
PROTOCOLS FOR DISCLOSURE AND MANAGEMENT OF CONFLICTS OF INTEREST

PROTOCOL STATEMENT

Lipscomb University (“Lipscomb”) remains a responsible steward of grants and cooperative agreements by ensuring that Investigators remain objective in the design, conduct, and/or reporting of Research. Lipscomb University consistently applies the standards and training requirements of [Title 42 CFR 50 Subpart F](#) across externally funded grants and unfunded Research projects.

PURPOSE

The purpose of these protocols is to promote objectivity in Research by establishing uniform standards that provide a reasonable expectation that the design, conduct, and/or reporting of Research and sponsored programs will be free from bias resulting from FCOIs. These protocols apply a consistent process for affected individuals to disclose any real or perceived COI, as well as the Management of disclosed conflicts that have the potential to affect or influence individuals or programs.

APPLICABILITY

These protocols are applicable to all Investigators, including students, faculty, staff, administrators, S/KP, and other individuals or entities engaged in the design, conduct, and/or reporting of Research and sponsored programs at or with Lipscomb.

DEFINITIONS

Acronyms used in these protocols have the following meanings, which may be further defined below:

AOR means Authorized Organizational Representative.

CFR means Code of Federal Regulations.

COI means Conflict of Interest.

CRO means the Lipscomb Chief Research Officer, which is the Associate Provost of Research and Graduate Studies and serves the role of the *Institutional Official* as identified in [Title 42 CFR 50 Subpart F](#).

FCOI means Financial Conflict of Interest.

HHS means the U.S. Department of Health and Human Services.

NIH means the National Institutes of Health.

ORG means the Lipscomb Office of Research and Grants.

PHS means the Public Health Service of HHS, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health. The PHS comprises all agency divisions of HHS, including:

- Administration for Children and Families;
- Administration on Aging;
- Agency for Healthcare Research and Quality;
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Centers for Medicare and Medicaid Services;

- Federal Occupational Health;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- NIH;
- Substance Abuse and Mental Health Services Administration; and
- Public Health Service Commissioned Corps.

PI/PD, specific to these protocols, means a Principal Investigator or Project Director of a PHS-funded Research project. The definition of S/KP includes any and all PI/PDs under [Title 42 CFR 50 Subpart F](#).

RCR means Responsible Conduct of Research.

SFI means Significant Financial Interest.

S/KP means Senior/Key Personnel.

U.S.C. means United States Code.

Capitalized terms used in these protocols have the following meanings:

Disclosure of SFIs means an Investigator's disclosure of SFIs to Lipscomb.

Financial Conflict(s) of Interest or *FCOI* means an SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

FCOI Report means Lipscomb's report of an FCOI to a PHS Awarding Component or other agency.

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

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Lipscomb, and as defined in these protocols, which may include for example: activities such as 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 means the PI/PD and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage or *Management* means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

PHS Awarding Component means the organizational unit of the PHS that funds the Research that is subject to [Title 42 CFR 50 Subpart F](#).

Research means, specific to these protocols, 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 these protocols, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel or *S/KP* means the PI/PD and any other person identified as S/KP by Lipscomb in the grant application, progress report, or any other report submitted to the PHS by Lipscomb under these protocols.

Significant Financial Interest or *SFI* means:

- A financial interest 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:
 - An *SFI* exists with regard to any publicly traded entity if the value of any remuneration received from the entity in the 12 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;
 - An *SFI* exists with regard to any non-publicly traded entity, if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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; 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 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.
- The term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Lipscomb to the Investigator if the Investigator is currently employed or otherwise appointed by Lipscomb, including intellectual property rights assigned to Lipscomb and agreements to share in royalties related to such rights; 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; 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.

PROTOCOLS AND PROCEDURES

Responsibilities of ORG

Protocols and Procedures. It is the responsibility of ORG to ensure that Lipscomb's protocols remain up-to-date (in accordance with the regulations in [Title 42 CFR 50 Subpart F](#)), are enforced, and are

publicly available on the ORG website. If Lipscomb's or ORG's website becomes unavailable, ORG shall make its written protocols available to any requestor within five business days of a request.

Dissemination. ORG shall inform Investigators within the campus community of: (i) Lipscomb's protocols; (ii) the Investigator's responsibilities regarding Disclosure of SFIs; and (iii) the regulations outlined in [Title 42 CFR 50 Subpart F](#). ORG shall disseminate this information through a variety of mechanisms, which may include, without limitation:

- New faculty or Investigator orientation;
- Opening meetings;
- RCR training;
- Personal or one-on-one meetings/training;
- Email, newsletters, or other electronic correspondence; and
- Online at the ORG website.

