

	RESEARCH INVESTIGATOR'S FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY			
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1. Purpose

The purpose of this policy is to safeguard the integrity, transparency with privacy, and credibility of research conducted at UGHE by identifying, disclosing, and managing potential financial conflicts of interest (FCOI) among investigators. UGHE is committed to ensuring that research findings are trustworthy and free from undue influence while supporting investigators in engaging ethically with partners, funders, and collaborators. For research funded or proposed for funding by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), this policy implements the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research." UGHE shall maintain and enforce this policy and the associated administrative process to identify, manage, and report Investigator financial conflicts of interest.

2. Scope

This policy applies to all UGHE faculty, staff, and students engaged in research; to investigators who design, conduct, or report research funded by internal or external sources; and to collaborators, consultants, or sub-awardees working under UGHE-administered projects. For purposes of PHS/NIH-funded research, this policy applies to every Investigator who is planning to participate in or is participating in PHS/NIH-funded research, including the PD/PI and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of the research. This may include collaborators and consultants. The PHS/NIH requirements apply to all NIH grants and cooperative agreements except PHS Phase I Small Business Innovation Research and Small Business Technology Transfer applications and awards. UGHE shall also ensure compliance by Investigators of subrecipient institutions as required under 42 CFR 50.604(c).

3. Definitions

- Investigator: Any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research.
- Institutional Responsibilities: An Investigator's professional responsibilities performed on behalf of UGHE, including, as applicable, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- Financial Conflict of Interest (FCOI): A Significant Financial Interest that UGHE, through its designated institutional official(s), reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research.
- Conflict of Interest: A situation in which an investigator's financial, personal, professional, or institutional interests could directly or indirectly compromise, or appear to compromise, their objectivity or integrity in conducting research.
- Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to salary, consulting fees, honoraria, gifts, equity interests, intellectual property rights and interests (e.g., patents and copyrights), upon receipt of income related to such rights and interests, or sponsored travel.
- Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by UGHE in the grant application, progress report, or any other report submitted to the PHS under 42 CFR Part 50, Subpart F.

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- PHS Awarding Component: The organizational unit of the U.S. Public Health Service that funds the research subject to 42 CFR Part 50, Subpart F. For NIH-funded grants and cooperative agreements, this is the applicable NIH awarding Institute or Center.
- Significant Financial Interest (SFI): A financial interest exceeding thresholds defined by UGHE consisting of one or more of the following interests of the Investigator, the Investigator's spouse, and dependent children that reasonably appears to be related to the Investigator's institutional responsibilities (<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F/section-50.603>):
 - **Publicly traded entity:** the aggregate value of remuneration received from the entity during the 12 months preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure exceeds US\$ 5,000.
 - **Non-publicly traded entity:** remuneration received from the entity during the 12 months preceding disclosure exceeds US\$ 5,000, or the Investigator, spouse, or dependent children hold any equity interest, regardless of value.
 - **Intellectual property:** intellectual property rights and interests, including patents and copyrights, upon receipt of income related to such rights and interests.
 - **Reimbursed or sponsored travel:** reimbursed or sponsored travel related to the Investigator's institutional responsibilities, subject to the exclusions and disclosure requirements stated in this policy. At a minimum, the disclosure shall include the purpose of the trip, identity of the sponsor/organizer, destination, and duration. UGHE may request additional information, including the monetary value of the travel, where necessary to determine whether an FCOI exists.
- SFI does not include:
 - salary, royalties, or other remuneration paid by UGHE to an Investigator currently employed or appointed by UGHE, including intellectual property assigned to UGHE and agreements to share royalties;
 - income from investment vehicles such as mutual funds and retirement accounts where the Investigator does not directly control investment decisions;
 - qualifying income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by U.S. federal, state, or local government agencies, U.S. institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with such U.S. institutions, subject to applicable NIH requirements. Financial interests received from institutions of higher education or foreign governments, including local, provincial, or equivalent governmental entities outside the United States, are not excluded solely because the source is a university or government. Such interests must be disclosed when they meet the applicable disclosure threshold.
- UGHE may separately identify and manage non-financial, professional, personal, or institutional conflicts of interest. Such interests are not Financial Conflicts of Interest for purposes of 42 CFR Part 50 Subpart F unless they involve an Investigator Significant Financial Interest meeting the criteria in this policy.

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4. Policy Statement

Investigators must disclose all potential conflicts of interest before engaging in research activities, and no investigator may participate in research under conditions where a significant unmanaged conflict of interest exists. UGHE will review, assess, and manage identified conflicts to ensure research integrity, and failure to disclose or comply with this policy may result in sanctions, including withdrawal of research approval.

5. Disclosure Requirements

All investigators must submit a Financial Conflict-of-Interest Disclosure Form at the time of appointment or onboarding, annually thereafter, and within 30 days of discovering or acquiring a new SFI. Disclosures must include financial interests or any equity interest in non-publicly traded entities, reimbursed or sponsored travel, external commitments, intellectual property income, and close personal relationships relevant to the Investigator's institutional responsibilities.

