

Lahey Health

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY FOR U.S. PUBLIC HEALTH SERVICE FUNDED RESEARCH

I. Introduction

To promote objectivity in research, Lahey Health (Lahey) implements this Policy governing financial conflicts of interest (“FCOI”) that may arise in the research setting. This Policy applies to all study investigators, sub investigators, coordinators, subrecipients, and subcontractors (all hereinafter referred to as “Investigators”) who participate and contribute to research activities at Lahey.

Lahey is committed to promoting objectivity and transparency in research, and assures that the design, conduct, and reporting of research funded by a Public Health Service (PHS) grant, cooperative agreement, or contract will not be biased by any conflicting financial interest of an Investigator (including the Investigator’s Immediate Family members) or Research Personnel who are planning to participate in or are participating in such research. In accordance with the federal regulations cited in 42 CFR Part 50 , Lahey Health System has established this Financial Conflict of Interest (FCOI) Policy For U.S. PHS Funded Research.

In addition, all Investigators and Research Personnel engaged in externally funded research are required to comply with Lahey’s Conflict of Interest Policy, Research Compliance Policy, Confidentiality Agreement for Authorized Use of Medical Records for Research Purposes, policies regarding patient privacy and research in accordance with federal HIPAA regulations, Human Subject Protection Policy, and other applicable policies of Lahey.

II. Public Access To Policy

Lahey’s Financial Conflict of Interest (FCOI) Policy for PHS funded research will be made available to the public on Lahey’s website at <http://www.Lahey.org>.

For persons who are unable to access Lahey’s FCOI Policy via the website, a written copy of the FCOI Policy will be provided within five (5) business days upon receipt of a request. A request can be made by contacting the Research Administration by telephone at (781) 744-8027 or by written request addressed to the following address:

Research Administration
Lahey Health
41 Mall Road
Burlington, MA 01805

III. Definitions

CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

Disclosure - an Investigator's / Research Personnel's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) - a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI Management Plan – formal initiative of Institution in taking action to address a Financial Conflict of Interest (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.

Immediate Family Members – includes the spouse, dependents, and all members of the household.

Institution -- any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or receives PHS research funding.

Investigator -- the Principal Investigator (PI) and other researchers (e.g., collaborators or consultants) who are responsible for the design, conduct, or reporting of research proposed for PHS funding or research funded by the PHS.

Research Personnel -- any person identified by the Institution to be involved in the grant application, progress report, or any other report submitted to the PHS by the Institution.

PHS Awarding Component -- the organizational unit of the U.S. Public Health Service that provides funds for research.

Research -- a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health (e.g., behavioral and social-sciences research), and encompasses basic and applied research (e.g., a published article, book) and product development (e.g., a diagnostic test or drug). For this FCOI Policy, research includes any such activity for which funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract (e.g., research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award).

Research Compliance Committee -- A standing committee created to monitor the FCOI Policy, research conflict of interest disclosure and the on-line electronic Conflict of Interest disclosure program. If a significant financial interest is present, or concerns are identified, a review will include, at a minimum, whether there is an appearance of a conflict of interest and an evaluation of the integrity of the research. The investigator may be asked to attend the meeting in which their disclosure is reviewed, or to provide additional information prior to the meeting. The investigators may also request to attend the meeting in which their disclosure is reviewed.

For further information regarding the Research Compliance Committee, please review the Research Compliance Committee Charter and Policies Regarding Conflicts of Interest in Research.

U.S. Public Health Service (“PHS”): An umbrella organization in the U.S. Federal Government consisting of eight HHS health Agencies (Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, the National Institutes of Health, and the Substance Abuse & Mental Health Services Administration), the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals).

IV. Significant Financial Interest

Significant Financial Interest (SFI) consists of one or more of the following types of interests of the Investigator (including the Investigator's Immediate Family members) that reasonably appears to be related to the Investigator's institutional responsibilities or interests of the Research Personnel who are engaged in the research.

- a. With regard to any *publicly traded entity*, a SFI 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); and 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. With regard to any *non-publicly traded entity*, a SFI 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 Immediate Family members) or Research Personnel holds any equity interest (e.g., stock, stock option, or other ownership interest);
- b. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- c. Any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator or Research Personnel and not reimbursed to the Investigator or Research Personnel so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities or Research Personnel's responsibilities. 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.

Significant Financial Interest (SFI) does not include the following types of interests.

