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THE AURUM INSTITUTE NPC

SPONSORED RESEARCH FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURES



**THE AURUM
INSTITUTE**

Policy Information

Policy Status: Approved

Maintained by: Grant Management

The signatures below certify that this document has been reviewed and accepted and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensure their provision.

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INTRODUCTION

1. The Aurum Institute NPC (“the Company”) is a not-for-profit public benefit organisation which conducts, transformational research and designs, tests and implements health systems and programs for people with HIV and TB and their communities in both the private and public sectors. New knowledge is disseminated through literature and other media.
2. The Company is responsible for maintaining objectivity in research by ensuring that the design, conduct, and reporting of research are not biased by conflicting financial, equity or intellectual property interests of Investigators responsible for Sponsored Research.

SCOPE

3. This Policy applies to any of the Company’s Sponsored Research, more specifically any Research Projects funded by any US (Federal) Government (USG) Agency or Office of the United States Public Health Service (PHS), which includes but is not limited to, Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and United States Agency for International Development (USAID).
4. This Policy applies to all Investigators of all subsidiaries, affiliates, countries, business units, business divisions, departments of the Aurum Group and its Subrecipients (when applicable).
5. The Company Official is responsible for ensuring implementation of this Policy and may suspend all relevant activities until the Financial Conflict of Interest (COI) is resolved or other action deemed appropriate by the Company Official is implemented.
6. Violation of any part of this Policy may also constitute cause for disciplinary or other administrative action pursuant to Company Policies.
7. This Policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize a COI, more specifically to research funded under USG Awards, and must respond appropriately when a COI arises.
8. This Policy informs Investigators about situations that generate COI related to Sponsored Research, provides mechanisms for Investigators and the Company to manage those COI that arise, and describes situations that are prohibited.
9. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of COI arises, an Investigator should discuss the situation with the Company Official.

IMPLEMENTATION OF THE POLICY

10. Related policies and manuals that were in force prior to the commencement of this policy are replaced with effect from this Policy’s Effective Date.

PURPOSE OF THE POLICY

11. The purpose of the Policy is to:
 - 11.1. promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of Sponsored Research will be biased by an Investigator’s COI; and
 - 11.2. ensure compliance with applicable Award’s Rules and/or Regulations so that all potential COI are disclosed to the Company and that the Company manages, reduces,

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or eliminates these COI so there is a reasonable expectation that the Sponsored Research is unbiased and the public trust is preserved.

DEFINITIONS AND ABBREVIATIONS

Definitions

12. **Award:** Shall mean any Proposal that the Company has submitted for funding, that is successful and receives a grant or contract, legal instrument, for funding from a Donor/Prime Grantee to implement Sponsored Research.
13. **Aurum Group:** Shall mean the group of companies and organisations consisting of the following legal entities:
 - 13.1. The Aurum Institute NPC (incorporated in South Africa);
 - 13.2. The Aurum Institute South Africa NPC (incorporated in South Africa);
 - 13.3. The Aurum Institute Ghana (incorporated in Ghana);
 - 13.4. Fundação Aurum (incorporated in Mozambique);
 - 13.5. The Aurum Institute Eswatini (incorporated in Eswatini);
 - 13.6. Aurum Institute Lesotho Pty (incorporated in Lesotho);
 - 13.7. The Aurum Institute USA (incorporated in Washington DC, United States of America);
 - 13.8. Aurum Institute Europe Foundation (incorporated in Switzerland);
 - 13.9. Aurum Innova (Pty) Ltd (incorporated in South Africa);
 - 13.10. Global Health Innovations (Pty) Ltd (incorporated in South Africa); and
 - 13.11. Youth Health Africa NPC (incorporated in South Africa).
14. **Clinical Trial:** Shall mean any Research Project that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.
15. **Company:** Shall mean the Aurum Group.
16. **Company Official:** Shall mean the individual within the Company that is responsible for the review of disclosures of COI including those of the Investigator's Family related to the Investigator's Company responsibilities. For the purposes of this Policy, the Company Official is designated as the Group Chief Operating Officer (GCOO), or his/her duly authorised designee.
17. **Company responsibilities:** Shall mean the Investigator's professional responsibilities associated with his or her Company appointment or position, such as research, teaching, clinical activities, administration, and Company internal and external professional committee services.
18. **Conflict of Interest Committee (COI Committee):** Shall mean the Company's Committee or designated individual that advises the Company Official on COI matters. For the purposes of this Policy, the COI Committee consists of:
 - 18.1. Group Chief Financial Officer (GCFO);
 - 18.2. Group Chief Scientific Officer (GCSO); and
 - 18.3. Company Secretary.

