



University of Cape Town Lung Institute (Pty) Ltd
[hereinafter Lung Institute]
Policy on Conflict of Interest and Disclosures of interests to be made

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Policy summary

1. Every staff member must make a full declaration of his or her financial interests and fiduciary roles and those of his or her immediate family members on appointment to the Lung Institute. These disclosures must be updated annually and may need to be updated at the start and/or the conclusion of a research project as well.
2. In any situation where a potential conflict of interest may arise, the person involved must withdraw from processes and decisions.
3. Every staff member must declare any past or present special relationship(s) with another staff member or an applicant for a post at Lung Institute that may have a bearing on his or her work.

Rationale and purpose

This policy and these procedures are necessary because they promote good governance and objectivity. These are also necessary because the Lung Institute's Code of Conduct requires them, and because the public (including research funding agencies) have a legitimate expectation that the Lung Institute will both conduct and be seen to conduct its affairs (including all research) with integrity and objectivity.

All members of committees, all other Lung Institute staff members, including academic researchers and in particular members of management, are elected and appointed to serve the interests of the Lung Institute. This makes them trustees for the benefit of the Lung Institute and the public the Lung Institute serves. It results in an obligation to fulfil responsibilities in a manner consistent with this situation. All work and decisions of members of committees, staff, managers and office bearers, is to be made solely on the basis of a desire to promote the best interests of the Lung Institute.

The Lung Institute must protect the integrity of the academic process and provide an environment in which all may reach their full potential, and in which all Lung Institute members may perform at the highest levels of competence, integrity, and security. This *inter alia* requires objectivity in research.

The Lung Institute recognises that staff may be involved in the affairs of other institutions and organisations, or have their own professional or business careers. This can be beneficial to the Lung Institute. Provision must be made, however, to deal with the potential, or perceived, conflicts of interest that may arise.

The significance and implications of such conflicts, potential or real, vary and include nepotism. At worst, there could be substantial detrimental effects for the Lung Institute, including litigation, loss of sponsorship, embarrassment and public criticism. On the other hand, circumstances surrounding potential conflict may be so inconsequential, or present such a small risk, that, on striking a balance, the implications of such conflict are wholly outweighed by the potential benefits to be derived.

A staff member is not to be discouraged from accepting an appointment which could bring a conflict of interest into being; however any such appointment/role must be openly disclosed and any resulting conflict appropriately managed, as described in this policy. In the final evaluation, it is the best interests of the Lung Institute that matter. All conflicts of interest declared will be considered with balance, fairness, integrity and transparency.

Policy applicable to

- Members of committees;
- All staff of the Lung Institute (where the Lung Institute as employer makes deductions for UIF contributions).
The policy applies on appointment as well as annually when declarations are updated.
- Researchers undertaking research at LUNG INSTITUTE and/or under a LUNG INSTITUTE contract, grant, or other award.
- Honorary staff including honorary research staff.
- Members of, or assessors in, disciplinary tribunals.

Definitions

(These definitions are offered as a guide to interpreting the policy, but are not all embracing.)

Term	Definition
Conflict of interest	<p>A conflict between the private interests (financial, fiduciary, personal or other) of an individual and the official responsibilities of the individual in a position of trust.</p> <p>In addition to his or her decision-making role as a committee member, or his or her position at the Lung Institute, an individual may have financial or fiduciary interest in a professional practice, firm, partnership, company, business, trusteeship or other organisation. This interest may give rise to a conflict as may the financial or fiduciary interest of a close family member such as a spouse or dependent child.</p>
Fiduciary	Relating to or involving a confidence or trust.
Family and special relationships	<p>For purposes of conflicts of interest reporting and disclosure, family relationships exist among “immediate family”, including spouses, parents, siblings, children and/or any other relative who resides in the same household as the individual subject to conflicts of interest disclosure and reporting requirements.</p> <p>Special relationships may include, but are not limited to: current and past friendships, romantic relationships; sexual relationships, kinship; or contractual (i.e. where some form of agreement exists between two parties which may, for example, include nomination of a beneficiary or evidence that the relationship is of a long term nature built upon mutual dependency and trust such as a joint bank account, joint ownership of property, or long term cohabitation); and relationships with a history of serious interpersonal conflict.</p>
Financial interest	<p>Financial interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., shares, share options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); recent sponsored or reimbursed travel (within 12 months), excluding travel that is reimbursed or sponsored by a national, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. For reporting purposes, relevant financial interests extend to the interests of the spouse (if any) and dependent children (if any) of a person making a financial disclosure.</p> <p>Exclusions: For reporting purposes, the term does not include salary, royalties, or other remuneration from LUNG INSTITUTE, income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities, income from service on advisory committees or review panels for public or non-profit entities.</p>
Recuse	To disqualify oneself as a judge in a particular case; to remove oneself from participation to avoid conflict of interest.
Researcher (or investigator, or research investigator)	A person, including a project director, principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of academic and/or scholarly research. The term is intended to be inclusive of collaborators and consultants, as well as persons identified as senior/key personnel in an application for funding, protocol, progress report, or other documentation associated with a research project or study.