Certification. ORG shall serve as the approved institutional office responsible for certifying compliance with [Title 42 CFR 50 Subpart F](#) and its COI protocols to funding agencies.

Training.

FCOI Training. ORG requires that each PHS Investigator complete FCOI training (currently located at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>) and submit certification of completion to ORG prior to engaging in Research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- Lipscomb revises its protocols in any manner that affects the requirements of Investigators;
- Lipscomb hires a new Investigator;
- ORG identifies that an Investigator is not in compliance with these protocols; or
- In any other circumstance required by HHS or the CRO. Non-PHS Investigators and other S/KP may complete Lipscomb RCR training, collaborative institutional training initiative training, and/or FCOI training to comply with training requirements.

NIH Recipients. In alignment with [NOT-OD-25-133](#) (July 17, 2025) and subsequent [NIH Grants Policy Statement](#) updates, all Lipscomb Investigators, co-Investigators, and other S/KP engaged in NIH awards or pass-through awards are required to complete Lipscomb training in COI, at the frequency prescribed by ORG, to ensure correct reporting of all active or pending support. This requirement may extend to awards from other agencies, including but not limited to the U.S. National Science Foundation, the Department of Energy, and the Department of Defense. ORG will notify each Lipscomb Investigator of specific training requirements; however, it is the responsibility of the Investigator to notify all subrecipients and S/KP of their requirement to complete training.

Annual Training. To ensure that all current and pending proposals are disclosed appropriately to the Federal government, including those disclosed at the time that any proposal is submitted by an AOR, Lipscomb requires that any faculty and/or researcher identified as a S/KP in any federal or federal flow-through proposal receive annual training provided by the ORG. This training complies with NIH policy [NOT-OD-25-133](#) to provide a holistic training to researchers regarding their requirements to disclose Research activities, affiliations (both current and pending), and international relationships. Such training may be included within Lipscomb's annual Responsible Conduct of Training calendar or provided individually as needed by any S/KP.

Subrecipients. ORG will utilize institutional subrecipient agreement form(s) to ensure that appropriate subrecipients comply with these protocols and the regulations enacted in [Title 42 CFR 50 Subpart F](#). Subrecipients shall certify, as part of any Lipscomb subaward agreement, that their protocols governing PHS- and non-PHS supported grants and cooperative agreements comply with [Title 42 CFR 50 Subpart F](#). If a subrecipient cannot provide such certification, subrecipient Investigators shall be subject to these protocols (and Lipscomb's required reporting deadline(s)) that are directly related to the subrecipient's work for Lipscomb which shall generally be reported to a PHS Awarding Component prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Record Access for PHS Projects. Prior to the expenditure of any funds under a PHS-funded Research project, Lipscomb shall, under the direction of the CRO, ensure public accessibility, via a publicly accessible website (which shall be updated at least annually and within at least 60 days of the identification of any new FCOI) or written response to any requestor within five business days of a request, of information concerning any SFI disclosed to the Lipscomb that meets the following three criteria:

- The SFI was disclosed and is still held by the S/KP;
- Lipscomb determines that the SFI is related to the PHS-funded Research; and
- Lipscomb determines that the SFI is a FCOI. The information will include, at a minimum, the following: the Investigator's name, title, and role with respect to the Research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, utilizing the following ranges:
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - \$20,000-\$100,000 by increments of \$20,000;
 - \$100,000 or more 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.

Responsibilities of CRO

Identification of the CRO. The Lipscomb official designated to solicit and review disclosures of SFI from each Investigator planning to participate in, or is participating in, any Research or sponsored program shall be the Associate Provost of Research and Graduate Studies and CRO:

Dr. Trace Hebert
Associate Provost for Research and Graduate Studies
Office of Research and Grants, Chief Research Officer (CRO)
Phone: 615.966.5325
Email: tshebert@lipscomb.edu

SFIs. The CRO shall, 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 shall specify the actions that have been, and will be, taken to Manage such FCOIs. Depending on the nature of the SFI, the CRO may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date of disclosure and the completion of the review.

CRO shall be responsible for determining whether an Investigator's SFI is related to PHS-funded Research and whether the SFI is a FCOI. An Investigator's SFI is related to PHS-funded Research when the CRO reasonably determines that the SFI could be affected by the PHS-funded Research or is in an entity whose FCOI could be affected by the Research. An FCOI exists when the CRO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research. Lipscomb upholds the same standard for non-PHS grants.