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19. **Conflict(s) of Interest (“COI”)**: Shall mean a Significant Financial Interest (SFI) (or, where the Company Official requires disclosure of other Financial Interests, a Financial Interest) that the Company reasonably determines could directly and significantly affect the design, conduct or reporting of Sponsored Research.
20. **Contract**: Shall mean a mechanism used by a Donor to provide funding for Research (Sponsored Research) and development Projects. Unlike a Grant or CoAg though, a Donor uses Contracts as a procurement mechanism whereby the products and/or related services required, when required, can be procured without the need for dealing with traditional procurement delays.
21. **Cooperative Agreement (CoAg)**: Shall mean a legal agreement between a Donor and any other entity, which occurs when the Donor transfers something of value, usually money, to a State Government, Municipality or Private Company for a public purpose. A CoAg is distinguished from a Grant in that it provides for substantial involvement between the Donor and the Company in carrying out the Project-related activities approved by the Donor.
22. **Donor and/or Awarding Agency**: Shall mean any Agency or Organisation who has awarded and/or is providing the funding to implement a Project.
23. **Family**: Shall mean any member of the Investigator’s immediate family, specifically, any dependent children and/or spouse.
24. **Financial Interest**: Shall mean anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.
 - 24.1. Financial Interest does NOT include:
 - 24.1.1. salary, royalties, or other remuneration from the Company;
 - 24.1.2. income from the authorship of academic or scholarly works;
 - 24.1.3. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for Donor, state or local governmental agencies; Higher Education Institutions (HEIs); research institutes, academic teaching hospitals, and medical centers; or
 - 24.1.4. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
 - 24.2. **For Investigators, Financial Interest**, also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Company responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by Donor, state or local governmental agencies; Higher Education Institutions (HEIs); research institutes, academic teaching hospitals, and medical centers.
25. **Grant**: Shall mean one of the Donor’s mechanisms for funding ideas and Projects to provide public services, stimulate the economy, and benefit the general public. Grants can be awarded for a wide-variety of activities, including but not limited to innovative research, recovery initiatives and infrastructure building.

