All investigators that plan to apply for funding (directly or flowing thru another agency) from the Public Health Service (PHS) of the US Department of Health and Human Services (including the National Institutes of Health (NIH)), or have current PHS funding, must comply with PHS FCOI Regulations. 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 University of Massachusetts PHS FCOI policy (also known as the UMass Policy for Promoting Objectivity in Biomedical Research) and the “PHS Disclosure Form” (also known as the PHS Summary Disclosure of Financial Interests Form and Guidelines) 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

PHS Disclosure Form: 
https://www.uml.edu/docs/UML%20PHS%20FCOI%20Summary%20Disclosure%20Form%20and%20Guidelines%208-5-13_tcm18-110974.docx

Process to Initiate and Track Disclosures:

At Proposal Stage

1. The Office of Research Administration (ORA) will send to the Principle Investigator (PI) the PHS Disclosure Form and alert them of the disclosure requirements for proposals submitted to PHS agencies and sponsors that utilize the PHS FCOI regulations. Disclosure requirements apply to all investigators associated with the proposal, and it is the responsibility of the PI to distribute the PHS Disclosure form to all other investigators on the proposal.

2. All investigators planning to participate in research subject to PHS FCOI regulations must complete the “PHS Disclosure Form” and the “Investigator’s Detailed Disclosure Form” as appropriate and return them to ORA prior to proposal submission. Note: The “Disclosures and Certifications” part of the PHS Disclosure Form is only to indicate if an investigator has a potential conflict or has received travel reimbursements. If an investigator has a significant financial interests or has received travel reimbursements, they should complete the “Investigator’s Detailed Disclosure Form”.

3. Each investigator should maintain a copy of their own PHS Disclosure 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 PHS Disclosure Form to ORA prior to proposal submission.

4. The check box for “PHS-FCOI” on the proposal information sheet should be checked (to alert and remind the ORA Grants & Contracts Administrators to notify OIC if the proposal is awarded).

5. At the time of proposal submission, ORA will add OIC to the Echosign distribution of the disclosure forms. As per the PHS FCOI Policy, OIC will evaluate the disclosures and reach out to
investigators as necessary to clarify potential financial conflicts/follow up on identified significant financial interests. OIC will maintain a record of the disclosure form submissions, the date of proposal submission, and any conflict management procedures that may be required if the proposal is awarded.

At Award Stage

1. When ORA is notified of an award subject to the PHS FCOI regulations, ORA will immediately notify OIC. If any financial disclosure has been or is made that could result in a conflict of interest, OIC will work with investigator(s) and the Conflicts Committees to develop and implement a plan to manage any conflicts of interest.

2. If any investigators did not submit disclosure(s) at the proposal submission because they were not individually identifiable at that time or the proposal mistakenly did not go through ORA, then these forms must be submitted directly to OIC before commencing their involvement on the project.

3. PHS requires that the disclosure forms be updated at least annually. At the time of submission of the required annual report for a PHS-funded awards, each investigator should submit to OIC an updated PHS Disclosure Form. If annual reports are submitted through ORA as with NIH’s Research Performance Progress Reports (RPPRs), then ORA will add OIC to the Echosign distribution of the related disclosure form(s). It is the responsibility of the PI to assure that each investigator participating in PHS-funded research has submitted an updated PHS Disclosure Form annually.

4. Disclosure forms must also be updated immediately at any time there is the acquisition or discovery of a new significant financial interest (as defined in the disclosure forms) which must be reviewed by OIC.

5. OIC will request a report bi-annually from ORA Post-Award for current PHS awards to verify disclosures have been made as required and to check training records are up to date.

Training:

1. If ORA is notified of an award subject to the PHS FCOI regulations, ORA will immediately notify OIC.

2. OIC will contact the Principle Investigator (PI) to alert/remind them of the training (and disclosure) requirements for all investigators associated with a PHS-funded award.

3. All investigators on the award should go to the CITI website for the “Conflicts of Interest (COI)” training (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.
Public Health Service (PHS) Agencies
(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 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