

ORI CES Community and Evaluation Services Scientific Conflict of Interest Policy

I. Statement of Philosophy

Purpose of Policy

ORI Community and Evaluation Services (ORI CES) and its employees are committed to conducting themselves and organization activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to conflict of interest and objectivity in research. It is the purpose of this policy to set forth the procedures for identifying significant financial interests, determining if those interests constitute a financial conflict of interest, and the procedures for reviewing and managing those conflicts. It is important to ensure that conflicts do not improperly affect Institute research and other activities. To maintain objectivity in research, ORI CES and its employees and investigators will completely disclose, appropriately review, and robustly manage identified conflicts.

A financial conflict of interest exists when ORI CES, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of all research at ORI CES, regardless of funding source.

Professional Interactions Encouraged

ORI Community and Evaluation Services actively encourages and participates in interactions with both the public and private sectors as an important component of its research activities. ORI CES encourages the recruitment, retention, and recognition of individuals with creative abilities who can contribute to technology transfer and interactions with private and public entities consistent with their primary commitment to ORI CES. Employees involved in such interactions may receive personal financial remuneration in accordance with the principles and guidelines provided in this policy. Professional interactions, including consulting arrangements, between employees and public and private entities advance ORI CES's ability to provide a high-quality research environment.

II. Application

This policy applies to any person employed by, under contract with or on the ORI CES Board of Directors who, on behalf of ORI CES, is: (1) responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity; or (2) in direct contact with suppliers or potential suppliers to ORI CES, or who have direct or indirect influence over purchasing decisions or contracts, or otherwise have official involvement in the purchasing or contracting process. This policy applies to all ORI CES research, regardless of funding source.

III. Compliance with Other Policies and Laws

Applicable State and Federal Laws

Employees must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research. These laws include but are not limited to: Federal Public Health Service regulations 42 CFR, part 50, subpart F; and 45 CFR, part 94.

Applicable Institute Policies

This policy complements the provisions of the ORI CES Research Misconduct Policy.

IV. Definitions¹

Conflict of Interest Committee (COIC) means a committee of the Board of Directors, consisting of two research scientists and the Board President. The Committee serves in an advisory role to the Designated Institutional Official and the Compliance Officer (COI staff). The Committee will review findings of the COI staff related to conflicts and provide input and feedback on conflict of interest management plans. In the event the COI staff cannot identify conditions to manage a conflict that are acceptable to the conflicted investigator, the committee will investigate the points of contention and facilitate a discussion between staff and investigators designed to establish conditions that are acceptable to both. In the event of unresolved issues, the Committee will determine whether a conflict exists, and if it does, how it will be managed. In the event the conflicted investigator disagrees with the Committee's determination, he/she may appeal to the ORI CES Board of Directors, which will have the final say.

Designated Institutional Official (DIO) means the ORI CES Executive Director who will solicit and review disclosures of significant financial interests to determine whether those interests represent a financial conflict of interest. Should a financial conflict of interest exist, the Executive Director and the Board President will work with the investigator/employee to develop a management plan to reduce or eliminate the conflict.

Disclosure of significant financial interests means an investigator's or an employee's disclosure of significant financial interests to ORI CES.

Employee means any person employed or contracted at ORI CES who on behalf of the Institute and/or a research project is in direct contact with suppliers or potential suppliers to ORI CES, or who have direct or indirect influence over purchasing decisions or contracts or otherwise have official involvement in the purchasing or contracting process.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of Institute research and/or the negotiation of contracts and the purchase of supplies and services.

¹ § 50.605

FCOI Report means ORI CES's report of a financial conflict of interest to all funding agencies subject to this regulation, e.g., any component of the Public Health Service of the United States Department of Health & Human Services, including the Centers for Disease Control and Prevention and the National Institutes of Health

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator's Institutional Responsibilities means an investigator's or employee's professional responsibilities on behalf of ORI CES, which may include: activities such as purchasing, contracting for services, research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator/Employee means the Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research which may include, for example, research associates, project managers, data analysts, and collaborators or consultants.

Manage means taking action to address a financial conflict of interest, 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.

ORI CES means ORI Community and Evaluation Services, a non-profit behavioral research Institute that routinely applies for, and receives, research funding from local, state, and federal government funding agencies, foundations, and donation-based funds.

PI means a Principal Investigator of a research project; the PI is included in the definitions of *Senior/Key Personnel* and *Investigator* in this policy.

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). As used in this policy, the term includes such activity as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award, regardless of funding source.