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26. **Investigator:** Shall mean any individual who is responsible for the design, conduct, or reporting of Sponsored Research, or Proposals for such funding. This definition is not limited to those titled or budgeted as Principal Investigator or Co-Investigator on a particular Proposal and/or Project, and may include Key Personnel such as Postdoctoral Associates, Senior Scientists, or Graduate Students. The definition may also include Subrecipients, Contractors, Subcontractors, Collaborators, Partners or Consultants as appropriate. For help in determining whether an individual meets the definition of an Investigator, please refer to the *COI Determination of Investigator Status Checklist* attached hereto marked *Annexure A*.
27. **Officers of the Company:** Shall mean the Officers of the Company authorised per the Board Resolution and/or the Delegation of Authority (DoA), (POL GOV 010).
28. **Partner(s):** Shall mean any Organisation that has been included in a Proposal and/or Project as a Subrecipient under a Subaward with the Company.
29. **Pass-Through Entity:** Shall mean the Prime Recipient and/or Grantee Organisation that provides funds to a third party to perform substantive work and/or provide required products and/or services to carry out part of the Project.
30. **Policy:** Shall refer to this/the Sponsored Research Conflict of Interest Policy and Procedures.
31. **Project:** Shall mean any programme and/or services to be implemented and aligns with the Company's Strategic Plan and Business Investment Strategy.
32. **Proposal:** Shall mean the development of any proposed Project documentation to apply for and/or secure funding to implement the proposed Project.
33. **Research:** shall mean a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioural 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).
34. **Rules and/or Regulations:** Shall mean the guidelines, rules and regulations of the Donor/Sponsor/Prime Grantee providing the funding for the implementation of the Project through an Award.
35. **Significant Financial Interest (SFI):** Shall mean a financial Interest that reasonably appears to be related to the Investigator's Company responsibilities, and remuneration and equity/ownership interests of the Investigator and/or Investigator's Family as defined in the Table 1 below.
 - 35.1. **Significant Financial Interest (SFI)** does not include:
 - 35.1.1. Salary, royalties, or other remuneration from the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
 - 35.1.2. Income from investment vehicles (e.g., mutual funds, retirement accounts) so long as the Investigator does not directly control the investment decisions made in these vehicles;
 - 35.1.3. Any ownership interests in an entity if the entity is an applicant under the USG Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs;
 - 35.1.4. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; and
 - 35.1.5. Income from service on advisory committees or review panels for public or non-profit entities.

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Table 1: Financial Interest

Type of entity	Type of Financial Interest	Value
Publicly traded entity	Any remuneration, including but not limited to:	Totaling \$5,000 or more in the preceding twelve months alone or in aggregate with equity interest in the same entity
	Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)	
Non-publicly traded entity	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Totaling \$5,000 or more (as determined through reference to public prices or other reasonable measures of fair market value) alone or in aggregate with other remuneration received from the same entity
	Any remuneration, including but not limited to:	Totaling \$5,000 or more in the preceding twelve months
	Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)	
N/A	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Any amount
	Intellectual property right and interests (e.g., patents, copyrights, and royalties from such rights)	Any amount
Any entity that is not a federal, state, or local government agency; an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education	<ul style="list-style-type: none"> Reimbursed travel Sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact 	Any amount

36. **Sponsored Research:** Shall mean any Research Project funded by a Donor.
37. **Subaward:** Shall mean the contract, legal instrument, between the Company as the Prime Grantee/PTE and the Subrecipient(s) relating to the Project Award.
38. **Subrecipient:** Shall mean any Organisation that receives a Subaward from a Prime Grantee/PTE to implement a Project in accordance with the terms and conditions of such a contract.
39. **US Public Health Service (USPHS or PHS):** Shall mean a collection of agencies of the [Department of Health and Human Services](#) (HHS) concerned with public health, containing nine out of HHS's twelve operating divisions.

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
GCEO	Group Chief Executive Officer
GCFO	Group Chief Financial Officer
GCOO	Group Chief Operating Officer
COI	Conflict of Financial, Equity and/or Intellectual Property Interest(s)
DoA	Delegation of Authority
FDA	Food and Drug Administration
GCEO	Group Chief Executive Officer
GCFO	Group Chief Financial Officer
GCSO	Group Chief Scientific Officer
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
NIH	National Institutes of Health
NPC	Not for Profit Company
PDF	Portable Document Format
PHS	United States Public Health Service
SBIR	Small Business Innovation Research program
SFI	Significant Financial Interest(s)
STTR	Small Business Technology Transfer program
TB	Tuberculosis
USAID	United States Agency for International Development
US	United States of America
USG	United States (Federal) Government

