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Major proposed changes to Public Health Service (PHS) financial conflict of interest (FCOI) regulations¹

| <i>Topic</i> | <i>Current</i> | <i>Proposed</i> |
|--|--|--|
| Significant Financial Interests (SFI) definition | - De minimis threshold of \$10,000 for disclosure generally applies to payments or equity interests - Exclusions include income from seminars, lectures, or teaching, and service on advisory committees or review panels, for public or nonprofit entities | - De minimis threshold of \$5,000 for disclosure generally applies to payments and/or equity interests - Includes any equity interest in non-publicly traded entities - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels, for government agencies or institutions of higher education |
| Investigator disclosure requirements | Only SFIs related to PHS-funded research as determined by the Investigator | - SFIs include financial interests that are related to an Investigator's institutional responsibilities - Institutions responsible for determining whether SFI relates to PHS-funded research and is a FCOI |
| Public disclosure | No requirement | Before spending funds for PHS-supported research, an Institution shall post on a publicly accessible web site information on certain SFIs that the Institution determines are related to the PHS-funded research and are FCOI < \$20K; <\$50K; , \$100K; <\$250K and >\$250K |
| Management of an identified FCOI by the Institution | Manner of compliance with regulation not specified (manage, reduce or eliminate are indicated as options) | - For all identified FCOI, Institutions must develop and implement a management plan (may include reduction or elimination of the SFI) - If FCOI is one that was not disclosed or reviewed in a timely manner, the Institution must also implement a mitigation plan which shall include review and determination as to whether any PHS-funded research conducted prior to identification and management of the FCOI was biased |
| Information on an identified FCOI reported by the Institution to the PHS funding component | - Grant/Contract number - Project Director/Principal Investigator (PD/PI) or Contact PD/PI - Name of Investigator with FCOI - Whether FCOI was managed, reduced, or eliminated | Current requirements, plus: - Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-\$100K by increments of \$20K or statement that a value cannot be readily determined. - Nature of FCOI , e.g., equity, consulting fees, travel reimbursements, honoraria, and description of how FCOI relates to PHS-funded research - Key elements of the Institution's management plan |
| Timing of reporting of an identified FCOI to the PHS-funding component | - Prior to the Institution's expenditure of any funds under the award - Within 60 days for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award | Current requirements, plus annual updates on any previously-identified FCOI for the duration of the research project |
| Scope of the regulation | Does not cover Small Business Innovation Research/Small Business Technology Transfer Research (SBIR/STTR) Phase I applications | Includes SBIR/STTR Phase I applications |
| Investigator training | No requirement | FCOI training required for Investigators before engaging in PHS-funded research, and every two years thereafter |
| HHS authority to inquire about FCOI | The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research | Clarifies that HHS authority applies before, during, or after an award with regard to any Investigator disclosure of financial interests, whether or not the disclosure resulted in the Institution's determination of a FCOI |

¹ This summary is for reference purposes only. Please see Federal Register (<http://edocket.access.gpo.gov/2010/pdf/2010-11885.pdf>) for full text of proposed regulations.