Senior/Key Personnel means the PI and any other person identified as senior/key personnel by ORI CES in the grant application, progress report, or any other report submitted to the funding agency by ORI CES under these regulations.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator or employee (and those of the investigator's/employee's spouse/domestic partner and dependent children) that reasonably is related to the investigator's or employee'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 \$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. 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 employee (or the investigator's or employee's spouse/domestic partner or dependent children) holds equity interest of any amount (e.g., stock, stock option, or other ownership interest); or
- iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income subject to the \$5,000 threshold related to such rights and interests.

Significant financial interest also includes occurrences of any reimbursed or sponsored travel related to an investigator's or employee's institutional responsibilities, the value of which is estimated to exceed \$5,000. This 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.

Significant financial interest does **not** include the following types of financial interests: salary, royalties, or other remuneration paid by ORI CES to the investigator or employee if the individual is currently employed or otherwise appointed by ORI CES, including intellectual property rights assigned to ORI CES and agreements to share in royalties related to such rights; any ownership interest in ORI CES held by the individual if ORI CES is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual 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; 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.

V. Training²

All ORI CES investigators/employees must complete training prior to engaging in research related to any research grant and prior to commencing an activity involving purchases of supplies, services and/or contracting at least every four years, and immediately under these circumstances: ORI CES's FCOI policy changes in a manner that affects investigator/employee requirements; an investigator/employee is new to ORI CES, or; ORI CES finds an investigator/employee noncompliant with ORI CES's FCOI policy or management plan.

VI. Disclosure³

Each investigator/employee who is planning to participate in research or planning to assume direct or indirect responsibility for purchases of supplies, services and/or contracts must disclose to the Executive Director his or her significant financial interests (and those of their spouse/domestic partner and dependent children). Disclosure forms reflecting an investigator's/employee's current significant financial interest must be provided prior to ORI CES's expenditure of any funds under a research project and annually thereafter to continue in the capacity of an investigator or an employee responsible for purchasing. Updated disclosures are also required within 30 days of a change in the significant financial interests of an investigator/employee that are related to the investigator's/employee's institutional responsibilities. Financial interest consists of one or more of the following interests that reasonably are related to the investigator's/employee's institutional responsibilities:

- 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;
- 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/employee (or their spouse/domestic partner or dependent children) holds equity interest of any amount (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income subject to the \$5,000 threshold related to such rights and interests.

Each investigator/employee who is participating in research and/or participating in purchasing decisions is required to submit an updated disclosure of significant financial interests within thirty (30) days of

² § 50.604 (b)

³ § 50.604 (e)

discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Each investigator/employee must submit an updated disclosure of significant financial interests annually, during the period of the award. Such disclosure shall include any information that was not disclosed initially to ORI CES or in a subsequent disclosure of significant financial interests and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Investigators/employees also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities, the value of which is estimated to exceed \$5,000. 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.

Traveling to scientific meetings and to present research findings to colleagues and other interested parties is an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers. ORI CES investigators' travel expenses are frequently reimbursed and/or sponsored by professional societies to enable the investigator to give presentations at professional society meetings.

To minimize administrative burden, ORI CES investigators/employees are required to disclose such travel only once a year. Investigators/employees will disclose their planned or anticipated reimbursed or sponsored travel in a prospective manner (e.g., over the next twelve months) annually, at the time of the annual update of financial disclosures. No further disclosure is needed that year, assuming there are no changes to the details of the purpose of the trip, identity of the sponsor/organizer, destination, and duration. However, an investigator/employee is required to disclose a new source of travel (i.e., that was not anticipated and disclosed at the annual reporting) within thirty (30) days if the additional travel value is estimated to exceed \$5,000.

The investigator/employee will attest in writing that he/she will comply with all provisions of ORI CES's Conflict of Interest Policy including the terms and conditions of a management plan, if applicable⁴.

VII. Management⁵

Prior to ORI CES's expenditure of any funds under a research project or the expenditure of any funds for purchasing supplies and services from an external business entity, ORI CES's Executive Director shall: review all investigator and employee disclosures of significant financial interests; determine whether any significant financial interests relate to the research or to the employee's institutional responsibilities for purchasing/negotiating contracts; determine whether a financial conflict of interest exists; and, if so, work

⁴ § 50.605(b)(3)(viii)(D)

⁵ § 50.605(a)(10)

with the Board President and the investigator/employee to develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. In cases where the conflicted investigator/employee is not the Principal Investigator on the project, the Principal Investigator will be involved in the development and implementation of the management plan.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research or purchasing duties;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

The management plan will be a formal document signed by both the investigator/employee and the Executive Director and will include the following key elements: (a) Role and principal duties of the conflicted investigator/employee in the research project; (b) Conditions of the management plan; (c) How the management plan is designed to safeguard objectivity in the research project; (d) Confirmation of the investigator's/employee's agreement to the management plan; (e) How the management plan will be monitored to ensure investigator/employee compliance; and (f) Other information as needed.