RELEVANT LEGISLATION AND CORPORATE GOVERNANCE PRINCIPLES

40. Strict controls and good corporate governance principles are set out and adhered to by the Company. This Policy has been compiled in compliance with all relevant legislation and good governance principles.
41. Any interactive mechanism or contract with government, industry or other private or public agencies or parties must provide a stated benefit to the Company's missions of instruction, research or service.
42. The interactive mechanism or contract must be in concurrence with the mission and policies of the Company.
43. The rights and interests of both parties must be fully recognized. All arrangements will, as far as is reasonably possible, be governed by a principle of fairness.
44. The Company must at all times require that the highest ethical and professional standards are followed in the implementation of all its Awards.
45. The Company's staff will be fully informed of these principles of interaction, will have participated in the formulation of related Company policies, and will know their responsibilities if they become involved.
46. This Policy must be implemented and aligned with the following USG Rules and/or Regulations, as amended from time-to-time:
 - 46.1. PHS Policies on Research Misconduct ([42 CFR Part 93](#))
 - 46.2. Promoting Objectivity in Research ([42 CFR Part 50 Subpart F](#));
 - 46.3. Responsible Prospective Contractors ([45 CFR Part 94](#));

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- 46.4. [HHS Office of Research Integrity \(ORI\) Policies](#);
- 46.5. [HHS Grants Policy Statement](#); and
- 46.6. [NIH Grants Policy Statement](#).

MANAGEMENT OF THE POLICY

- 47. The GCOO of the Company is mandated by the GCEO to act as custodian of this Policy. However, full accountability and responsibility lies with the GCEO.
- 48. The provisions of this Policy shall be strictly followed at all times, subject to paragraph 50 below.
- 49. In the event that a need or intent to deviate from this Policy is envisaged, a written document must be prepared stating the nature and the reasons for the proposed deviation and submitted to the GCOO for consideration and approval as per the DoA.

ROLES AND RESPONSIBILITIES

GCOO

- 50. Mandated by the GCEO to act as custodian of this Policy and therefore is responsible for the control, implementation and compliance of this Policy together with GCEO.
- 51. To approve this Policy and ensure implementation of the approved Policy.
- 52. To periodically review the Policy for approval in terms of the Company's Policy Framework.

GCEO

- 53. Is the custodian of this Policy and therefore ultimately responsible for the control, implementation and compliance of this Policy.
- 54. Must appoint an independent and impartial person (appointed person) for the resolution of any disputes, objections, complaints and queries arising as a result of this Policy.
- 55. Assist the appointed person to perform his/her functions effectively.
- 56. Ensures compliance and knowledge of its elements and for taking immediate and appropriate corrective actions where warranted.

Company Secretary

- 57. Ensuring access to PDF copies of all signed COI Disclosure Forms and Management Plans for all Investigators of the Company.
- 58. Ensuring the original signed COI Disclosure Forms and Management Plans are filled for safe keeping.
- 59. Ensuring compliance and knowledge of its elements and for taking immediate and appropriate corrective actions where warranted.

All Business and/or Operational Directors, Project/Programme Managers and Grants Management Staff

- 60. Are assigned with the responsibility for implementing this Policy.
- 61. Assisting the GCOO with periodic reviews and updates to this Policy, when applicable.
- 62. Ensuring compliance and knowledge of its elements.

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KEY PRINCIPLES

Training

63. Each Investigator must complete training on COI, the Investigator's responsibilities regarding disclosure and the applicable Donor Rules and/or Regulations before Sponsored Research funding and activities commence, and at least every 4 (four) years thereafter.
64. All other Investigators (such as students and technicians) must also complete training on this Policy before Sponsored Research funding and activities commence, and at least every 4 (four) years thereafter.
65. Investigators serving as Principal Investigators, Co-Principal Investigators, Co-Investigators or Project Directors must complete training on COI before any new Proposal is submitted to a Donor.
66. Additionally, under the following circumstances, training must be completed by Investigators within 30 (thirty) days of the occurrence:
 - 66.1. The Company revises this Policy in any manner that affects the requirements of the Investigators;
 - 66.2. When an Investigator newly affiliated with the Company has an existing Research Project he/she will be continuing at the Company;
 - 66.3. When a new Investigator begins work on an ongoing Research Project at the Company; and
 - 66.4. The Company finds that an Investigator is not in compliance with this Policy or a prescribed COI Management Plan related to their activities.