Significant financial interest	<p>With regard to any <u>publicly traded</u> 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 R50, 000.</p> <p>Equity interests need not be declared where they are less than five per cent of the equity of the entity.</p> <p>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;</p> <p>With regard to any non-publicly traded entity (such as a privately-held business), 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 R50,000, or when the researcher (or the researcher's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);</p> <p>Significant financial interests further include intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</p> <p>For reporting purposes, the term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Lung Institute to a currently employed or otherwise appointed person, including intellectual property rights assigned to Lung Institute and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement funds, as long as the person does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a national, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a national, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.</p>
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Note: The ORI is the Office for Research Integrity.

Policy details

1. **Every committee member must make a full declaration of his or her business and financial interests and fiduciary roles and those of his or her immediate family members as required by the Lung Institute's Code of Conduct, and this policy on appointment. These disclosures must be made annually.**
2. **Every staff member must make a full declaration of his or her business and financial interests and fiduciary roles and those of his or her immediate family members on appointment to the Lung Institute. These disclosures must be updated annually. This must be done in writing.**
 - 2.1. In the course of carrying out duties for the Lung Institute, staff members must notify the Lung Institute of any conflict-or possible conflict of interest before the Lung Institute procures any goods or services from the staff member or an organisation within which the staff member holds an interest.
 - 2.2. Should a staff member fail to disclose a conflict of interest, any person may inform of the conflict of interest of which that person may be aware.
3. **Researchers, especially Principal Investigators (PIs), have special obligations to make full declarations of any**

financial interest in general and in particular when involved or intent to be involved in any U.S. federally funded project, and if in doubt must consult the office of the Manager of the Office of Research Integrity (ORI).

- 3.1. Investigators must undertake and retain documentation of training in financial conflicts of interest. Training must be completed prior to engaging in research, and at least once every four years thereafter for the duration of the investigator's affiliation(s) with Lung Institute. In addition, training is separately required when Lung Institute revises its policy or procedures in a manner that impact investigators and following any determination of an investigator's noncompliance with the Lung Institute's policy or a management plan associated with a disclosed conflict of interest.

Training options provided by the Office of Research Integrity (ORI) shall include the free tutorial available at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in its most recent version or successor.