In the event of unresolved issues, the Committee will determine whether a conflict exists, and if it does, how it will be managed. If the conflicted investigator disagrees with the Committee's determination, he/she may appeal to the ORI CES Board of Directors, which will have the final say.

VIII. Reporting⁶

Prior to the ORI CES's expenditure of any funds under a research project, ORI CES shall provide to any funding agency requiring such a report an FCOI report regarding any investigator's/employee's significant financial interest found by ORI CES to be conflicting and ensure that ORI CES has implemented a management plan in accordance with the regulations. In cases in which ORI CES identifies a financial conflict of interest and eliminates it prior to the expenditure of awarded funds, ORI CES shall not submit an FCOI report to the funding agency.

⁶ §50.605(b)(1)

Any FCOI report required should include sufficient information to enable the funding agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of ORI CES's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PI or Contact PI if a multiple PI model is used;
- Name of the investigator/employee with the financial conflict of interest;
- Name of the entity with which the investigator/employee has a financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the research and the basis for the institution's determination that the financial interest conflicts with such research; and
- A description of the key elements of ORI CES's management plan, including:
 - Role and principal duties of the conflicted investigator/employee in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the investigator's/employee's agreement to the management plan;
 - How the management plan will be monitored to ensure investigator/employee compliance; and
 - Other information as needed.

For any financial conflict of interest previously reported by ORI CES with regard to an ongoing research project, ORI CES shall provide to any funding agency requiring such a report an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. ORI CES shall provide annual FCOI reports to the funding agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the funding agency.

New Personnel: For any significant financial interest that ORI CES identifies as conflicting subsequent to ORI CES's initial FCOI report (e.g., upon the participation of an investigator/employee who is new to the research project), ORI CES shall provide to any agency requiring such a report, within sixty (60) days, an FCOI report regarding the financial conflict of interest. ORI CES will implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. Depending on the nature of the significant financial interest, ORI CES may determine that additional interim measures are necessary with regard to the investigator's/employee's participation in the research project and/or purchasing activities between the date that the financial conflict of interest or the investigator's /employee's noncompliance is determined and the completion of ORI CES's review.

Untimely disclosure: If ORI CES identifies a significant financial interest that was not disclosed timely by an investigator/employee or, for whatever reason, was not previously reviewed or managed by ORI CES (e.g., was not timely reviewed or reported by a subrecipient), the Executive Director shall, within

sixty (60) days: review the significant financial interest; determine whether it is related to the research; determine whether a financial conflict of interest exists; and, if so: implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

ORI CES is responsible for ensuring any subrecipient's compliance with the regulations and reporting identified financial conflicts of interest for subrecipient investigators/employees to the awarding agency⁷. ORI CES must incorporate as part of a written agreement with a subrecipient, terms that establish whether the Financial Conflict of Interest policy of ORI CES or that of the subrecipient will apply to subrecipient investigators/employees and include periods to meet disclosure and/or financial conflict of interest reporting requirements. ORI CES is responsible for monitoring subrecipient's compliance with the financial conflict of interest regulations, management plans, and for reporting all identified financial conflicts of interest prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

IX. Noncompliance and Retrospective Review⁸

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the investigator/employee to disclose a significant financial interest that is determined by ORI CES to constitute a financial conflict of interest; failure by ORI CES to review or manage such a financial conflict of interest; or failure by the investigator/employee to comply with a financial conflict of interest management plan, ORI CES shall, within one hundred twenty (120) days of ORI CES's determination of noncompliance, complete a retrospective review of the investigator's/employee's activities and the research project and/or purchasing responsibilities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Such retrospective review shall be completed by the Conflict of Interest Committee.

ORI CES's documentation of the retrospective review shall include, but not necessarily be limited to, all the following key elements:

- Project number;
- Project title;
- PI or contact PI if a multiple PI model is used;
- Name of the investigator/employee with the FCOI;
- Name of the entity with which the investigator/employee has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

⁷ §50.604(c) (1) – (2)

⁸ §50.605(a)(3)(ii)(A)

Based on the results of the retrospective review, if appropriate, ORI CES shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, ORI CES is required to notify any funding agency subject to these regulations promptly and submit a mitigation report⁹ to the funding agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and ORI CES's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, ORI CES will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, ORI CES may determine that additional interim measures are necessary with regard to the investigator's/employee's participation in the research project between the date that the financial conflict of interest or the investigator's /employee's noncompliance is determined and the completion of ORI CES's retrospective review.

