

**FINANCIAL CONFLICTS OF INTEREST****A. Purpose and Expectations**

Exact Sciences is committed to maintaining the public’s trust in the integrity of its publicly-funded research activities by the Public Health Service (“PHS”), including the National Institutes of Health (“NIH”), by preventing financial conflicts of interest (“FCOI”) by investigators from impacting their work. As such, in compliance with the requirements in Title 42 Code of Federal Regulations (“CFR”), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (the “FCOI Regulations”), Exact Sciences will promote objectivity in its research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS, including NIH, grants or cooperative agreements will be free from bias resulting from any investigator financial conflicts of interest.

This FCOI Policy applies to investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by PHS or NIH. Pursuant to this Policy, all investigators planning to participate or participating in PHS or NIH-funded research are required to disclose to Exact Sciences their known significant financial interests (and those of their spouse and dependent children) that reasonably appear to be related to the investigator’s institutional responsibilities.

**B. Definitions**

1. The term “investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, including the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.
2. The term “senior/key personnel” means the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report or any other report submitted to the PHS, including the NIH.
3. The term “research” means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
4. The term “institutional responsibilities” means an investigator’s professional responsibilities on behalf of Exact Sciences, including research, research consultation, clinical or other professional

practice, participation in scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

5. The term “significant financial interest” means a financial interest – defined as anything of monetary value, whether or not readily ascertainable – 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.
  - a. Publicly Traded Entities – 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 \$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.
  - b. Privately Held Entities – 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 \$5,000, or when the investigator (or the investigator’s spouse and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - c. Intellectual Property – Intellectual property rights and interests (e.g., patents, copyrights) must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests. The filing of any patent application also should be disclosed.
  - d. Travel Expenses – 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 in the twelve months preceding the disclosure if the value of such travel, when aggregated from all sources, exceeds \$5,000; 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 USC § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosures relating to travel expenses must specify at a minimum the purpose and duration of the trip, the identity of the sponsor/organizer, and the destination.
6. The term “significant financial interest” **does not include** the following types of financial interests:
  - a. Salary or consulting fees paid by Exact Sciences to the investigator if the investigator is currently employed or otherwise appointed by Exact Sciences.

- b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
  - c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
  - d. Travel by a PHS or NIH-funded investigator that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
7. “Immediately” shall mean the training is provided or made accessible and the investigators participate in the training expeditiously following the event that triggers the training requirement.
8. “Manage” means taking action to address an FCOI, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

## **C. Investigator Training Requirements**

Exact Sciences’ FCOI administrator, or their designee(s), will be responsible for the procedures under this FCOI Policy. Further, the FCOI administrator is responsible for ensuring that each investigator is informed about: (i) this FCOI Policy, (ii) the investigator’s responsibilities regarding disclosure of significant financial interests relating to the investigator’s institutional responsibilities, and (iii) the FCOI Regulations.

The FCOI administrator shall ensure that each investigator completes training regarding items (i) through (iii) prior to engaging in research related to any PHS or NIH-funded grant or cooperative agreement, immediately upon being hired and at least every four years. Investigators are required to complete the FCOI training module prior to being engaged in PHS or NIH-supported research at least every four years, and immediately under the designated circumstances: (1) Exact Sciences’ FCOI policies change in a manner that affects investigator requirements, (2) an investigator is new to Exact Sciences, or (3) Exact Sciences finds an investigator noncompliant with Exact Sciences’ FCOI Policy.

The FCOI administrator shall further ensure that each investigator completes training immediately when any of the following applies: (1) this FCOI Policy or procedures are revised in any manner that affects the requirements of the investigators, or (2) Exact Sciences finds that an investigator is noncompliant with this FCOI Policy or a management plan.

## **D. Disclosure Requirements**

Prior to or in connection with the submission to PHS or NIH of an application for a research grant, the principal investigator shall identify to the FCOI administrator: (1) all investigators anticipated to be participating in the research, (2) those who are senior/key personnel, and (3) those who are subrecipients and the institution(s) employing them.

In addition, prior to submission of the application, the FCOI administrator shall ensure that each investigator submits a listing of their known significant financial interests and those of their spouse and dependent children that reasonably appear to be related to the investigator's institutional responsibilities, if any. The FCOI administrator shall also ensure that subrecipient investigators either comply with this FCOI Policy or require that their institution(s) confirm, in writing, that the subrecipient will comply with their own compliant FCOI policy. In either case, the FCOI administrator shall ensure that the proper documentation as required under the FCOI Regulations is executed. Subrecipients who rely on their own FCOI policy must report identified financial conflicts of interests to Exact Sciences in sufficient time to allow Exact Sciences to report the FCOI to the PHS awarding component. A subrecipient's failure to promptly comply with these requirements may be considered grounds for termination by Exact Sciences of any applicable subaward.

