

CHA Guidance on PHS COI regulations regarding “design, conduct, or reporting of research”

Why

US Public Health Service (PHS) regulations [42 CFR 50, subpart F](#) establish the responsibility of applicants for promoting objectivity in research for which PHS funding is sought. [Revised PHS regulations](#) and new conflict of interest (COI) rules went into effect on 24 August 2012.

CHA has a policy that is compliant with PHS regulations and it promotes objectivity in research by establishing standards that provide reasonable expectation that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

Who

The policy applies to any CHA employee, subcontract personnel, or collaborator responsible for the design, conduct, or reporting of research activities and receives PHS funding by means of a grant or cooperative agreement. The following agencies are included:

- [Agency for Healthcare Research & Quality](#) (AHRQ)
- [Agency for Toxic Substances and Disease Registry](#) (ATSDR)
- [Centers for Disease Control](#) (CDC)
- [Food and Drug Administration](#) (FDA)
- [National Institutes of Health](#) (NIH)
- [Health Resources and Services Administration](#) (HRSA)
- [Substance Abuse & Mental Health Services Administration](#) (SAMHSA)

Recipients of Phase I Small Business Innovative Research (SBIR) or Small Business Technology Transfer applications (STTR) are not subject to these reporting requirements and should refer to other institutional COI policies. However, Phase II SBIR/STTR applications/awards are subject to this policy.

In addition, the following have adopted the PHS FCOI regulations:

- [Alliance for Lupus Research](#)
- [American Cancer Society](#)
- [American Heart Association](#)
- [American Lung Association](#)
- [Arthritis Foundation](#)
- [California Breast Cancer Research Program](#)
- [California HIV/AIDS Research Program \(CHRP\)](#)
- [Juvenile Diabetes Research Foundation](#)
- [Lupus Foundation of America](#)
- [Susan G. Komen Foundation](#)

For purposes of financial disclosure only, the reporting requirements of this policy also apply to an Investigator’s spouse and dependent children.

Project Directors/Principal Investigators (PD/PI), Co-Principal Investigators, Senior/Key Personnel, and any other person, *regardless of title* (including sub-recipients, contractors, consortium participants, collaborators, post-docs, graduate students, and consultants), responsible for the design, conduct, or reporting of research that is funded by a grant or cooperative agreement from the PHS or any of its components are subject to the new COI rules.

What is “design, conduct, or reporting of research?”

Research design is the creation of the plan, the strategy, the methodology, the procedures, and the structure of conducting a research study. Anyone involved in creating, developing, or substantively contributing to those aspects of scientific research is subject to the regulations. Similarly, persons who materially influence the research questions pursued are subject to the regulations.

Conduct of research pertains to the direction, execution, or management of the study plan. It includes all aspects of carrying out a study, including subject recruitment, selection, enrollment, or retention; data or specimen collection, analysis or interpretation; maintenance of regulatory binders and other study documents; data and safety monitoring, study drug or device accountability, and management of study-related records.

Reporting of research includes the reporting and attribution of adverse events; the presenting of data/results; submitting information to the IRB (*e.g.*, continuing review); completion of case report forms; and contributing to the presentation or publication of the research.

It is impossible to detail every component of what constitutes design, conduct, or reporting of research. Some interpretation by PIs will be needed. CHA expects all personnel to make a good faith effort to meet the spirit of the COI training and disclosure requirements and to seek guidance from the Office of the Chief Compliance Officer, as needed.