaluate the disclosures per the appropriate agency FCOI Policy and thresholds, and reach out to investigators as necessary for clarification and follow up on identified significant financial interests. OIC will maintain a record of the detailed disclosure form submissions, and the date of award.
3. OIC will work with investigator(s) and the Conflicts Committee to discuss potential COIs and help to develop a management plan that may be required at the time of the award.
4. If an investigator did not submit disclosure(s) at the proposal submission stage because they were not individually identifiable at that time or the proposal mistakenly did not go through ORA, then the forms must be submitted directly to OIC before commencing on the project.
5. The summary disclosure forms will be updated at least annually. At the time of submission of the required annual report for a PHS-funded awards, each investigator will submit an updated FCOI Disclosure Form to ORA. It is the responsibility of the PI to assure that each investigator participating in funded research has submitted an updated FCOI Form annually.
6. Disclosure forms must be updated immediately at any time there is the acquisition or discovery of a new significant financial interest (as defined in the disclosure forms). This information will be reviewed by OIC.
7. OIC will request a report bi-annually from ORA Post-Award for current awards to verify disclosures have been made as required and to verify that training records are up to date.

#### **PHS FCOI Training Requirement and Process:**

Requirement: All persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research, and may include students, postdocs, collaborators, and research associates affiliated with the project must complete COI training every four years.

1. When ORA is notified of an award that is subject to the PHS FCOI regulations, ORA will immediately notify OIC of the award. OIC will verify training is up to date for all individuals as required for all PHS funded activities.
2. OIC will contact the Principle Investigator (PI) to remind them of the training (and disclosure) requirements for all investigators associated with a PHS-funded award.
3. To take the training, go to the CITI website for the "Conflicts of Interest (COI)" training ([www.citiprogram.org](http://www.citiprogram.org)). All investigators associated with the award must complete the COI training prior to the expenditure of funds and participation in the research. It is the responsibility of the PI to assure that all training has been completed. The PI should maintain copies of all completed training certificates for audit purposes. A 'Refresher' training module is also available for those who have completed the initial Stage 1 module.
4. So that OIC can track compliance with PHS requirements, prior to the start of the award, the PI should provide to OIC the names of all investigators who will be participating in the research. OIC should be alerted to any personnel changes as they occur during the life of the award.
5. Training must be renewed every four years. While OIC will track this information to assure compliance with PHS requirements, it is the responsibility of the PI to track the date that each investigator completed the training and to assure that training is renewed as necessary.

## Forms

The forms related to the FCOI disclosure policy for sponsored research\* can be found at <https://www.uml.edu/Research/OIC/Conflict-of-Interest/Forms.aspx>. All UML researchers should complete the summary form for sponsored research at the proposal stage. The forms are initiated and sent to you by ORA. Additional forms may be necessary if there is anything to disclose, a subcontract is required, or outside investigators are involved. The various forms for sponsored research activities are:

- 1) Summary Financial Conflict of Interest Disclosure Form for All Sponsored Projects
- 2) Investigator's Detailed Financial Interest Disclosure Form
- 3) Subrecipient Commitment Form
- 4) Non-UML PHS Individual Investigator Disclosure of Financial Interests

*\*Note: these requirements are for all sponsored research activities. Additional forms may be required by the Massachusetts State Ethics Commission for Outside Activity Disclosures and potential conflicts of interests.*

## Public Health Service (PHS) Agencies

([http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596) updated 9/15/2015)

1. Administration for Children and Families (ACF)
2. Agency for Healthcare Research and Quality (AHRQ)
3. Agency for Toxic Substances and Disease Registry (ATSDR)
4. Centers for Disease Control and Prevention (CDC)
5. Food and Drug Administration (FDA)
6. Health Resources and Services Administration (HRSA)
7. Indian Health Service (IHS)
8. National Institutes of Health (NIH)
9. Office of Global Affairs (OG)
10. Office of the Assistant Secretary for Health (OASH)
11. Office of the Assistant Secretary for Planning and Evaluation
12. Office of the Assistant Secretary for Preparedness and Response (ASPR)
13. Office of Public Health and Science
14. Substance Abuse and Mental Health Services Administration (SAMHSA)

**Sample sponsors using PHS FCOI regulations in their award terms** – Please note this list is not exhaustive. Sponsor terms and conditions must be reviewed to verify whether PHS FCOI regulations are employed by the sponsor, and if so all SOPs above for disclosure and training apply.

([http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596) updated 3/10/2015)

1. Alliance for Lupus Research (ALR)
2. Alpha-1 Foundation
3. American Asthma Foundation
4. American Cancer Society (ACS)
5. American Heart Association (AHA)
6. American Lung Association (ALA)
7. Arthritis Foundation (AF)
8. CurePSP
9. Juvenile Diabetes Research Foundation (JDRF)
10. Lupus Foundation of America (LFA)
11. Patient-Centered Outcomes Research Institute (PCORI)
12. Susan G. Komen for the Cure