

## Financial Conflict of Interest (FCOI) Policy

This document reflects Square2 Systems' Financial Conflict of Interest (FCOI) policy to comply with Public Health Service (PHS) requirements (42 CFR Part 50 Subpart F).

### Definition of Significant Financial Interest

A Significant Financial Interest (SFI) is defined by the regulations as:

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 reasonable appears to be related to the Investigators institutional responsibilities:
  - With regard to any publically 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 \$5,000. For the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
  - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interests (e.g. stock, stock options, or other ownership interest) or
  - 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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, 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 a FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, 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 retirements 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, research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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.

### **Training Requirements**

Each research Investigator working with Square2 Systems who is engaged, or planning to engage, in PHS-compliant research will be required to complete training related to FCOI. And if any conflicts of interest are found or known, they must be disclosed. Investigators who are engaged in PHS-compliant Research are required to repeat such training no less than every four years provided that they continue to be engaged, or are planning to engage, in such Research Activities. And, Investigators will be required to repeat such training immediately if Square2 Systems revises its FCOI policy that affects requirements of Investigators, an Investigator is new to the Institution, or an Investigator is not in compliance with the FCOI policy or management plan.

Additional relevant information developed by the National Institutes of Health (NIH) is accessible at: (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

### **Disclosure, Review and Monitoring Requirements**

Investigators engaged, or planning to engage, in research activities must disclose all Significant Financial Interests to Square2 Systems' Institutional Official using an institution-provided disclosure form. This designated official will review all disclosures and evaluate whether they include any FCOI. If a reportable FCOI is identified, it will be included in a FCOI report in the

eRA Commons FCOI module. And the Institutional Official will work with the Investigator to create a FCOI management plan, as needed. Additionally, the Institutional Official will be responsible for monitoring the Investigator compliance with management plans. Investigators will be required to complete the FCOI disclosure form at least annually. If a new FCOI arises for a given Investigator after they have completed their initial or annual disclosure form, the new FCOI must be reported to Square2 Systems within 30 days.

### **Reporting Requirements to NIH**

Square2 Systems will report any FCOIs to NIH at the time of funding (prior to the expenditure of funds) and will send any updates on FCOIs at least annually. Square2 Systems will also report a new FCOI to NIH within 60 days of learning of the new FCOI.

Square2 Systems will also notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and will submit a Mitigation Report to the NIH in accordance with the regulation [42 CFR 50.605(a)(3)(iii)]. Square2 Systems will also notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or if a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

### **Maintenance of Records**

Records of all FCOI disclosures and all associated actions taken by Square2 Systems will be maintained for at least three years from the date of submission of the final expenditures report to the NIH.

### **Enforcement Mechanisms and Remedies and Noncompliance**

If an investigator is determined to be non-compliant with Square2 Systems' FCOI policy and/or management plan, within 120 days, Square2 Systems shall complete a retrospective review of the Investigator's activities and will work with the Investigator to mitigate the situation. Investigators who have not reported a given FCOI will be required by Square2 Systems to disclose the FCOI in each public presentation with research results and request an addendum to previously published presentations. In extreme cases of bias, an Investigator may no longer be permitted to work on a research project or receive future NIH funding.

### **Subrecipient Requirements**

If Square2 Systems carries out any Research Activity through subrecipients, it shall establish a written agreement with each subrecipient that requires such subrecipients to agree to either comply with the FCOI policy of Square2 Systems or the FCOI policy of the subrecipient. If

applicable, Square2 Systems will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows Square2 Systems to report FCOIs to NIH as required by the regulation.

### **Public Accessibility**

Information about any FCOIs identified among senior/key personnel Investigators will be posted on Square2 Systems' website or made available within 5 calendar days of a written request. Any FCOI information posted on the website will be updated at least annually and updated within 60 days of a newly identified FCOI. Information about FCOIs will remain available for at least three years from the date the information was most recently updated.