
Financial Conflict of Interest Policy

1. PURPOSE

Evotec SE and its group companies worldwide (collectively the "Company") is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by personal financial conflicts of interest. The purpose of this Financial Conflict of Interest Policy is to establish standards and disclosure requirements that promote the integrity and objectivity of research and to comply with the FCOI Regulations.

2. SCOPE

This policy applies to all employees of the Company and Investigators who will participate in or are participating in an In-Scope Project. Participation includes being involved in the design, conduct, reporting, research, management, or other related services.

3. DEFINITIONS

For the purpose of this policy, the following definitions apply:

- **"FCOI Regulations"** refer to the requirements of 42 CFR Part 50 and 45 CFR Part 94 that are applicable to research funded in whole or in part under the Public Health Service of the U.S. Department of Health and Human Services grants or cooperative agreements including components or organization units thereunder such as the National Institute of Health ("NIH") (collectively referred to as **"PHS"**).
- **"Financial Conflict of Interest" ("FCOI")** is a SFI that is reasonably determined to be related to the In-Scope Project and it could directly and significantly affect the design, conduct, or reporting of the PHS funded research.
- **"In-Scope Project"** any work proposed, applied for, or in progress, under an agreement, grant, cooperative agreement, or bid that is funded in whole or in part by the PHS and that is subject to FCOI Regulations.
- **"Institution"** any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that submits a proposal, or that receives, PHS research funding.
- **"Institutional Official"** the individual(s) who shall be responsible for implementing the requirements of this policy for the specific In-Scope Project. It is the responsibility of the Institutional Official to solicit and review disclosures of SFIs to determine if an FCOI exists, coordinate and implement management plans in response to identified FCOIs when necessary, and to act as the point of contact between the Company and PHS. Lastly, Institutional Officials shall ensure that the subcontractors or consultants who perform services in connection with an In-Scope Project do not act in a way that is prohibited by the requirements of this policy or the FCOI Regulations.
- **"Investigator"** the project director or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of an In-Scope Project, which may include, for example, collaborators or consultants. It is the responsibility of Investigators to understand and follow the provisions of this policy and the FCOI Regulations. Investigators shall ensure that they identify their interests or the interests of their immediate family members (spouse/domestic partner/dependent(s)) that are implicated by the requirements of this policy and disclose the details as provided herein. Investigators shall cooperate with the Company and the Institutional Official as necessary to support compliance with the FCOI Regulations.
- **"Significant Financial Interest" ("SFI")** means the following:
 - a.) A financial interest of the Investigator or the Investigator's immediate family (spouse/domestic partner/dependent(s)) consisting of one or more of the following interests that would reasonably appear to be related to the Investigator's responsibilities to the Company or Institution:

- i. An interest or stake in a publicly traded entity, 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 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. An interest or stake in a non-publicly traded entity, if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator or the Investigator's immediate family (spouse/domestic partner/dependent(s)) holds any equity interest (e.g., stock, stock option, or other ownership interest).
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - b.) Reimbursed or sponsored travel received from any entity other than the Company in the prior twelve (12) months of disclosure when the estimated aggregate amount received is equivalent to \$5,000 or more. This excludes travel that is reimbursed or sponsored by a federal, state, or local government agency located in the U.S., a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.
 - c.) Income received and paid by any entity other than the Company, for seminars, lectures, or teaching engagements, service on advisory committees or review panels, and reimbursed or sponsored travel with an estimated aggregate amount of \$5,000 or more.
 - d.) Exclusions - SFI does not include: salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Company held by the Investigator; and 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.
- **"Subrecipients"** collectively refers to any subcontractor or consultant that performs services in connection with an In-Scope Project.

4. MANDATORY TRAINING

Training on the requirements described herein is required by Investigators: prior to the Company engaging in research on an In-Scope Project, on at least a four (4) year basis thereafter, immediately when the Company revises this policy in any manner that affects the requirements of Investigators, when a new Investigator is added to an on-going In-Scope Project, and when the Company finds that an Investigator is not in compliance with this policy or a management plan.

At the discretion of the Company, training assigned in connection with this policy may be provided through internal and/or external resources. Investigators assigned training in connection with this policy must complete it in a timely manner. If advised that they must complete external training materials (such as training provided by NIH or another PHS component) then they must complete such training and provide proof of completion in a timely manner.

5. DISCLOSURE REQUIREMENTS

The Institutional Official shall solicit and Investigators shall disclose SFIs:

- i. No later than at the time of application for PHS funding (e.g. NIH grant)
- ii. Within thirty (30) days of discovering or acquiring a new SFI,
- iii. Within thirty (30) days of modifying the value amount of an existing SFI, and
- iv. On an annual basis while the In-Scope Project is in effect.