- 3.2. Investigators must, unless they have already done this as staff, and before commencing a research project or—in the case of funded research—prior to the date of an application or submission for funding, declare any business, commercial or financial activities undertaken for significant financial gain that may raise a conflict or a possible conflict of interest with sponsors or entities affected by the research. The research contract, grant, or award may require a new disclosure form and may also require disclosure by all study participants, whether these are staff or not. In such cases the onus is on the PI to ensure that these disclosures are made.
- 3.3. All financial disclosures must be updated at the start of a research project during the period of the award or research project, either on an annual basis or as new significant financial interests arise.
- 3.4. The Lung Institute Management and the Office of Research Integrity (ORI) are to play a special role in monitoring and managing research-related conflicts of interest by keeping records and reporting to funders on steps taken to manage conflicts of interest. Lung Institute Management are designated to review all investigator disclosures of significant financial interests, and ORI staff to review all other conflicts of interest associated with research; Lung Institute Management and/or ORI will determine whether any significant financial interests relate to funded research and/or whether other conflicts of interest exist; if so, they will, respectively, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such conflict(s) of interest.
 - 3.4.1. Regardless of whether or not a disclosure results in the final determination of a financial conflict of interest, Lung Institute Management will maintain records relating to all Investigator disclosures of financial interests, reviews thereof, response thereto, and all actions under Lung Institute's policy or retrospective review, if applicable, for a period specified by the research funder or at least three years from the date on which a final expenditures report is made, whichever is later.
 - 3.4.2. Prior to Lung Institute's expenditure of any external research funds, the designated Lung Institute official(s) shall, consistent with Section 7, "Procedures" of this policy: 1) review all disclosures of significant financial interests; 2) determine whether any significant financial interests relate to funded research; 3) determine whether a financial conflict of interest exists; if so, 4) 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; and 5) issue reports as appropriate or required to funders.
 - 3.4.3. For any financial conflict of interest previously reported by Lung Institute with regard to an ongoing funded research project, Lung Institute shall by request, requirement, or regulation provide to the funder an annual report that addresses the status of the conflict of interest and any changes to the management plan. Lung Institute will further endeavour to provide reports in accordance with the time and manner specified by the funder. Lung Institute shall do so for the duration of the funded research project, indicating whether the conflict of interest is being managed or explaining why the conflict of interest no longer exists.
- 3.5. When the Lung Institute carries out sponsored research through sub-grantees, contractors, or collaborators, Lung Institute Management or ORI must take reasonable steps to ensure that investigators working for such entities comply with any applicable conflict of interest requirements, either by requiring those investigators to comply with this policy or by requiring the entities to provide assurances that their own policies are consistent with this policy or the policy of applicable external authorities (such as Title 42, US Code of Federal Regulations (CFR), Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which [Public

Health Service (PHS)] Funding is Sought"). An institution receiving a sub-contract, sub-grant, or other sub-award from Lung Institute shall:

- 3.5.1. Execute a written agreement that establishes whether the Lung Institute policy or the conflict of interest policy of the subrecipient institution will apply to the subrecipient-investigators.
 - 3.5.1.1. If the subrecipient-investigators are obligated to comply with the subrecipient institution's conflicts of interest policy, the subrecipient institution shall certify as part of its agreement with Lung Institute that its policy is consistent with Lung Institute's policy and/or regulatory requirements applicable to Lung Institute as the awardee of research funding. If the subrecipient institution cannot provide such certification, the agreement shall state that subrecipient investigators are subject to Lung Institute's policy for disclosing conflicts of interest and, specifically, significant financial interests that are directly related to the subrecipient's work associated with the funded research;
 - 3.5.1.2. If the subrecipient-investigators must comply with the subrecipient institution's conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Lung Institute. Such time period(s) shall be sufficient to enable Lung Institute to provide timely reports, as may be necessary to research funders;
 - 3.5.1.3. Alternatively, if the subrecipient-investigators must comply with Lung Institute's policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all investigator disclosures of significant financial interests to Lung Institute. Such time period(s) shall be sufficient to enable the awardee institution to comply timely with its review, management, and reporting obligations consistent with this policy.
- 3.5.2. Provide reports to Lung Institute regarding all conflicts of interest of all subrecipient-investigators consistent with this policy, notably prior to the expenditure of funds, and within sixty (60) days of any subsequently identified conflict of interest.
- 3.6. Lung Institute Management shall certify, when required by a sponsor, that there is a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from a sponsor.
- 3.7. Prior to Lung Institute's expenditure of any funds awarded by a sponsor, Lung Institute Management or ORI will report to the sponsor the existence of a conflicting interest if there is one (but not the nature of the interest or other details) and assure the sponsor that the interest has been managed, reduced or eliminated in accordance with this policy to protect the research from bias. This will be done within sixty days of the conflict of interest being identified. Any conflict of interest that emerges subsequent to its initial report will be similarly managed and reported.
- 3.8. Where applicable Lung Institute Management or ORI will ensure compliance with the legal requirements regarding conflicts of interest of any country from which funds are received. Compliance will include, for example, filing annual reports as may be required by funder and/or regulation to specify whether a conflict is managed or to explain why a potential or perceived conflict of interest does not or no longer exists. Lung Institute will honor applicable reporting requirements such as those specifying timeliness of reports to, for example, coincide with annual research progress reports also due to a funder or periods applicable (e.g. 60 days) to reports for new investigators or the occurrence of new, reportable significant financial interests.
- 3.9. Lung Institute Management or ORI must report any identified conflicts of interest between a researcher and a research project/research funder, and the steps taken to manage the conflict, to the Lung Institute Research Committee and with appropriate communication and coordination with the Managing Director.
- 3.10. Lung Institute shall ensure public accessibility to information, via a page of its publicly accessible website such as a page administered and updated at least annually by the ORI, for all disclosures made by a researcher and/or related to research projects that present an identifiable conflict of interest. The accessibility standard shall apply to: A significant financial interest disclosed and retained by Lung Institute researchers as defined by this policy;