SUBRECIPIENT REQUIREMENTS

67. When Sponsored Research, for which the Company is the Prime Recipient/Grantee/PTE, includes a Subrecipient Investigator (an individual whose primary affiliation is with an entity other than the Company) - whether a Subgrantee, Contractor, Subcontractor, Consultant or Collaborator - the Subrecipient Investigator is also subject to Donor's COI Rules and/or Regulations.
68. To ensure compliance, the Subrecipient must certify in writing whether the Subrecipient's Investigators will follow this Policy of the Company or the Subrecipient's own COI policy.
69. The Subaward issued by the Company to the Subrecipient under any Award for Sponsored Research, must include the following COI Certification clause:
"Promoting Objectivity in Research (COI):
Subrecipient must designate herein which entity's Conflict of Interest Policy (COI) will apply: [PTE or Subrecipient (select the applicable entity)].
 - *If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Awarding Agency as identified herein: [insert relevant Awarding Agency Name and Policy Reference/Link].*
 - *If applying PTE's COI policy, by execution of this Subaward, Subrecipient's Investigators under the Award must submit a completed and signed COI Disclosure to PTE upon signature of the Subaward, irrespective of whether or not there is a COI, and within 30 days of any subsequently identified COI. The PTE's COI Policy and COI Disclosure form are annexed hereto marked Annexures [insert the COI Policy Annex Number] and [insert the COI Disclosure form Annex Number].*

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Subrecipient shall report any conflict of interest to PTE's Grants Management Department by submitting the required completed and signed COI Disclosure form via email to grantsmanagement@auruminstitute.org.

Any conflicts of interest identified shall, when applicable, subsequently be reported to the relevant Awarding Agency by PTE. Such reports shall be made before expenditure of funds authorised in this Subaward and within 30 business days of any subsequent potential and/or identified COI."

70. The Company's staff serving as Subrecipient Investigators on Sponsored Research are subject to this Policy; in such a case, the Company Investigators are required to submit a completed and signed COI Disclosure under the following circumstances:
 - 70.1. before the submission deadline of a Proposal by a Prime Grantee (an entity other than the Company applying for funding as a Prime Applicant) to a Donor for Research funding, and must be submitted to the applicable GMS for inclusion in the Proposal documentation submission to the Prime Grantee and to the Company's COI Committee;
 - 70.2. before signature of any Subaward per 70.1 above, if a COI has arisen since the Proposal submission by the Prime Grantee, and must be submitted the applicable GMS for submission to the Prime Grantee with the signed Subaward and to the Company's COI Committee;
 - 70.3. within 30 business days of any subsequent potential and/or identified COI, and must be submitted to the applicable GMS for submission to the Prime Grantee and to the Company's COI Committee.
71. Subrecipient Investigators who are subject to the Company's COI Policy must fulfil all requirements for Investigators as described in this Policy, particularly in regard to responsibilities related to the disclosure of COI and COI Training.
72. For Subrecipient Investigators who are subject to their affiliated Company's COI policy, Subrecipient Organisation must report all identified COIs to the Company's applicable GMS as soon as possible following internal review of disclosed COIs and prior to the expenditure of funds. Early reporting will help to ensure timely commencement of funding following an Award. For subsequently identified COIs, the Subrecipient Organisation must provide a COI report to the Company's applicable GMS within 30 business days of when a new COI is discovered or acquired. COI reports made to the Company for Subrecipient Investigators must include the following information:
 - 72.1. Name of the entity with which the Investigator has a COI;
 - 72.2. Nature of the COI (e.g., equity, consulting fees, travel reimbursement, honoraria);
 - 72.3. Value or estimated value of the financial interest;
 - 72.4. Description of how the financial interest relates to Sponsored Research and the basis for the determination that it conflicts with the research; and
 - 72.5. Key elements of the Management Plan:
 - 72.6. Role and principal duties of Investigator in the research project;
 - 72.7. Conditions of the Management Plan;
 - 72.8. How the Management Plan will safeguard objectivity in the research project;
 - 72.9. Confirmation of the Investigator's agreement to the Management Plan;
 - 72.10. How the Management Plan will be monitored to ensure compliance; and

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72.11. Other pertinent information.