- a. Salary, royalties, or other remuneration paid by the Institution to the Investigator / Research Personnel, 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);
- b. Any ownership interest in the Institution held by the Investigator / Research Personnel, if the Institution is a commercial or for-profit organization;
- c. Income from investment vehicles (e.g., mutual funds and retirement accounts) provided that the Investigator / Research Personnel do not directly control the investment decisions made in these vehicles;
- d. Income from seminars, lectures, or teaching engagements sponsored by 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
- e. 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. Investigator / Research Personnel Responsibilities

a. Training

Prior to engaging in PHS-funded (externally funded) research, each Investigator / Research Personnel must be familiar with and adhere to the investigator/research personnel responsibilities listed in 42 CFR Part 50 (<http://grants.nih.gov/grants/policy/coi/>). Completion of the CITI COI module and familiarity with Lahey's FCOI Policy (see <http://www.Lahey.org>) is also required.

FCOI training must take place at least every four (4) years, or immediately when any of the following apply: (1) Lahey revises its FCOI Policy in any manner that affects the requirements of Investigators; (2) an Investigator / Research Personnel is new to Lahey; or (3) Lahey finds that an Investigator / Research Personnel is not in compliance with Lahey's FCOI Policy or management plan.

b. Disclosure

Each Investigator / Research Personnel, who is planning to participate in PHS funded research, must disclose to Lahey his/her SFI (and those of the Investigator's Immediate Family members) no later than at the time of application for PHS-funded research.

Each Investigator / Research Personnel, who is participating in PHS-funded research, must submit to Lahey an updated disclosure of SFI at least annually during the PHS-funded research award period, or within a comparable time period as specified by Lahey. A periodic disclosure must include (1) information that was not initially disclosed at the time of application for PHS funding or (2) information that was not subsequently disclosed (e.g., FCOI identified on a PHS-funded research project that was transferred from another Institution), and (3) updated information regarding any previously disclosed SFI (e.g., current value of a previously disclosed equity interest).

Each Investigator / Research Personnel, who is participating in the PHS-funded research, must submit to Lahey an updated disclosure of SFI immediately of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance).

In addition, consistent with Lahey's Conflict of Interest Policy, and related compliance policies, Lahey may require an Investigator / Research Personnel to report other types of financial interests (i.e., aside from that defined in 42 CFR Part 50 Subpart F).

VI. Sub-recipient Responsibilities

Lahey, as the awardee institution, assures that the Sub-recipient's Investigators (e.g., subcontractors or consortium members) / Research Personnel involved with its PHS-funded research award will comply with the regulatory requirements of 42 CFR Part 50 Subpart F.

A written agreement will establish whether Lahey's FCOI Policy or the Sub-recipient's FCOI Policy will apply to the Sub-recipient's Investigators / Research Personnel.

- a. If the Sub-recipient's Investigators / Research Personnel must comply with the Sub-recipient's FCOI Policy, the Sub-recipient must certify, as part of the agreement, that its FCOI Policy complies with 42 CFR Part 50 Subpart F.
- b. If the Sub-recipient cannot provide this certification, the agreement will state that the Sub-recipient's Investigators / Research Personnel must comply with Lahey's FCOI Policy for disclosing SFI directly related to the Sub-recipient's research work for Lahey.
- c. If the Sub-recipient's Investigators / Research Personnel must comply with the Sub-recipient's FCOI Policy, the agreement will specify the time period(s) for the Sub-

recipient to disclose all identified FCOI to Lahey in order for Lahey to provide timely FCOI reports to the PHS Awarding Component (i.e. the organizational unit of the PHS that funds the research).

- d. If the Sub-recipient's Investigators / Research Personnel must comply with Lahey's FCOI Policy, the agreement will specify the time period(s) for the Sub-recipient to disclose its Investigators' / Research Personnel's SFI to Lahey in order for Lahey to timely comply with its review, management, and reporting obligations.
- e. Reports of all FCOI of the Sub-recipient's Investigators / Research Personnel will be provided to the PHS Awarding Component prior to the expenditure of funds, and within 60 days of any subsequently identified FCOI.

VII. Institutional Responsibilities

Certification by Institution

Lahey certifies, in each application for PHS research funding, that it:

- a. Maintains an up-to-date, written, and enforced administrative process to identify and manage FCOI related to all research projects for which PHS funding is sought or received;
- b. Promotes and enforces Investigator / Research Personnel compliance with the regulatory requirements of 42 CFR Part 50 Subpart F including the disclosure of SFI;
- c. Manages FCOI, and provides initial and ongoing FCOI reports to the PHS Awarding Component;
- d. Agrees to promptly furnish information (upon request) to the U.S. Department of Health and Human Services (HHS) relating to any Investigator /Research Personnel disclosure of financial interests, and Lahey's review of and response to such disclosure (i.e., whether or not the disclosure resulted in Lahey's determination of a FCOI); and
- e. Complies fully with the regulatory requirements of 42 CFR Part 50 Subpart F.