Each Investigator who is planning to participate in PHS/NIH-funded research must disclose to UGHE's designated institutional official all domestic and foreign SFIs, and those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's institutional responsibilities: (a) no later than the time of application for PHS/NIH-funded research; (b) at least annually during the period of the award; and (c) within 30 days of discovering or acquiring a new SFI.

The annual disclosure shall include any information not previously disclosed and updated information concerning any previously disclosed SFI, including, where applicable, the updated value of a previously disclosed equity interest.

Investigators are responsible for disclosing SFIs that reasonably appear to be related to their institutional responsibilities. UGHE, through its designated institutional official(s), is responsible for determining whether a disclosed SFI is related to PHS/NIH-funded research and, if so, whether the SFI constitutes an FCOI.

Investigators must disclose reimbursed or sponsored travel related to their institutional responsibilities in accordance with this policy. At a minimum, the disclosure shall include the purpose of the trip, identity of the sponsor/organizer, destination, and duration. UGHE may request additional information, including the monetary value of the travel, when necessary to determine whether an FCOI exists. Travel shall be disclosed within 30 days of each occurrence.

6. Review and Management

The Office of Research Administration (ORA) will initially screen disclosures, after which the IGHED Director will review each disclosed SFI and determine:

1. Whether the SFI is related to the PHS/NIH-funded research. An SFI is related when UGHE reasonably determines that the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.
2. If related, whether the SFI constitutes an FCOI. An FCOI exists when UGHE reasonably determines that the

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SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

The Investigator may provide information relevant to relatedness, but the final determination of relatedness and FCOI rests with the IGHER Director.

Review deadlines: Before expenditure of any PHS/NIH funds, UGHE shall review all required Investigator SFI disclosures, determine whether any SFI is related to the funded research, determine whether an FCOI exists, and, where an FCOI exists, develop and implement an appropriate management plan. For an Investigator who joins an ongoing project or for a newly disclosed or newly identified SFI, UGHE shall complete its review within 60 days and, if an FCOI exists, implement at least an interim management plan.

Where a FCOI exists, the IGHER Director will direct on appropriate management strategies. These may include public disclosure in publications or presentations, independent data monitoring and analysis, modification of the research plan and responsibilities, divestment or reduction of the conflicting interest, disclosure of the FCOI directly to human research participants, where appropriate, and severance of relationships creating the conflict; or, if the conflict cannot be managed, prohibition of the research activity. UGHE shall monitor Investigator compliance with the management plan on an ongoing basis until completion of the PHS/NIH-funded research project.

The Director of IGHER is the designated institutional official responsible for reviewing disclosures and determining whether a financial conflict of interest exists. Where the Director of IGHER has an actual or potential conflict of interest in the matter under review, the Director shall be recused and the determination shall be made by an alternate institutional official designated by UGHE who has no conflict concerning the matter and who has authority to perform the responsibilities required under this policy.

7. Training

All investigators must complete financial conflict of interest (FCOI) training prior to participating in UGHE-administered research and must refresh this training every three years. In addition, an investigator must complete FCOI training whenever the institution revises its FCOI policy, when the investigator is new to the institution, or when the investigator has been found noncompliant.

Training covers the federal FCOI regulation for PHS/NIH-funded research project, this UGHE policy, and the Investigator's disclosure responsibilities.

8. Reporting to Sponsors and Regulators

UGHE will comply with all sponsor and regulatory reporting requirements related to investigator FCOI, including disclosure to donors, government bodies, and ethics committees as appropriate.

A. Public Accessibility of FCOI Information

Before expenditure of PHS/NIH funds, UGHE shall make publicly accessible, either through a publicly accessible UGHE website or by written response within five business days of a request, information concerning an SFI where: the SFI was disclosed and is still held by senior/key personnel; UGHE determines that the SFI is related to PHS/NIH-funded research; and UGHE determines that the SFI constitutes an FCOI. Publicly

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accessible information shall include the Investigator's name; title and role with respect to the research project; name of the entity in which the SFI is held; nature of the SFI; and approximate dollar value of the SFI, using the permitted ranges of US\$0–4,999; US\$5,000–9,999; US\$10,000–19,999; amounts between US\$20,000 and US\$100,000 in increments of US\$20,000; amounts above US\$100,000 in increments of US\$50,000; or a statement that the value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

The information shall be updated at least annually and within 60 days of identifying a new reportable FCOI. The website or written response shall state that the information is current as of the date specified and is subject to updates at least annually and within 60 days of UGHE's identification of a new FCOI. Information shall remain publicly available for at least three years from the date it was most recently updated.

B. FCOI Reporting to PHS/NIH

For PHS-funded research, UGHE shall submit required FCOI reports to the applicable PHS Awarding Component. For NIH-funded grants and cooperative agreements, UGHE shall submit required reports to the NIH awarding Institute or Center through the eRA Commons FCOI Module. UGHE shall submit an FCOI report:

- before expenditure of PHS/NIH funds for an identified FCOI;
- within 60 days of identifying an FCOI involving an Investigator who is new to an ongoing project or an FCOI that is newly identified during an ongoing project;
- annually thereafter for the duration of the project, including extensions with or without funds;
- and where required following a retrospective review.