73. In the event a Subrecipient Investigator has a COI to report, the Company will provide a Subrecipient COI report with the above information to the Donor and/or Prime Grantee, through the Company's applicable GMS, prior to the expenditure of funds and within 45 business days of any subsequently identified COI.

PROCEDURES

Disclosure Of COI

74. All Investigators are required to disclose their outside financial interests as defined above to the Company on an annual and on an ad-hoc basis, as described below.
75. The COI Committee is responsible for the distribution, receipt, processing, review and retention of disclosure forms, and reporting of any disclosed and/or identified potential, current or future conflicts of interest to the Company Official.
76. The Company Official is responsible for reviewing, managing and reporting any such disclosed and/or identified conflicts of interest to:
- 77. the Company's Audit Committee and Board of Directors;
 - 78. the applicable Donor and/or Prime Grantee via the Company's applicable GMS;
 - 79. the HHS ORI as part of the Company's annual renewal of its Research Misconduct Assurance by submitting a report annually through the ORI website beginning 1 January and no later than 30 April of each year. The Company Official may delegate the responsibility of the ORI submission to any of the Company's GMS.

Annual Disclosures

80. All Investigators must disclose their COI that are related to the Investigator's Company responsibilities to the Company's COI Committee, through the applicable GMS, on an annual basis. The Company Official will then submit a report at least annually to the Company's Audit Committee and Board of Directors. All forms should be submitted to the Company's COI Committee, through the applicable GMS, by no later than 31 January for the current calendar year.

Ad hoc Disclosures

81. In addition to annual disclosure, certain circumstances require ad-hoc disclosure.
82. All Investigators must disclose their COI to the Company's COI Committee, through the applicable GMS, within 30 business days of their initial appointment or employment.
83. Prior to entering into any Sponsored Research or Proposals for Sponsored Research, where the Investigator has a COI, the Investigator must affirm the currency of the annual disclosure or submit to the Company's COI Committee, through the applicable GMS, an ad-hoc updated disclosure of his or her COI with the outside entity. The Company will not submit a Proposal unless the Investigator(s) have submitted such ad-hoc disclosures.
84. In addition, all Investigators must submit to the Company's COI Committee, through the applicable GMS, an ad-hoc disclosure of any COI they acquire or discover during the course of the year within 30 business days of discovering or acquiring the COI.

Travel

85. Investigators must also disclose reimbursed or sponsored travel related to their Company responsibilities, as defined above in the definition of Financial Interest and Significant Financial

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Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Company's COI Committee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes COI with the Investigator's research.

REVIEW AND DECISION OF THE COMPANY OFFICIAL

86. If a disclosure form reveals a COI, it will be referred by the Company's COI Committee for prompt review by the Company Official for a determination of whether it constitutes a COI. If a COI exists, the Company Official will take action to manage the COI, including the reduction or elimination of the COI, as appropriate. The Company Official may consult the Company's COI Committee for guidance in specific cases, or in the application of the Policy to particular situations.
87. A COI will exist when the Company Official determines that a COI could directly and significantly affect the design, conduct, or reporting of Sponsored Research. If the Company Official determines that there is a COI that can be managed, the Company's COI Committee will be instructed to develop and implement a written COI Management Plan. The affected Investigator must formally agree to the proposed management strategies and sign the written COI Management Plan before any related Sponsored Research goes forward.
88. The Company Official and the Company's COI Committee will periodically review the ongoing activity, monitor the conduct of the activities (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the COI Management Plan.

Clinical Trials - Review of COI related to Clinical Trials

89. Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.
90. In the event of non-compliance with reporting and/or management of a COI involving a Clinical trial whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose the COI in each public presentation of the results of the affected Sponsored Research and request an addendum to previously published presentations.