and a significant financial interest identified by Lung Institute to be related to funded research that is retained by Lung Institute researchers.

3.10.1. Lung Institute will make the following information publicly accessible: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; the approximate financial value of the significant financial interest (R0-R49,999; R50,000-R99,999; R100,000-R199,999; amounts between R200,000-R1,000,000 by increments of R200,000; amounts above R1,000,000 by increments of R500,000), 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.

3.10.2. The web page will be updated within sixty days of the receipt or identification of information concerning any additional significant financial interest of the researchers engaged in a funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of researchers new to a funded research project, if Lung Institute determines that the significant financial interest is related to the funded research and is a financial conflict of interest. The web page shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. The web page shall record the information for at least three years from the date that the information was most recently updated, or three years from the final reporting of the conflict to Lung Institute.

4. In any situation where a potential conflict of interest may arise, the person involved must withdraw from processes and decisions.

4.1. A member of Lung Institute Management or of staff with a conflict of interest is obliged to recuse himself or herself (immediately withdraw) from the situation which is linked to the conflict, or during the discussion of the matter and the voting thereon.

4.2. Researchers are required to postpone further research activities and/or investigative work where a conflict of interest is identified, pending clearance by Lung Institute Management/ORI.

4.3. Conflicts of interest situations reported to, taken into account or otherwise considered by Lung Institute Management shall be recorded, with adequate particulars, in the minutes of Lung Institute Management or of the committee concerned.

5. A staff member may not conduct business directly or indirectly with the Lung Institute unless three conditions laid down in the have been met. In particular a staff member may not in his or her official capacity contract, or propose a contract between himself/herself in his/her private capacity and the Lung Institute. Only Lung Institute Management may sanction contracts between Lung Institute and an entity in which a staff member has a direct or indirect interest.

5.1 Only Lung Institute Management may sanction a staff member's contract that entails or may entail a conflict of interest with the Lung Institute.

5.2 Lung Institute Management may do so when the contract meets the following criteria:

- (i) the goods, products or services in question are unique;
- (ii) the supplier is a sole provider; and
- (iii) it is in the best interest of the Lung Institute.

5.3 Each case has to be considered on its merits, with a full record of all the matters considered and the reasons for arriving at the decision in question.

5.4 One outcome of Lung Institute Management's consideration is that there is in fact no conflict or one of such triviality that it should be disregarded. However, a staff member may only remain in the situation which gave rise to a conflict of interest when Lung Institute Management has made the assessment above and he or she is notified by Lung Institute Management to stay or, having withdrawn, to return.

- 5.5 Where a committee (or other body) holds Lung Institute Management-delegated power to act, and the committee is of the opinion that a transaction should be entered into notwithstanding a conflict of interest, no final decision shall be taken by the committee. Instead, the decision concerned shall take the form of a recommendation to Lung Institute Management supported by a report fully explaining the conflict concerned, and furnishing reasons for its recommendation, indicating how the conflict of interest shall be managed.
- 5.6 Where, in the case of a matter dealt with directly by Lung Institute Management, Lung Institute Management reaches a decision to the same effect this shall be recorded.
- 5.7 Conflicts of interest must be managed in such a way as to reduce or eliminate the conflicts identified. Conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
- (i) Limiting participation in committee discussions to supplying of relevant information without any further participation in the proceedings;
 - (ii) Public disclosure of significant financial interests;
 - (iii) Monitoring of processes, decisions and research by independent reviewers;
 - (iv) Modification of processes and research plans;
 - (v) Disqualification from participation in all or a portion of processes and research projects
 - (vi) Divestiture of significant financial interests;
 - (vii) Severance of relationships that create actual or potential conflicts; or
 - (viii) In the case of tenders, bids, or propositions, ensuring that procedures take all such precautions as may be necessary to ensure that the Lung Institute Management member, committee member or staff member is not accorded any advantages over other competing parties.