Managing and Enforcing FCOIs. The CRO is responsible to take such actions as necessary to Manage and enforce FCOIs, including any FCOIs of a subrecipient Investigator. Management of an identified FCOI requires development and implementation of a Management plan and, if necessary, a retrospective review and a mitigation report pursuant to [Title 42 CFR § 50.605\(a\)](#).

Management and Enforcement Plan. The CRO is empowered with the authority to implement a COI Management plan. Based on the disclosure and additional information provided by Investigators, the CRO may impose restrictions, including but not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing the Research);
- For Research projects involving human subjects Research, disclosure of FCOI 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 FCOI;
- 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;
- Reduction or elimination of the FCOI; or
- Severance of relationships that create(s) any such FCOIs.

Retrospective Reviews. Whenever the CRO identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS-funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the CRO shall, 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 Management plan that shall specify the actions that have been, and will be, taken to Manage such FCOI going forward. In addition, whenever a FCOI is not identified or Managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI, Lipscomb shall, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. The CRO's retrospective review documentation will include, but not necessarily be limited to:

- The PHS award project number;
- Project title;
- PI/PD or contact PI/PD if a multiple PI/PD model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- 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.

If appropriate, the CRO shall update any previously submitted FCOI Report(s), specifying the actions, including interim actions, that will be taken to Manage the FCOI going forward. If bias is found, the CRO is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS funding agency. The mitigation report will 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 Lipscomb'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; and analysis of whether the Research project is salvageable).

Reporting. Prior to the expenditure of any funds under a PHS- or non-PHS funded Research project, the CRO shall provide required initial and ongoing FCOI Reports to PHS or other funding agencies and make information available, promptly upon request, relating to any Investigator disclosure of FCOI and Lipscomb's review of, and response to, such disclosure, whether or not the disclosure resulted in the Lipscomb's determination of a FCOI. However, should a FCOI be eliminated prior to the expenditure of externally awarded funds, Lipscomb shall not submit an FCOI Report to the awarding entity. Submitted FCOI Reports shall include:

- The award project number;
- PI/PD or contact PI/PD if a multiple PI/PD model is used;
- Name of the entity with which the Investigator has a FCOI;
- The entity with which the Investigator has an FCOI;
- The nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- The value of the Financial Interest, utilizing the following ranges:
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - \$20,000-\$100,000 by increments of \$20,000;
 - \$100,000 or more 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;
- A description of how the Financial Interest relates to the funded Research and the basis for Lipscomb's determination that the Financial Interest conflicts with such Research; and
- A description of the key elements of Lipscomb's Management plan, including:
 - Role and principal duties of the conflicted Investigator 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 agreement to the Management plan;
 - How the Management plan will be monitored to ensure Investigator compliance; and
 - Other information as deemed appropriate by the CRO.

Recordkeeping. The CRO shall maintain records relating to all Investigator disclosures of Financial Interests and Lipscomb's review of, and response to, such disclosures (whether or not a disclosure resulted in Lipscomb's determination of an FCOI) and all actions under these protocols or retrospective review, if applicable, for at least five years (or longer, as may be required by State of Tennessee pass-through requirements) from the date the final expenditures report is submitted to

the funding agency or, where applicable, from other dates specified in [45 CFR § 75.361](#) for different situations. Such records shall include any records made available on Lipscomb's website pursuant to disclosures noted below.

Responsibilities of Investigators.

Initial Disclosure. Each Investigator who is planning to participate in any funded Research is required to disclose to the CRO the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for externally funded Research.

Disclosures shall utilize the attached Financial or Significant Financial COI Disclosure Form and contain details of the disclosure sufficient to ensure that a transparent record is available. Disclosures of any financial compensation for travel must, at a minimum, include: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; (iv) the duration; and (v) any and all remuneration and the purpose of remuneration (e.g., honoraria, and reimbursement for travel).

Annual Disclosure for Awarded Investigators. Each Investigator who is participating in any funded Research is required to submit an updated Disclosure of SFIs at least annually, as prescribed by ORG, during the period of the award. Such disclosure shall include any information that was not disclosed initially or in a subsequent Disclosure of SFIs (e.g., any FCOI identified on a PHS-funded project that was transferred from another Institution) and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Updated Disclosures. Each Investigator who is participating in any funded Research must submit an updated Disclosure of SFIs within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Compliance with Directives. Investigators are required to comply with directives issued by the CRO with regard to COIs.

Open (Public) Disclosure. In any case in which the CRO or funding agency determines that a PHS-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 with a FCOI that was not Managed or reported by Lipscomb as required by [Title 42 CFR 50 Subpart E](#), Lipscomb requires the Investigator to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations to disclose such interests.