REPORTING TO DONORS AND/OR PRIME GRANTEE

91. The Company Official will report COI or non-compliance to the applicable Donor and/or Prime Grantee in accordance with the applicable Rules and/or Regulations of the Donor and/or Prime Grantee. If the funding for the Research is made available from a Prime Grantee under a Subaward to the Company, such reports shall be made to the Prime Grantee prior to the expenditure of any funds of the Subaward and within 60 business days of any subsequently identified COI such that the Prime Grantee may fulfil their reporting obligations to the applicable Donor.

INVESTIGATOR NON-COMPLIANCE

Disciplinary Action

92. In the event of an Investigator's failure to comply with this Policy, the Company Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or

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other action deemed appropriate by the Company Official is implemented.

93. The Company Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Company Official, will be described in a written explanation of the decision to the Investigator, the Company's COI Committee and, where applicable, the applicable Ethics Committee and/or Institutional Review Board (IRB), and will notify the individual of the right to appeal the decision. The Company will promptly notify the Donor of the action taken or to be taken. If the funding for the Research is made available from a Prime Grantee, such notification shall be made promptly to the Prime Grantee for reporting to the applicable Donor.

Retrospective Review

94. In addition, if the Company Official determines that a COI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Financial Interest that is determined to be a COI, or failure by an Investigator to materially comply with a COI Management Plan, an independent committee appointed by the Company Official will complete a retrospective review of the Investigator's activities and the Sponsored Research to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.
95. Documentation of the retrospective review shall include the project number, project title, principal investigator, name of Investigator with the COI, name of the entity with which the Investigator has the COI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.
96. The Company Official will update any previously submitted report to the Donor and/or Prime Grantee relating to the Research, specifying the actions that will be taken to manage the COI going forward. This retrospective review will be completed in the manner and within the timeframe established in the Award and/or Subaward, or the applicable Rules and/or Regulations. If bias is found, the Company will promptly notify the Donor and/or Prime Grantee and submit a mitigation report in accordance with the applicable Rules and/or Regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

RECORD RETENTION

97. The Company's COI Committee will retain all disclosure forms, COI Management Plans, and related documents for a period of 3 years from the date the final expenditure report of the applicable Project is submitted to the Donor and/or Prime Grantee, unless any litigation, claim, financial management review, or audit is started before the expiration of the 3 year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

CONFIDENTIALITY

98. To the extent permitted by law, all disclosure forms, COI Management Plans, and related information will be confidential. However, the Company may be required to make such information available to the Donor and/or Prime Grantee, to a requestor of information concerning COI related to Donor funding or to the primary entity who made the funding available to the Company, if requested or required. If the Company is requested to provide disclosure forms, COI Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

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PUBLIC ACCESSIBILITY

99. Prior to the expenditure of funds, the Company will publish on a publicly-accessible website or respond to any requestor within 10 business days of the request, information concerning any COI that meets the following criteria:
- 99.1. The COI was disclosed and is still held by the Investigator;
 - 99.2. A determination has been made that the COI is related to Donor-funded Research; and
 - 99.3. A determination has been made that the Financial Interest is a COI.
100. The information to be made available shall be consistent with the requirements of the Donor and/or Prime Grantee's Rules and/or Regulations.

REGULATORY AUTHORITY

101. This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR Part 94, as amended, where there are substantive differences between this Policy and the abovementioned requirements, the requirements shall take precedence.

CONFLICT OF INTEREST DISCLOSURE FORM

102. All disclosures shall be made by using the Conflict-of-Interest Disclosure Form (FRM-GM-001);
103. All completed disclosure forms must be duly dated and signed by the disclosing party; and
104. All completed, dated, and signed disclosure forms must be scanned and submitted as a PDF document to the Company's COI Committee, through the applicable GMS, via email to grantsmanagement@auruminstitute.org, and the original hand delivered to the Company Secretary at the Company's Parktown Head Office for safekeeping.