6. Every staff member must declare any special relationships with another staff member or a student that may have a bearing on his or her work.

- 6.1. A staff member who has or had a special relationship to, or with, a student with whom he or she has job-related interaction, shall disclose the relationship to the Head of Department, or senior line manager. The HOD or senior line-manager shall keep a confidential written record of this and report this to the Managing Director. A Head of Department or senior line-manager who has a special relationship with a student shall disclose this to the Managing Director, who shall keep a confidential record of this. A Managing Director in such a position will disclose this to the Board of Directors.
- 6.2. The HOD, senior line-manager, Managing Director shall take whatever steps are necessary to ensure that conflicts of interest that arise through special relationships are disclosed and that the academic process is not compromised, that fairness in access to resources, opportunities and/or services is not damaged, and that bias, or perceptions of bias are avoided.
- 6.3. Steps taken to manage special relationships shall be similar to that of a situation of conflict of interest, where the staff member is required to withdraw from processes and decisions concerning a student. For example, no member of the academic staff may supervise the research of a student with whom he or she has a special relationship.
- 6.4. A member of staff who has or had any special relationship to, or with, a member of staff or job applicant in the department or section of which he or she is a member shall disclose the relationship to the Head of Department or Managing Director. In the case of a Head of Department who has a special relationship with a member of staff or job applicant the relationship must be reported to the relevant Managing Director, or Lung Institute Management.
- 6.5. A member of staff who serves on a selection committee and has any special relationship to, or with, a member of staff or job applicant who is the subject of discussion of the committee, shall disclose the relationship to the Chair of the committee. A Chair of a committee who has any special relationship to, or with, a member of staff or job applicant who is the subject of discussion of the committee shall disclose the information to the relevant senior authority.

Procedures

7. Procedure for new staff on appointment

7.1 A new staff member completes a Disclosure Form (UCTLI report form) which is submitted with other HR forms on appointment.

7.2 HR scans the Disclosure Form (UCTLI report form) and stores it digitally.

7.3 Procurement reviews the Disclosure Form (UCTLI report form) digitally and lists those entities (companies, CCs, trusts, partnerships) in which a staff member or a Lung Institute Management or Committee member has an interest, and makes this list available.

7.4 A disclosure made by a researcher and/or related to a research project is forwarded to the Director of Lung Institute Management if the research is supported by a grant, contract or other source of funding, and to the ORI when the conflict relates to other commitments of research and/or teaching.

8. Procedure for Lung Institute Management members and members of Lung Institute Management committees

8.1 The Board requires each Lung Institute Management member and each Lung Institute Management committee member to make a full disclosure on appointment, and annually before the first Lung Institute Management meeting of each year.

8.2 The Business Manager arranges for scans of these and (a) retains them; and (b) makes them available to Procurement; and (c) informs the Lung Institute Management and relevant Chairs of Committees of all declared interests.

8.3 The Business Manager maintains the register of declared interests and has it available at all Lung Institute Management meetings.

9. Procedures for new conflicts of interest and annual updates of all declarations

9.1 Conflicts of Interest Disclosures will be updated annually as part of the HR department's annual data verification exercise. The Business manager will be accountable for doing this. In the execution of this duty, the Business Manager will ensure that information on Lung Institute's financial conflicts of interest policy is broadly and effectively conveyed to all persons from whom disclosures are required, and that responsibilities regarding disclosure of significant financial interests are specified in accordance with applicable laws, regulations, and Lung Institute policies.

9.2 When there has been a change in information, staff must complete and submit a new Disclosure Form within thirty (30) calendar days of the occurrence of the change.

9.3 If a staff member discovers or acquires (e.g., through purchase, marriage, or inheritance) a new significant financial interest, he or she must complete and submit a new Disclosure Form within thirty (30) calendar days of the occurrence of the change.