Requirements for Investigators

Lahey requires that each Investigator / Research Personnel, who is participating in the PHS funded research, submit an updated disclosure of SFI immediately of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Further, Lahey requires that each Investigator / Research Personnel, who is participating in PHS funded research, submit an updated disclosure of SFI at least annually during the PHS funded research award period, or within a comparable time period as specified by Lahey. In addition, consistent with Lahey's

Conflict of Interest Policy, and related compliance policies, Lahey may require an Investigator /Research Personnel to report other types of financial interests (i.e., aside from that defined in 42 CFR Part 50 Subpart F).

- a. A periodic disclosure must include any information that was not initially disclosed to Lahey (i.e., at the time of application for PHS funding) or in a subsequent disclosure of SFI (e.g., FCOI identified on a PHS-funded research project that was transferred from another Institution), and/or updated information regarding any previously disclosed SFI (e.g., updated value of a previously disclosed equity interest).

Lahey requires that each Investigator / Research Personnel, who is planning to participate in the PHS-funded research, disclose his/her SFI (including those of the Investigator's Immediate Family members) no later than at the time of application for PHS-funded research. Lahey requires that each Investigator / Research Personnel, who is new to participating in the PHS-funded research, disclose his/her SFI (including those of the Investigator's Immediate Family members) prior to commencing participation in the PHS-funded research.

Designation of Institutional FCOI Official

Lahey's Research Compliance Committee or designee will solicit and review disclosures of SFI of each Investigator (including the Investigator's Immediate Family members) / Research Personnel who is planning to participate in, or is participating in, the PHS-funded research.

Lahey will provide guidelines consistent with 42 CFR Part 50 Subpart F for the Institutional FCOI Official or designee to determine whether an Investigator's / Key Research Personnel's SFI is related to PHS-funded research, and if related, whether the SFI is a FCOI, prior to the expenditure of research funds.

- a. An Investigator's / Research Personnel's SFI is related to PHS-funded research when (1) the SFI could be affected by the research, or (2) the SFI is in an entity whose financial interest could be affected by the research.

Lahey may involve the Investigator / Research Personnel in the Institutional FCOI Official's or designee's determination of whether a SFI is related to the PHS-funded research.

Institutional FCOI Reporting

Lahey provides initial and ongoing FCOI reports to the PHS Awarding Component as required by 42 CFR Part 50.605(b).

Before expending any funds under a PHS-funded research project, Lahey will provide

a report regarding any Investigator's / Research Personnel's FCOI to the PHS Awarding Component, and will ensure that Lahey has implemented a FCOI management plan.

- a. If Lahey eliminates a FCOI prior to expending PHS-awarded funds, Lahey does not need to submit a FCOI report to the PHS Awarding Component.

If Lahey identifies any FCOI after the initial FCOI report and during a PHS-funded research project (e.g., regarding a new Investigator / Research Personnel on the research project), Lahey will provide a FCOI report to the PHS Awarding Component within 60 days, and will ensure that a FCOI management plan was or will be implemented.

- a. If this FCOI report involves a SFI that was not disclosed timely by an Investigator / Research Personnel or was not previously reviewed or managed by Lahey (e.g., SFI was not reviewed timely or was not reported by a Subrecipient), Lahey will complete a retrospective review to determine whether any PHS-funded research (or portion thereof), which was performed before the identification / management of the FCOI, was biased in its design, conduct, or reporting.
- b. If bias is found, Lahey will promptly notify and submit a mitigation report to the PHS Awarding Component.

Any FCOI report must include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of Lahey's FCOI management plan.

- a. The FCOI report will include (but not limited to) the following:
 1. Project Number; Principal Investigator (PI) or contact information for PI if a multiple PI model is used; Name of the Investigator / Research Personnel with the FCOI; Name of the Entity with which the Investigator / Research Personnel has a FCOI; Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 2. Value of the 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 financial interest's value cannot be readily determined by reference to public prices or other reasonable measures of fair market value;
 3. A description of how the financial interest relates to the PHS-funded research and the basis for Lahey's determination that the financial interest conflicts with such research; and
 4. A description of the key elements of Lahey's FCOI management plan,

including: (a) the conflicted Investigator's / Research Personnel's role and principal duties in the research project; (b) the conditions of the FCOI management plan; (c) how the FCOI management plan is designed to safeguard objectivity in the research project; (d) confirmation of the Investigator's / Research Personnel's agreement to the FCOI management plan; (e) how the FCOI management plan will be monitored to ensure Investigator / Research Personnel compliance; and (f) other information as needed.