All disclosures must be updated annually during the period of the award or within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance, or expansion of responsibilities) a new significant financial interest. The FCOI administrator shall ensure that annual update forms are sent to and promptly returned by each investigator (one annual disclosure is sufficient to cover all ongoing PHS or NIH awards). Each investigator is responsible for submitting disclosure forms within 30 days of discovering or acquiring a new significant financial interest. Disclosures shall be provided by an investigator at any other time upon request.

## **E. Review of Disclosures and Monitoring and Reporting FCOI**

The FCOI administrator shall be responsible for reviewing all forms disclosing a significant financial interest, making the requisite determinations and taking any subsequent action. Prior to the expenditure of funds or, with respect to an ongoing PHS or NIH-funded project, within 60 days of the disclosure or discovery of a significant financial interest, the FCOI administrator shall:

1. Review all disclosure forms and determine whether: (1) an investigator's significant financial interest is related to PHS or NIH-funded research, and (2) if so related, whether the significant financial interest is an FCOI;
2. In the case of an FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and
3. Submit initial and ongoing FCOI reports to the PHS awarding component as required under the FCOI Regulations.

An FCOI exists when the FCOI administrator reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS or NIH-funded research. In determining whether there is an FCOI, the FCOI administrator will consider all relevant factors and information, including, but not limited to, the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision of whether an FCOI exists, the FCOI administrator may impose interim measures, may ask the investigator to submit additional information, and may meet or communicate with the investigator. The investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI. In the event of an actual or potential FCOI, the FCOI administrator may impose conditions or restrictions, including, but not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
2. For research involving human subjects, disclosure of financial conflicts to research participants;
3. Monitoring of the research by independent reviewers/monitors to protect the design, conduct, and reporting of the research;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest; and/or
7. Severance of relationships that create such conflicts.

For all management plans, the FCOI administrator shall: (1) monitor ongoing investigator compliance, and (2) submit annual updates to the PHS awarding component at the time and in the manner specified by the PHS awarding component, both until the completion of the PHS or NIH-funded research project to which the FCOI relates. With respect to FCOI related to research sponsored by NIH, annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period (including extensions with or without funds) at the same time annual progress reports are required to be submitted and at the time of extension (if any). If the FCOI is identified and eliminated prior to the expenditure of any PHS or NIH-awarded funds, no FCOI report needs to be submitted.

## **F. Noncompliance and Remedies**

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI was not identified, reviewed, or managed in a timely manner, the FCOI administrator shall within 120 days of the determination of noncompliance conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS or NIH-funded research or portion

thereof conducted during the period of noncompliance was biased in design, conduct, or reporting. The review shall be documented consistent with the FCOI Regulations. If bias is found during the course of the review, the FCOI administrator will promptly notify the PHS awarding component (which may take its own action and/or require further action by Exact Sciences and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations. If appropriate, the FCOI administrator will update the previously submitted FCOI report. In any event, the FCOI administrator shall submit FCOI reports annually thereafter.

If the Department of Health and Human Services determines that a PHS or NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts, and oral presentations), and Exact Sciences shall request an addendum to previously published presentations.

## **G. Maintenance of Records**

The FCOI administrator shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS or NIH.

## **H. Enforcement Mechanism and Sanctions**

All persons to whom this FCOI Policy applies are expected to fully and promptly comply with it. Failure on the part of an investigator to comply with this Policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the investigator, and/or any other enforcement action mandated by the applicable PHS awarding component agency or Exact Sciences.

## **I. Public Accessibility Requirements**

This FCOI Policy will be posted on Exact Sciences' publicly accessible website. To the extent there is an identified FCOI held by senior/key personnel, Exact Sciences shall make such information available to a public requester's written request within five business days of receipt of the written request. The information provided shall include the name of senior/key personnel, their role in the research project, the name of the entity in which the FCOI exists, the nature of the FCOI, and the approximate value of the FCOI or a statement that said value cannot be reasonably determined. The information shall remain available for three years from the date the information was most recently updated. Informational requests may be made to Exact Sciences via email at [compliance@exactsciences.com](mailto:compliance@exactsciences.com).