

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3219

The objectivity of research is of paramount importance and the basis for obtaining and maintaining public trust. To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among Government, research Institutions, and the private sector, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors* (commonly known as the Financial Conflict of Interest (FCOI) regulations). These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations were written to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigators' financial conflicts of interest, and strengthen NIH's compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

What is the purpose of this regulation? (Institution and Investigator)

The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation.

Who is required to disclose financial interests? (Institution and Investigator)

Under the 2011 revised regulation, Investigators (as defined by the regulation) who are planning to participate in, or are participating in, NIH-funded research, with the exception of Phase I SBIR/STTR applications, are required to disclose to the designated official(s) of the Institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

Who is covered by the regulation? (Institution and Investigator)

The regulation is applicable to each Institution that is applying for, or that receives, NIH research funding by means of a grant or cooperative agreement and, through the implementation of the regulation by the Institution, to each Investigator who is planning to participate in, or is participating in, such research. The regulation, however, does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications. For purposes of financial disclosure only, the regulation covers the Investigator's spouse and dependent children. The regulation also applies to those few cases where an individual, rather than an Institution, is applying for or receives NIH research funding. However, in those cases, the NIH will make case-by-case determinations on the steps an Institution or an Investigator must take, consistent with the regulation, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a Financial Conflict of Interest of the individual.