Lahey will provide an annual FCOI report (i.e., at the same time as the annual progress report, multi-year progress report [if applicable], or request for extension) for the duration of the PHS-funded research project or project period (including extensions with or without funds). This annual report will address the status of previously identified FCOI, and any changes to the FCOI management plan (e.g., whether the FCOI is still being managed or why the FCOI no longer exists).

Management of Financial Conflicts of Interest

A FCOI exists when Lahey, through its Institutional FCOI Official or designee, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Lahey will manage each Investigator's / Research Personnel's and Sub-recipient Investigator's / Research Personnel's FCOI. Management of an identified FCOI requires development and implementation of a FCOI management plan and, if applicable, a retrospective review and mitigation report (in accordance with 42 CFR Part 50.605[a]).

In addition to the types of FCOI as defined in 42 CFR Part 50 Subpart F that must be managed, Lahey may require the management of other FCOI in line with its FCOI Policy.

Lahey will establish adequate enforcement mechanisms and appropriate Investigator / Research Personnel sanctions or other administrative actions to ensure Investigator / Key Research Personnel compliance.

Prior to Lahey's expenditure of any funds under a PHS-funded research project, the Institutional FCOI Official or designee will initiate the following in accordance with 42 CFR Part 50.604[f]:

- a. Review all Investigator / Research Personnel disclosures of SFI, determine whether any SFI relate to the PHS-funded research, determine whether a FCOI exists; and, if so
- b. Develop and implement a FCOI management plan that specifies the actions to manage the FCOI, which may include the following conditions or restrictions:
 - (1) public disclosure of FCOIs (e.g., when presenting or publishing the research

or by addendum to previous presentations or publications); (2) for human subjects research projects, disclosure of FCOI directly to participants; (3) appointment of an independent monitor to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; (4) modification of the research plan; (5) change of Research Personnel or Research Personnel responsibilities, or disqualification of Research Personnel from participation in all or a portion of the research; (6) reduction or elimination of the financial interest (e.g., sale of an equity interest); and (7) severance of relationships that create financial conflicts.

Whenever an Investigator / Research Personnel who is new to the PHS-funded research project discloses a SFI, or an existing Investigator / Research Personnel discloses a new SFI, Lahey's Institutional FCOI Official or designee will, within 60 days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement (on at least an interim basis) a FCOI management plan that specifies the actions to manage such FCOI.

Depending on the nature of the SFI, Lahey may impose additional interim measures regarding the Investigator's / Research Personnel's participation in the PHS-funded research project between the date of disclosure and completion of its review.

Whenever Lahey identifies a SFI that was not disclosed timely by an Investigator / Key Research Personnel or was not previously reviewed by Lahey during an ongoing PHS-funded research project (e.g., SFI was not reviewed timely or was not reported by a Subrecipient), the Institutional FCOI Official or designee will, within 60 days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement (on at least an interim basis), a FCOI management plan that specifies the actions to manage such FCOI;

Retrospective Review

Whenever a FCOI is not identified or managed in a timely manner because of failure by (a) the Investigator / Research Personnel to disclose a SFI that is determined by Lahey to constitute a FCOI, (b) Lahey to review or manage such a FCOI, or (c) the Investigator / Research Personnel to comply with a FCOI management plan: Lahey will, within 120 days of determining noncompliance, complete a retrospective review of the Investigator's / Research Personnel's activities and PHS-funded research project to ascertain whether any PHS-funded research (or portion thereof) conducted during the period of noncompliance was biased in its design, conduct, or reporting.

Lahey will document the retrospective review, which will include (but not limited to) the following key elements: Project Number; Project Title; Principal Investigator (PI) or contact information for PI if a multiple PD/PI model is used; Name of the Investigator / Research Personnel with the FCOI; Name of the Entity with which the Investigator / Research Personnel has a FCOI; Reason(s) for the retrospective review; Detailed description of methodology used for the retrospective review (e.g., review process and methods, review panel members, documents reviewed); Review Findings; and Review Conclusions.

Depending on the results of the retrospective review, Lahey will update the previously submitted FCOI report, and specify the actions to manage such FCOI.

Mitigation Report

If bias is found during the retrospective review, Lahey will promptly notify and submit a mitigation report to the PHS Awarding Component.

