## **UNDERSTANDING FINANCIAL CONFLICT OF INTEREST (FCOI)**

## **Ten Things You Need to Know**

- Under *FCOI* regulations you are considered an *Investigator* on a research project if you would be responsible for the design, conduct, or reporting of research funded by the National Science Foundation (NSF) or the Public Health Service (PHS) regardless of your title or position.
- Before submitting a proposal for external funding by NSF or PHS Investigators must complete a Financial Conflict of Interest Disclosure form, to disclose Significant Financial Interest (SFI) that will be reviewed by designated campus administrators to determine whether a Financial Conflict of Interest exists.
- A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to an NSF-, PHS-, or other funded research project and could directly and significantly affect the design, conduct, or reporting of the NSF-, PHS- or other- funded research.
- An Investigator's *Institutional Responsibilities* are an Investigator's professional responsibilities on behalf of the Institution, and as defined by the institution in FCOI policy, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, or Data and Safety Monitoring Boards.
- Significant Financial Interests (SFI) that an Investigator must disclose are
  - "(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's *institutional responsibilities*:
  - (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$1,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$1,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure of the travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- (3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education."
- Prior to expenditure of funds on a PHS-funded research project SJSURF is required ensure public accessibility to the disclosed FCOI information when the disclosed FCOI is still held by the Senior/Key personnel identified for a PHS-funded project by SJSU in the grant application, progress report, or any

- other required report submitted to a PHS-agency, determined by SJSU to be related to the PHS-funded research, and that SJSU determines to be a FCOI.
- Investigators must complete mandatory FCOI training before engaging in a research project funded by PHS. Complete the training, print out the certificate, and provide the certificate to your designated Sponsored Programs Manager at the SJSU Research Foundation ASAP.

http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

- Investigators must complete refresher FCOI training every four years, if you affiliate with a new institution, and as FCOI regulations or forms change.
- Investigators must be prepared to complete a Financial Conflict of Interest disclosure form prior to each applicable proposal submittal and to promptly submit a new FCOI disclosure form annually and whenever a new SFI is implemented or discovered. Your designated Sponsored Programs Manager at the SJSU Research Foundation will provide the FCOI form, which is also found at <a href="http://www.sjsufoundation.org/html/sjsuf-employees-resources/forms.htm">http://www.sjsufoundation.org/html/sjsuf-employees-resources/forms.htm</a>
- After disclosing a Significant Financial Conflict of Interest, SJSU may determine that an FCOI exists. Investigators should thus be prepared to work with a chair, dean, and other SJSU administrators to prepare a management plan to reduce or eliminate the FCOI.