X. Remedies.

ORI CES will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure investigator and employee compliance as appropriate.

If the failure of an investigator/employee to comply with ORI CES's financial conflict of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the research, ORI CES shall promptly notify the funding agency of the corrective action taken or to be taken. If the funding agency is subject to these regulations (e.g., an organizational component of the Public Health Service, including the Centers for Disease Control and Prevention (CDC) or the National Institutes of Health (NIH)), it will consider the situation and, as necessary, take appropriate action, or refer the matter to ORI CES for further action, which may include directions to ORI CES on how to maintain appropriate objectivity in the PHS-funded research project. The funding agency may, for example, require institutions employing such an investigator/employee to enforce any applicable corrective actions prior to a grant award or when the transfer of a grant(s) involves such an investigator/employee.

The funding agency may inquire at any time before, during, or after award into any investigator/employee disclosure of financial interests and ORI CES's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in ORI CES's determination of a financial conflict of interest. ORI CES is required to submit, or permit on-site review of, all records pertinent to compliance with the regulations. To the extent permitted by law, the funding agency will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS funding agency may decide that a particular financial conflict of interest will bias the objectivity of the research to such an extent that further corrective action is needed or that ORI CES has not managed the financial conflict of interest in accordance with the regulations. The funding agency may determine that imposition of special award conditions under 45 CFR

⁹ §50.605(a)(3)(iii)

74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

In any case in which the funding agency determines that a funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator/employee with a financial conflict of interest that was not managed or reported by ORI CES as required by the regulations, ORI CES shall require the investigator/employee involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XI. Public Accessibility¹⁰

ORI CES will post its financial conflict of interest policy on its publicly available website. Prior to ORI CES's expenditure of any funds under a research project, ORI CES shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to ORI CES that meets the following three criteria: (1) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy; (2) ORI CES determines that the significant financial interest is related to the research; and (3) ORI CES determines that the significant financial interest is a financial conflict of interest.

The information shall include, at a minimum, the following: the investigator's/employee's name; the investigator's/employee's title and role with respect to ORI CES and/or the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. ORI CES will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of ORI CES's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. This information remain available, for responses to written requests for at least three years from the date that the information was most recently updated¹¹.

XII. Submission of the FCOI Policy to NIH

In accordance with NIH requirements, ORI CES will submit its Financial Conflict of Interest (FCOI) policy to the NIH via the eRA Commons Institution Profile (IPF) Module. This submission will be completed by the institutional Signing Official (SO) and will include the current PDF version of the policy, formatted to meet NIH specifications.

- The FCOI policy will be uploaded to the *Policy Documents* tab in the IPF Module.

¹⁰ §50.605(a)(5)(i-ii)

¹¹ §50.605(a)(5)(iv)

- Updates to the policy will be re-submitted promptly, at least annually, and whenever substantive changes are made to ensure ongoing compliance.
- ORI CES will maintain registration and active participation with eRA Commons to ensure timely submission and updates.
- NIH's acceptance of the policy submission will be monitored, and any required corrections or clarifications will be addressed in a timely manner.

XIII. Maintenance of Records¹²

Each year, within the first quarter, updated disclosure forms will be required of all investigators/employees who are planning to participate in research or planning to assume direct or indirect responsibility for purchases of supplies, services, and/or contracts. It is the responsibility of the Designated Institutional Official and the Conflict of Interest Compliance Officer to maintain these forms, and to ensure that a current form is on file for all investigators/employees at the time of a new grant submission and annual progress reports as required by Federal regulations. Financial conflicts of interest will be reported to funding agencies, as required, and a record of those reports and related management plans will also be maintained by the Designated Institutional Official and the Conflict-of-Interest Compliance Officer.

ORI CES will maintain records relating to all investigator and employee disclosures of financial interests and ORI CES's review of, and response to, such disclosures (whether or not a disclosure resulted in ORI CES's determination of a financial conflict of interest) and all actions under ORI CES's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the funding agency or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

ORI CES will certify, in each application for funding to which the regulations apply, that ORI CES (1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received ; (2) Shall promote and enforce investigator and employee compliance with the regulation's requirements including those pertaining to disclosure of significant financial interests; (3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to any funding agency which requires such reports consistent with the regulations; (4) Agrees to make information available, promptly upon request, to the funding agency relating to any investigator or employee disclosure of financial interests and ORI CES's review of, and response to, such disclosure, whether or not the disclosure resulted in ORI CES's determination of a financial conflict of interest; and (5) Shall fully comply with the requirements of the regulations.

¹² §50.604(i)