9.4 Changes to information are routed as per steps 7 above.

9.5 For any significant financial interest that is reported to and/or identified by Lung Institute as conflicting subsequent to initial disclosures for ongoing funded research project Lung Institute shall inform the research funder, within sixty (60) days, and ensure that the conflict is accommodated or otherwise resolved through a management plan or other responsive action.

9.6 Whenever Lung Institute implements a management plan pursuant to this policy, Lung Institute shall monitor compliance with the management plan on an ongoing basis until the completion of the project or other activity that presents the conflict of interest, or the conflict of interest itself no longer exists, whichever shall occur first.

10. Access to conflict of interest declarations

Disclosure forms are accessed via a secure web interface, after sign on with Lung Institute credentials. Only authorised members of the HR department and Procurement can access these records.

Failures of Disclosure and Untimely and/or Incomplete Disclosures, and Retrospective Reviews

11. Failure to disclose a conflict of interest, or to adhere to a management plan for a conflict of interest

- 11.1. A failure to disclose an interest, to do so in a timely and complete manner, and/or to adhere to a management plan for a disclosed conflict of interest is subject to discipline in accordance with Lung Institute Employee Relations: Disciplinary Procedures
- 11.2. In the context of research, a failure to an interest, and a conflict of interest in particular, to do so in a timely and complete manner, and/or to adhere to a management plan is a violation of Lung Institute Policy and actionable thereunder. In addition, if the failure of an Investigator to comply with either Lung Institute's policy or a conflict of interest management plan appears to have biased the design, conduct, or reporting of research, Lung Institute shall promptly notify any funders of the research about the occurrence of the noncompliance as well as corrective actions taken or to be taken in response.
- 11.3. In the event that a research funder determines that a research 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 financial conflict of interest that was not managed or reported by the Institution as required by this policy, Lung Institute may, in its sole discretion or as required by grant, contract, law, regulation, or other authority, compel the Investigator 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.
- 11.4. In the event that Lung Institute identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed and/or appropriately managed (e.g., was not reviewed or reported by a subrecipient in a timely manner), Lung Institute may be required to complete a retrospective review to determine whether any funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, Lung Institute may be required to promptly notify the research funder and to submit a mitigation report.

12. Retrospective Reviews

- 12.1. Whenever Lung Institute identifies a significant financial interest in the context of a research project that was not disclosed timely by a researcher or, for whatever reason, was not previously reviewed during an ongoing funded research project (e.g., was not timely reviewed or reported by a subrecipient), then Lung Institute shall, through Lung Institute Management and/or ORI, and within sixty days:
 - 1) review all disclosures of significant financial interests;
 - 2) determine whether any significant financial interests relate to funded research;
 - 3) determine whether a financial conflict of interest exists; if so,
 - 4) 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; and
 - 5) issue reports as appropriate or required to funders.
- 12.1.1. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner Lung Institute shall, within 120 days of the determination of nondisclosure and noncompliance with this policy, complete a retrospective review of the researcher's activities and funded research project(s) to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Circumstances that merit a retrospective review include, but are not limited to, 1) failure by the researcher to disclose a significant financial interest that is later determined by Lung Institute to constitute a financial conflict of interest; 2) failure by Lung Institute to review or manage such a financial conflict of interest; or 3) failure by the researcher to comply with a financial conflict of interest management plan.
- 12.1.2. Documentation for a retrospective review shall include, but not necessarily be limited to, all of the following: Project number; Project title; PI or contact PI if a multiple PI model is used; Name of the

researcher who possesses a significant financial interest; Name of the entity with which the Investigator has a financial conflict of interest; Reason(s) for the retrospective review; Methodology 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.

- 12.2. Based on the results of a retrospective review, and if appropriate and/or required, Lung Institute shall update any report previously submitted to a funder, specifying the actions that will be taken to manage going forward any retrospectively identified conflict of interest. In the context of research, if bias is found to be associated with a retrospectively identified conflict, Lung Institute will promptly notify any funder(s), develop a mitigation plan that may include additional notifications to, for example, publishers, and submit mitigation reports as may be required by standards and expectations for the responsible conduct of research, grant or contract, and/or regulation. A 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 Lung Institute'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, Lung Institute shall manage a retrospectively identified conflict of interest as specified elsewhere in this policy. Depending on the nature of the conflict of interest, Lung Institute may determine that additional interim measures are necessary.