

## Conflict of Interest and PHS (Public Health Science) Sponsored Specific Requirements

Researchers at the MBL are subject to the Institute's Conflict of Interest Policy (No. K.1.3) which supports compliance with Federal and sponsor specific conflict of interest (COI) disclosure requirements. Acceptance of sponsored research funds puts specific obligations on the MBL to indicate the conditions under which outside activities and financial interests are proper or improper, to provide for notification of conflict of interest, and to have a sound policy for dealing with violations. Anyone submitting a proposal for sponsored research should read the MBL Conflict of Interest Policy **MBL Policy No. K.1.3 [MBL Conflict of Interest Policy](#)**

The NSF requires conflict of interest disclosures from *all* investigators, who are defined as "the principal investigator, co-principal investigators/co-project directors, and any other person at the organization who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by the NSF". **Subawardee investigators should make their disclosures to the organization that will accept the subaward.**

It is the policy of the MBL that each Investigator must disclose a Significant Financial Interest (SFI) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI:

- a. No later than at the time of application for PHS-funded research
- b. At least annually during the period of the award (February 15th, per MBL policy)
- c. Within 30 days of discovering or acquiring a new SFI

### **[MBL Conflict of Interest Form](#)**

In addition to completing an annual Conflict of Interest Disclosure, scientists at the MBL receiving funds from Public Health Services (PHS) agencies, must complete a Conflict of Interest on-line tutorial every *four* years. Training is provided through the Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/>

The Conflict of Interest Training consists of three modules; 1.) Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules, 2.) Institutional Responsibilities as They Affect Investigators, and 3.) Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest.

**Federal PHS Sponsors:** National Institutes of Health (NIH), the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, and Substance Abuse and Mental Health Services Administration. The most current list can be found at <http://www.usphs.gov/aboutus/agencies/hhs.aspx>

**Foundations following PHS COI Guidelines:** Alfred P. Sloan Foundation, Alliance for Lupus Research (ALR), American Cancer Society (ACS), American Heart Association (AHA), Arthritis Foundation (AF), California Breast Cancer Research

Program (CBCRP), California HIV/AIDS Research Program (CHRP), Lupus Foundation of America (LFA) and Susan G. Komen for the Cure

**Conflict of Interest Training through CITI must be taken:**

- a. Prior to engaging in research related to any PHS-funded grant
- b. At least every 4 years
- c. Immediately, if:
  - 1. Institution revises its FCOI policy that affects requirements of Investigators
  - 2. An Investigator is new to any Institution
  - 3. An Investigator is not in compliance with the policy or management plan

**Conflict of Interest Training via CITI** <https://www.citiprogram.org/>

## Who is an Investigator?

Investigator means the individual or individuals who are independently responsible for the design, conduct, or reporting of the research project. This is typically the principal investigator and any co-principal investigator (i.e. the project leadership), though in some cases the principal investigator may determine that others are independently responsible for the project. While a title alone cannot determine who is an Investigator, postdoctoral appointees and graduate students are rarely considered independently responsible for a project. For NIH projects, the individuals identified in the proposal as “key personnel” may be Investigators.

The PHS Conflict of Interest regulations apply to all Investigators. ***An Investigator is the principal investigator, co-principal investigator or any other individual who is independently responsible for the design, conduct, or reporting of PHS funded research.***

Principal Investigators are responsible for appropriately identifying individuals who meet this definition for each proposal and award. The NIH definition of senior/key personnel and Investigator are closely related.

## MBL OSP Guidance for Identifying PHS Investigators

Title and/or Role	Senior/Key Personnel *	Investigator **	MBL Guidance
PI/PD Project Director or Principal Investigator	Always	Always	Includes multi-PIs
Co-Investigator	Always	Always	Are named at the PD/PI’s discretion. Are involved with the PD/PI in the scientific development or execution of a project. May include research scientists, senior research scientists and senior postdoctoral associates, although this is not common. The designation of a co-investigator, if applicable, does not affect the PD/PI’s roles and responsibilities
Graduate or Postdoctoral Fellows paid on fellowships	Always	Always	

Sponsor for Postdoctoral or Graduate Fellows	Always	Always	
Graduate or Postdoctoral Fellows paid on training grants	Never	Never	
Postdoctorals paid on research grants	Sometimes	Only if Senior/Key	In most instances, postdoctorals, while engaged in research, do so under the guidance and mentorship of a PI and do not meet the criteria necessary to be categorized as Senior/Key  Principal Investigators should be judicious in identifying Senior/Key personnel. <b><i>Misidentifying personnel as Senior/Key personnel unnecessarily increases burden for the preparation of the application, submission of Just-in-Time information and annual reporting requirements, in addition to FCOI disclosure</i></b>
Graduate Students (RAs)	Rarely	Only if Senior/Key	Only in rare circumstances would a graduate student meet the criteria of Senior/Key. They are in training and conduct research under the guidance and mentorship of a PI
Other Significant Contributors (OSCs)	Never	Never	These individuals are typically included with "effort of zero person months" or "as needed." Per NIH, these are not acceptable levels of involvement for those designated as Senior/Key Personnel
Consultants	Infrequently	Only if Senior/Key	Consultants are individuals who generally provide a 'fee for service' and do not typically conduct research. They may provide insight and expertise to the PI but independently are not responsible for the design, conduct or reporting of research. In most cases, they do not meet the definition of investigator  If a non-MBL employee is responsible for conducting research, that research should be conducted through their home institution and they should be included in the proposal as a subrecipient and, as such, are entitled to intellectual property rights. The PI on a subaward is considered an investigator, as defined by the PHS regulations
Collaborators (unpaid)	Never	Never	Unpaid collaborators do not contribute measurable effort, do not meet the criteria of Senior/Key personnel. They should be included as OSCs
Collaborators (paid) at MBL	Sometimes	Only if Senior/Key	
Collaborators (paid) at another Institution	Never	Never	Should be included in the proposal as a subrecipient. May be an Investigator at his/her home institution
Subrecipient PIs and Senior/Key Personnel	Always	Always	MBL requires that subrecipient Investigators comply with the FCOI policy of their home institution. To designate the lead investigator at a subaward or consortium site, the role of <b>Subaward Investigator</b> (instead of Co-Investigator) should be used. Select "Other" for the Project Role field and then insert the appropriate role descriptor in the Other Project Role field

**\*Senior/Key Personnel:** As identified in the grant application, progress report, or any other report submitted to the PHS.

The program director/principal investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

**\*\*Investigator:** 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 by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

## **PUBLIC ACCESSIBILITY**

PHS requires MBL to make information regarding Financial Conflict of Interests reported to PHS, available to the public upon request. The minimum amount of information that must be made available includes the following:

1. Investigator's name;
2. Investigator's title and role with respect to the research;
3. Name of the entity in which the Significant Financial Interest is held or from which it is received;
4. Nature of the Significant Financial Interest; and
5. Approximate value of the Significant Financial Interest, which value may be expressed as being within a range as described above or if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact. Information request should be submitted in writing to the following address:

Marine Biological Laboratory  
Office of Human Resources  
7 MBL Street  
Woods Hole, MA 02543

For more information on specific federal policies:

**NIH Conflict of Interest Policy:** <http://grants.nih.gov/grants/policy/coi/>

**NSF Conflict of Interest Policy:** [www.nsf.gov/pubs/policydocs/pappguide/nsf14001/aag\\_4.jsp#IVA](http://www.nsf.gov/pubs/policydocs/pappguide/nsf14001/aag_4.jsp#IVA)