- a. The mitigation report will include (at a minimum): (1) key elements documented in the retrospective review; (2) description of the impact of the bias on the research project, and Lahey's plan to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm); (3) qualitative and quantitative data to support any actual or future harm; and (4) analysis of whether the research project is salvageable. Thereafter, Lahey will submit FCOI reports annually depending on the nature of the FCOI, Lahey may impose additional interim measures regarding the Investigator's / Research Personnel's participation in the PHS-funded research project between the date that the FCOI or the Investigator's / Research Personnel's noncompliance is determined and completion of its retrospective review.

Lahey will monitor Investigator / Research Personnel compliance with the FCOI management plan on an ongoing basis until the completion of the PHS-funded research project.

Remedial Actions

If an Investigator's / Research Personnel's failure to comply with Lahey's FCOI Policy or management plan appears to have biased the design, conduct, or reporting of the PHS funded research, Lahey will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

The PHS Awarding Component will consider the situation and take appropriate action (or refer the matter to Lahey for further action), which may include directions on how to maintain appropriate objectivity in the PHS-funded research project.

The PHS Awarding Component and/or U.S. Department of Health and Human Services (HHS) may inquire before, during, or after the PHS-funded research award into any Investigator / Research Personnel disclosure of financial interests and Lahey's review of and response to such disclosure (i.e., regardless of whether the disclosure resulted in Lahey's determination of a FCOI).

- a. Lahey will submit to or permit onsite review of all records related to compliance with 42 CFR Part 50 Subpart F. The PHS Awarding Component and HHS will maintain the confidentiality of all records of financial interests to the extent permitted by law.

- b. On the basis of its review of available records or other information, the PHS Awarding Component and/or HHS may decide that a FCOI will bias the objectivity of the PHS-funded research to an extent that further corrective action is needed or that an Institution has not managed the FCOI in accordance with 42 CFR Part 50 Subpart F.
- c. The PHS Awarding Component and/or HHS may impose special award conditions (in accordance with 45 CFR 74.14 and 92.12), or suspend funding or take other enforcement action (in accordance with 45 CFR 74.62 and 92.43) as necessary until the matter is resolved.

In cases in which the PHS Awarding Component and/or HHS determines that a PHS funded project of clinical research to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator / Research Personnel with a FCOI, which was not reported or managed by an Institution, the Institution will require the Investigator / Research Personnel to disclose the FCOI in each public presentation of the research and to request an addendum to previously published presentations.

Records Retention

Lahey will maintain records relating to (a) Investigator / Research Personnel disclosures of financial interests; (b) Lahey's review of and response to such disclosures (whether or not a disclosure was a FCOI); and (c) management actions implemented under Lahey's FCOI Policy, for at least three (3) years from the date of the final expenditures report submitted to the PHS Awarding Component (or from other dates specified in 45 CFR 74.53[b] and 92.42 [b] for different situations, where applicable).

Public Accessibility

Before expending any funds under a PHS-funded research project, Lahey will ensure public accessibility (via a publicly accessible website or written response to any requestor within five [5] business days) of information concerning any SFI disclosed to Lahey that meets the following three criteria: (a) the SFI was disclosed and is still held by the Investigator / Research Personnel; (b) Lahey determines that the SFI is related to the PHS-funded research; and (c) Lahey determines that the SFI is a FCOI.

The information that Lahey makes available via a publicly accessible website or written response will include (at a minimum) the following:

- a. Investigator's / Research Personnel's Name; Investigator's / Research Personnel's Title and Role in the research project; Name of the Entity in which the SFI is held; Nature of the Significant Financial Interest (SFI); and
- b. 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 financial interest's value cannot be readily determined by reference to public prices or other reasonable measures of fair market value.

Lahey will update (at least annually) this information on its publicly accessible website.

Lahey will update its website within 60 days of receipt or identification of information concerning any additional SFI of the Investigator / Research Personnel for the PHS-funded research project that was not previously disclosed, if Lahey determines that the SFI is related to the PHS-funded research and is a FCOI.

Lahey will update its web site within 60 days upon the disclosure of a SFI of Investigator / Research Personnel new to the PHS-funded research project if Lahey determines that the SFI is related to the PHS-funded research and is a FCOI.

Lahey's website will note that the information provided is current (i.e., as of the date listed) and will be updated on at least an annual basis and within 60 days of Lahey's identification of a new FCOI.

In written responses to requestors submitting written requests, Lahey will note that the information provided is current (i.e., as of the date of the correspondence) and is subject to updates on at least an annual basis and within 60 days of Lahey's identification of a new FCOI (which should be subsequently requested by the requestor in writing). Information concerning SFI will remain available for posting via Lahey's publicly accessible website or for responding to written requests for at least three (3) years from the date of the most recent update.

