

University of New Orleans Financial Conflict of Interest (FCOI) Information Digest

The purpose of this Document is to provide to UNO researchers an overview of the 2011 revised U.S. Public Health Service (PHS) FCOI regulation entitled **Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)**. UNO's Policy on Conflicts of Commitment and Interest was revised to meet those regulatory requirements. This revised policy is effective November 1, 2012.

The regulation requires the University to inform each PHS Investigator of the policy at the time of application for PHS funds. This Digest serves to meet those obligations. Note that, prior to engaging in PHS sponsored research, Investigators must also be formally trained on the policy through the UNO Office of Research and Sponsored Programs training program. Resources for additional information on the regulation and policy are provided below.

Topic	Requirement/Definitions
PHS entities subject to the revised regulation	National Institutes of Health (NIH), Centers for Disease Control (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA); Food and Drug Administration (FDA), Office of the Inspector General (OIG); Substance Abuse and Mental Health Services Administration (SAMHSA); Agency for Toxic Substances and Disease Registry (ATSDR); and Indian Health Services (IHS).
Significant Financial Interests (SFI) threshold	UNO requires that all financial interests be disclosed. The Vice President for Research and Economic Development determines whether the interest meets the threshold to warrant referral to the CIRC.
SFIs that need to be disclosed (once the threshold is met)	All SFI related to the Investigator's institutional responsibilities.
SFIs excluded from disclosure requirement	Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Income from investment vehicles, such as mutual funds and retirement accounts, do not have to be disclosed as long as the Investigator does not directly control the investment decisions made in these vehicles.
Travel reimbursements and sponsored travel	There is no de minimis threshold for sponsored travel. Investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Investigators are NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution

	<p>of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Travel that is reimbursed to an Investigator from sponsored projects that reside in UNO's accounting system are not subject to this disclosure rule.</p> <p>UNO will determine if any travel requires further analysis, including determination as to potential FCOI or disclosure of the monetary value.</p>
Subrecipient Institutions/Investigators and Reporting of identified FCOIs	Written agreements between UNO and collaborating Institutions under PHS grants must establish whether the COI policy of UNO or that of the subrecipient will apply to subrecipient. Subrecipients that rely on their COI policy must report identified FCOIs to UNO in sufficient time to allow UNO to file reports to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module).
Affiliated PHS Investigator	Individual named as Key Personnel who is not a UNO employee. This could be an outside collaborator or consultant on a PHS sponsored project awarded to UNO.
Subrecipient PHS Investigator	Individual named as Key Personnel on a PHS funded project conducted by a subawardee (e.g. in a consortium arrangement).
Public Accessibility	UNO must make certain information available concerning identified COIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request.
FCOI training	Each Investigator must complete training prior to engaging in research related to any PHS-funded award and at least every four years, and immediately under these circumstances: 1) UNO's COI policy changes in a manner that affects Investigator requirements; 2) An Investigator is new to UNO; and 3) UNO finds an Investigator noncompliant with its COI policy or management plan.
Retrospective Review ("Mitigation plan")	UNO is required to conduct a retrospective review in those cases of non-compliance with the regulation. UNO will be required to submit a report to the PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions that UNO has taken, or will take, to eliminate or mitigate the effect of the bias.
Other resources	<p>UNO Policy on Conflict of Interest</p> <p>ORSP training on COI</p> <p>NIH FCOI website</p> <p>NIH FAQs on FCOI for PHS Investigators</p>

	U.S. institutions/organizations that have COI policies compliant with the 2011 PHS regulation
Links to complete UNO's annual/update disclosure forms	Disclosure of Conflict of Interest for UNO Faculty and Staff and for non-UNO employees (e.g. Affiliated PHS Investigators, Subrecipient PHS Investigators) who opt to/must comply with UNO's COI policy: www.uno.edu/compliance