CONFLICT

These protocols are subject to applicable law. In the event of a conflict between the provisions of these protocols and applicable law, including, without limitation, [Title 42 CFR 50 Subpart E](#), the provisions of applicable law shall control.

FORMS

Financial or Significant Financial COI Disclosure Form (attached)
Financial or Significant Financial COI Management Plan (attached)

CONTACT

For additional information or questions regarding these protocols, contact the Office of Research and Grants, which can be reached at 615.966.5907.

EFFECTIVE DATE

These protocols were approved by the Office of the Provost on February 9, 2026.



FINANCIAL or SIGNIFICANT FINANCIAL COI DISCLOSURE FORM

This form is required to be submitted to ORG: (i) for each Investigator conducting Research or submitting a proposal to PHS or other funding entities; (ii) annually (during the period of the award) for each Investigator participating in any externally funded Research; and (iii) within 30 days of discovery of any real or perceived COI. This form shall disclose COIs for the Investigator and his/her spouse and children. Any questions about the completion of this form shall be directed to the Office of Research and Grants. Pages may be added as needed. This form is subject to the terms of the Lipscomb University's Protocols for Disclosure and Management of Conflicts of Interest (the "Protocols"), and capitalized terms used in this form have the definitions set forth in the Protocols.

Investigator Information	
Name: INSERT	Title: INSERT
Dept: INSERT	College: INSERT
Email: INSERT	Phone: INSERT
Proposed or Current Funding Entity	
Funding Entity: INSERT	
Title of Proposal: INSERT	
Award Number: INSERT	
Period of Performance: INSERT	
PI/PD or Contact PI/PD: INSERT	
Entity Information	
The Investigator, spouse, or dependent children have no real or perceived FCOI with the project.	
The Investigator has a real or perceived financial conflict interest with:	
Entity Name: INSERT	
Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium):	
INSERT	
Value of Financial Interest (or a statement that the interest has a value which cannot be readily determined through reference to public prices or other measures of fair market value):	
INSERT	
A description of how the Financial Interest relates to the PHS-funded Research and the basis for the Institution's determination that the Financial Interest conflicts with such Research	
INSERT	

Assurances:

By signing below, I certify that the provided information is current, accurate, and complete to the best of my knowledge. This includes, but is not limited to, information regarding foreign (including Foreign Government Talent Recruitment Programs) and domestic conflicts. By signing below, I acknowledge and agree that I may be subject to prosecution and liability pursuant to federal regulations regarding misrepresentations and/or omissions in disclosure.

Signature: _____

Date: _____



FINANCIAL or SIGNIFICANT FINANCIAL COI MANAGEMENT PLAN

This form is required to be completed by ORG for the Management of Investigator-disclosed conflicts of interest. This form is subject to the terms of the Lipscomb University's Protocols for Disclosure and Management of Conflicts of Interest (the "Protocols"), and capitalized terms used in this form have the definitions set forth in the Protocols.

Investigator Information	
Name: INSERT	Title: INSERT
Dept.: INSERT	College: INSERT
Email: INSERT	Phone: INSERT
Proposed or Current Funding Entity (as applicable)	
Funding Entity:	INSERT
Title of Proposal:	INSERT
PHS Award Number:	INSERT
Period of Performance:	INSERT
PI/PD or Contact PI/PD:	INSERT
Investigator with the FCOI:	INSERT
Entity with which the Investigator has a financial conflict of interest, and role and principal duties of the conflicted Investigator in the Research project:	
INSERT	
Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium):	
INSERT	
Value of the Financial Interest (utilizing the following ranges: \$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:	
INSERT	
Description of how the Financial Interest relates to the PHS-funded Research and the basis for the Institution's determination that the Financial Interest conflicts with such Research:	
INSERT	

Upon thorough review, the CRO requires the following conditions of the Management plan (check all that apply):

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
- For Research projects involving human subjects Research, 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;
- Reduction or elimination of the Financial Interest;
- Severance of relationships that create(s) any such financial conflict(s);
- Other (Identify): **INSERT**

The CRO has designed the following Management plan safeguard objectivity in the Research project:

INSERT

The CRO will ensure that the Management plan will be monitored to promote Investigator compliance:

INSERT

The CRO includes other information specific to this Management plan, as appropriate:

INSERT

Affirmations:

Investigator: By signing below, the Investigator affirms his/her agreement to comply, in full, with the Management plan implemented by the CRO.

Printed Name: **INSERT** _____

Signature: _____

Title: **INSERT** _____

Date: **INSERT** _____

Chief Research Officer:

Printed Name: **INSERT** _____

Signature: _____

Title: **INSERT** _____

Date: **INSERT** _____