Investigators have an obligation to disclose the relative details of all known SFIs to the Institutional Officer whether or not they are prompted by a solicitation to do so.

SFI disclosures shall be submitted using the **FCOI Disclosure Form** and shall include all details necessary for the Institutional Officer to determine if an FCOI exists.

Investigators shall cooperate with Institutional Officers and support them in assessing SFI disclosures by providing timely responses and any additional information that may reasonably be requested to complete the assessment.

6. SFI & FCOI ASSESSMENT REQUIREMENTS

Upon receipt of a SFI disclosure or identification through any other means, an assessment must be conducted by the Institutional Official within sixty (60) days to determine if the SFI is related to the In-Scope Project and if an FCOI exists.

If an FCOI exists, the Institutional Official shall implement, at least on an interim basis, a management plan that specifies the actions that have been/shall be taken to mitigate or eliminate the FCOI. *See additional resources for guidance on conducting FCOI assessments and reporting obligations.*

Conditions or restrictions that might be imposed to manage an FCOI include but are not limited to:

- i. External or public disclosure (reporting to PHS or the public via the external Company internet page),
- ii. Disclosure to involved participants for research projects involving human subjects research,
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against relative bias,
- iv. Modification of the research plan,
- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research,
- vi. Reduction or elimination of the FCOI (Ex., sale of an equity interest), or
- vii. Severance of relationships that create the FCOI.

7. REPORTING REQUIREMENTS

The Company shall submit initial, annual, and revised FCOI reports with all information as required by the FCOI Regulations and as stated below:

- i. Prior to the expenditure of funds received pursuant to a PHS award.
- ii. Within 60 days of identification for an Investigator who is newly participating in the project.
- iii. Within 60 days for new, or newly identified, FCOIs for existing Investigators.
- iv. At least annually, at the same time as when the company is required to submit the annual progress report. The annual report shall provide the status of the FCOI and any changes to the management plan, if applicable, until completion of the project. FCOI reporting will end during the period of an award if a submitted annual FCOI report indicates that the FCOI "No Longer Exists."
- v. After a retrospective review to update a previously submitted report if new information is discovered following completion of the review.
- vi. Promptly if an Investigator (or subrecipient Investigator) fails to comply with the requirements provided herein or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the In-Scope Project.

8. MAINTENANCE OF RECORDS

The Company shall maintain all disclosures collected from Investigators and of the Company's review and response actions, whether or not a disclosure resulted in a FCOI finding. Records will be archived in an audit-proof manner for three (3) years from the date the final expenditure report is submitted unless another applicable law or regulation requires a longer retention period.

9. SUBRECIPIENTS

Subrecipients must also comply with FCOI Regulations and the following must be established via written agreement:

- i. Whether the Subrecipient will follow this policy or the Subrecipient's own financial conflict of interest policy which will apply to Investigators,
- ii. Certification that the Subrecipient's policy complies with the FCOI Regulations if not following this policy and mandatory compliance with this policy if certification is not provided,
- iii. Specified time period(s) for the Subrecipient to report all FCOIs identified pursuant to the Subrecipient's financial conflict of interest policy so to enable the Company to comply with its requirements under the FCOI Regulations, or
- iv. If the Subrecipient cannot provide certification or if it does not have its own policy, a requirement to solicit and review subrecipient Investigator disclosures to enable the Company to be able to identify, manage and report identified FCOIs pursuant to the FCOI Regulations.

10. QUESTIONS & COMPLIANCE

Questions about this policy or its requirements may be directed to Grant Management, the team responsible for maintaining this policy and its publication, at: FCOIDirective@evotec.com, or US Legal & Compliance.

Compliance with the requirements set forth in this policy is mandatory. Violations may result in disciplinary action, up to and including termination of employment.

11. EXCEPTIONS / EXEMPTIONS

There are certain research projects that may be funded by a grant award by the PHS that are exempt from FCOI Regulations, such as those designated as Small Business Innovative Research or Small Business Technology Transfer. For such research projects this policy would not apply. However, whether or not this policy applies, potential conflicts of interest shall always be considered, acknowledged and disclosed pursuant to applicable Company Code of Ethics and Business Conduct, handbooks, policies, and procedures.

12. REFERENCES & RELATED DOCUMENTS

- Public Health Service, Code of Federal Regulations (42 CFR Part 50, Subpart F and 45 CFR Part 94), August 25, 2011. See, <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.
- Additional resources available for Company personnel can be found on the Grant Management intranet page.