REPORTING OF NON-COMPLIANCE TO THE POLICY

105. Compliance with the Policy by all Company staff is mandatory.
106. Any practices found to contravene the provisions contained in this Policy will be regarded as unauthorised – and must be halted immediately and must be reported to the GCOO who, if he or she deems it necessary, may report such contravention to the Audit Committee and Board of Directors for further direction. When reporting any non-compliant practice(s) to the above, the exact nature of the non-compliant transactions must be accurately described, as well as the corrective action already taken or to be taken in order to eliminate the non-compliant practice(s) in question in future.
107. In the case of the contravention of this Policy, the Company staff who are found guilty of contravening this Policy will be dealt with in terms of the relevant Human Resources policies and procedures including, where necessary, the Company's Disciplinary policy and Schedule 8 of the Labour Relations Act's Code of Good Practice: Dismissals.

CHANGES TO POLICY

108. This Policy will be periodically reviewed at least every two (2) years. The GCEO and GCOO are the custodians of this Policy. The custodians are ultimately responsible for the control,

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implementation and compliance of this Policy. All changes to the Policy must be approved by the GCOO.

CONCLUSION

109. Responsibility for Policy compliance and monitoring is vested in the Officers of the Company where contracts relate to their portfolio of responsibility.
110. Operational monitoring of contracts is vested in the appointed Business and/or Operational Directors; for the purposes of compliance and for making business decisions based on the performance of contracts.

REFERENCES

- 110.1. PHS Policies on Research Misconduct ([42 CFR Part 93](#))
- 110.2. Promoting Objectivity in Research ([42 CFR Part 50 Subpart F](#));
- 110.3. Responsible Prospective Contractors ([45 CFR Part 94](#));
- 110.4. [HHS Office of Research Integrity \(ORI\) Policies](#);
- 110.5. [HHS Grants Policy Statement](#); and
- 110.6. [NIH Grants Policy Statement](#).

ANNEXURES/FORMS

Forms	Number
COI Determination of Investigator Status Checklist;	Annexure A
COI Disclosure Form	FRM GM 001 A

* All forms are available on SharePoint

REVISION HISTORY

Amendment Record

This document is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual changes, additions or omissions is given below.

Ver #	Approval date	Next Review date	Context	
			Page No.	Significant Changes
1	November 2018	October 2020	1-18	Creation of Policy
2	April 2023	April 2025	1-18	Updates to Abbreviations, Definitions and nomenclature to match Group structure and correction of paragraph and typographical errors.

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ANNEXURE A: COI DETERMINATION OF INVESTIGATOR STATUS CHECKLIST

1. The PHS Conflict of Interest (FCOI) regulation applies to all individuals defined as Investigators. Individuals who qualify as Investigators may extend beyond a project's Principal Investigator(s) and may include Students, Subcontractors, Subgrantees, Consultants, and/or other Collaborators engaged in Sponsored Research.
2. To assist you in determining whether an individual participating in a research project qualifies as an Investigator, use this checklist to determine their status.
3. If you respond "yes" to any of the questions below, the individual fits the definition of an Investigator and is subject to the PHS COI regulation.

Is the individual responsible for the design of the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the individual responsible for the conduct of the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the individual responsible for the reporting of the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the individual responsible for the programmatic outcomes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the individual being compensated with research Award funds?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will the individual be a collaborator on a publication related to the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
For students: Will the student be independently responsible for the design, conduct, or reporting of the research without direct supervision of someone who is an investigator?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

4. Please note that a person's role in a project may change over time and may need to be re-evaluated to determine Investigator status (e.g., in the case of a student involved in a project over an extended period who eventually progresses to a more substantial role).
5. If you have questions about the definition of an investigator or the applicability of this Policy, please contact your applicable GMS or send an email with your question(s) or request for clarification to grantsmanagement@auruminstitute.org.