

DataJoint Financial Conflict of Interest Policy

June 2021

This Company policy outlines the requirements to comply with the Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research ([42 CFR Part 50 Subpart E](#)). Any questions regarding this policy should be directed to Company Administration.

1. Training Requirements

- a. Process for informing each investigator of Company Policy:** Company will provide each investigator with a copy of this FCOI Policy and require a signature confirming receipt and review of its contents.
- b. Responsibility of Investigator to disclose Financial Conflict of Interest:** Investigators must review the FCOI Policy prior to performing any work on a new contract to determine if they have any financial conflicts of interest that they would be required to report or that would preclude the Investigator from performing work on any particular project.
- c. Federal Regulation:** Each Investigator must provide to the Company a FCOI disclosure form prior to the undertaking of any project to which a financial conflict of interest may arise. The FCOI Disclosure Form may be obtained by asking the Company administrator for a form. The Company will review each financial disclosure form and determine whether the Investigator can continue to work on said project where a financial conflict of interest may arise. For any contracts that company has where financial conflict of interest may exist, Company has the responsibility to ensure that the contracting scope of services and charges for services are in line with other projects of similar scope and size. Any contract terms that are not in alignment with current terms and pricing should be reworked to comply with standardized pricing and scope for similar contract work.
- d. What is a Financial Conflict of Interest:**
 - i. A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

2. FCOI training:

- a. When FCOI Training is Required for Company Investigators:** The following are the conditions requiring FCOI training of an investigator:
 - i. Prior to engaging in research related to any PHS-funded grant
 - ii. At least every 4 years
 - iii. Immediately, if:
 - 1. Company revises its FCOI policy that affects requirements of Investigators
 - 2. An Investigator is new to a Company

3. An Investigator is not in compliance with the policy or management plan

3. Disclosure, Review and Monitoring

- a. **Significant Financial Interest (SFI) Disclosure:** SFI means anything of monetary value, including but not limited to compensation, equity, gifts, and intellectual property of an investigator or the immediate family member of an investigator, whether or not the value is readily ascertainable. Company requires each Investigator to disclose SFIs - and those of the Investigator's or affiliated party's spouse and/or dependent children - related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI:
 - i. No later than at the time of application for PHS-funded research
 - ii. At least annually during the period of the award
 - iii. Within 30 days of discovering or acquiring a new SFI
- b. **Solicitation for SFIs:**
 - i. At the beginning of a new project, on an annual basis, or upon hire, the Company will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities.
- c. **Determination of FCOI:** Company guidelines, consistent with the regulation for the designated institutional official(s), will determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. The SFI will be deemed related to an FCOI under the following conditions:
 - i. The Company is currently a non-publicly traded entity. An SFI exists if the value of any remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or
 - ii. An SFI exists 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.
- d. **Prior to Company's expenditure of funds, the Company will:**
 - i. Review all Investigator SFI disclosures
 - ii. Determine if any SFIs relate to PHS-funded research
 - iii. Determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)
 - iv. Develop and implement management plans, as needed to manage FCOIs
- e. **Company's Process to Review Disclosures of SFIs:** Company will review disclosures of SFIs, make determination of FCOIs, and implement a management plan when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.
- f. **Company's Process to Review Undisclosed SFIs:** Company will implement a management plan within sixty days whenever an Institution identifies an SFI that

was not disclosed timely by an Investigator or not previously reviewed by the Institution.

- g. **Managing FCOIs:** Company will actively manage all FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

4. Reporting Requirements to NIH

- a. **Annual Disclosure Forms:** On an annual basis, or at time of hire, Company will provide and collect SFI and FCOI disclosure forms from all company personnel who:
 - i. Are an officer of the Company
 - ii. Are a senior Investigator on a project (defined as someone who directs the research of a project and/or has input, influence, or management control over awarding or management of contracts)
 - iii. A person with more than 10% ownership interest in the Company
 - iv. All individuals with the above status will be asked to complete SFI and FCOI disclosures for all Company projects whether or not they actively work on that project.
- b. **Disclosure to NIH:** Either annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) or upon new hire of an individual, Company will provide results of FCOI disclosure submittals.
- c. **Discovering Bias:** If an undisclosed FCOI is discovered to be leading to bias in the design, conduct, or reporting of the NIH-funded research with regard to any of the above mentioned personnel, Company will promptly notify NIH, submit a mitigation report in accordance with the regulation, and take corrective action to remove the FCOI from the project entirely.

5. Maintenance of Records

- a. **Location of Records:** Company will maintain a record of all SFI and FCOI disclosure forms on Company HRIS system, Gusto, and those records will be associated with each individual employee. Company will also maintain records of any inquiries or mitigation plans for disclosed or undisclosed FCOIs.
- b. **Records Retention:** Company will maintain records of all SFI/FCOI activities for a period of at least 36 months following the date of the final expenditures report submitted to the PHS.

6. Enforcement Mechanisms and Remedies and Noncompliance

- a. **Failure to Disclose FCOI by an employee:** If an employee fails to disclose any FCOIs, employee will be given a written warning regarding the violation of this policy, will receive remedial training on FCOIs, and will be removed from participation on the contract in question for a period of time until the mitigation plan can be implemented. If the employee commits a second violation of this policy, and the second violation of this policy results in bias in the design,

conduct, or reporting of the NIH-funded research, Company will have the option to terminate employee at Company discretion.

- b. **Time to complete review:** Company will document and review, within 120 days of the Company's determination that a non-compliance event has occurred with respect to SFIs and FCOIs.
- c. **Clinical Research to Evaluate Safety and Effectiveness of a Drug, Medical Device, or Treatment:** Company does not, nor does it have plans now or in the near future, to participate in said activities.

7. Subrecipient Requirements

- a. **Contracts with Subrecipient:** Company will include in all contracts with subrecipients, a clause that requires all subrecipients in a contract to have an up to date FCOI policy that complies with current regulations.
- b. **Language in subrecipient agreement:** The language in the subrecipient will have the following elements but may be different in final form for each contract:
 - i. Parties agree to each maintain and enforce and active FCOI policy that complies with all current regulations.

8. Public Accessibility Requirements

- a. **Posting of FCOI Policy for Public Review:** Company will post its most current FCOI policy on its website and will be accessible within 1-2 clicks from the home page.
- b. **FCOI Disclosure:** Company will list all disclosed FCOIs on the same page as and immediately following the FCOI Policy.
- c. **FCOI Mitigation Disclosure:** If the Company is engaged in a current FCOI mitigation, Company will disclose on the website the presence of a mitigation plan that can be viewed upon request.
- d. **Expiration of Relevant Information:** Company will remove disclosure from website for all FCOIs and mitigation plans within 36 months post relevance.