Where UGHE identifies an FCOI and eliminates it before expenditure of PHS-awarded funds, UGHE shall not submit an FCOI report concerning that eliminated FCOI.

Each required FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict and assess the appropriateness of UGHE's management plan.

1. project number;
2. PD/PI or Contact PD/PI where a multiple PD/PI model is used;
3. name of the Investigator with the FCOI;
4. name of the entity with which the Investigator has the FCOI;
5. nature of the financial interest;
6. value of the financial interest using the permitted dollar ranges above, or a statement that its value cannot readily be determined;
7. a description of how the financial interest relates to the PHS/NIH-funded research and the basis for UGHE's determination that the financial interest conflicts with the research;
8. and the key elements of the management plan, including the role and principal duties of the conflicted Investigator; conditions of the management plan; how the plan safeguards objectivity in the research; confirmation of the Investigator's agreement to the management plan; how compliance with the plan will be monitored; and other information as needed.

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For any previously reported FCOI involving an ongoing PHS/NIH-funded research project, the annual FCOI report shall address the status of the FCOI and any changes to the management plan and shall specify whether the FCOI continues to be managed or explain why the FCOI no longer exists.

UGHE's FCOI policy shall be posted on a publicly accessible UGHE website and submitted to NIH through the eRA Commons Institution Profile Module.

9. Subrecipient FCOI Requirements

Every NIH/PHS subaward agreement must specify whether: A. the subrecipient's FCOI policy applies, in which case the subrecipient must certify as part of the written agreement that its policy complies with 42 CFR Part 50 Subpart F and the agreement shall establish a timeframe for the subrecipient to report all identified FCOIs to UGHE sufficiently early to permit UGHE to meet its reporting obligations to the PHS Awarding Component; or B. UGHE's FCOI policy applies, in which case the agreement shall establish deadlines for subrecipient Investigators to submit required SFI disclosures to UGHE sufficiently early for UGHE to meet its review, management, and reporting obligations under this policy.

If a subrecipient cannot certify that its FCOI policy complies with 42 CFR Part 50, Subpart F, the written agreement shall state that the subrecipient Investigators are subject to UGHE's FCOI policy for purposes of disclosing significant financial interests directly related to the subrecipient's work for UGHE.

UGHE shall provide required FCOI reports to the applicable PHS Awarding Component concerning identified FCOIs of subrecipient Investigators prior to expenditure of funds and within 60 days of any subsequently identified FCOI, as applicable.

10. Record Retention

UGHE shall maintain records relating to all Investigator disclosures of financial interests, institutional reviews and determinations, whether or not a disclosure resulted in a determination of an FCOI, management plans, monitoring, FCOI reports, retrospective reviews, mitigation reports, and other actions taken under this policy for at least three years from the date the final expenditures report is submitted to the PHS, or, where applicable, from other dates specified in 2 CFR 200.334.

11. Retrospective Review/Noncompliance

Whenever an FCOI is not identified or managed in a timely manner, including failure by an Investigator to disclose an SFI that UGHE determines constitutes an FCOI, failure by UGHE to review or manage an FCOI, or failure by an Investigator to comply with an FCOI management plan, UGHE shall complete a retrospective review within 120 days of its determination of noncompliance to determine whether the PHS/NIH-funded research, or any portion thereof, conducted during the period of noncompliance was biased in its design, conduct, or reporting.

The retrospective review shall document, at a minimum: project number; project title; PD/PI or Contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the FCOI; name of the entity with which the Investigator has the FCOI; reason(s) for the retrospective review; detailed methodology used for the

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retrospective review, including the methodology of the review process, composition of the review panel or reviewer(s), and documents reviewed; findings; and conclusions.

Based on the results of the retrospective review, where appropriate, UGHE shall update any previously submitted FCOI report to specify the actions that will be taken to manage the FCOI going forward.

If bias is found, UGHE shall promptly notify the applicable PHS Awarding Component and submit a mitigation report. The mitigation report shall include, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project, including the extent of any harm and relevant qualitative or quantitative information, and UGHE's plan of action or actions taken to eliminate or mitigate the effect of the bias.

In addition, if an Investigator's failure to comply with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of PHS-funded research, UGHE shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

Where HHS determines that NIH-funded clinical research evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required, UGHE shall require the Investigator to disclose the FCOI in each public presentation of the research results and request an addendum to previously published presentations.

12. Institutional Certification and Federal Oversight

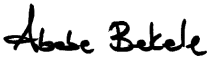
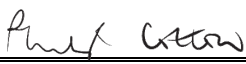
For each application subject to 42 CFR Part 50 Subpart F, UGHE shall certify that it has an up-to-date, written and enforced administrative process to identify and manage FCOIs; promotes and enforces Investigator compliance; manages identified FCOIs and provides required initial and ongoing FCOI reports; will make relevant information available promptly to HHS/NIH upon request; and will fully comply with the requirements of 42 CFR Part 50 Subpart F. UGHE shall promptly provide or permit review of records relevant to compliance when requested by NIH/HHS or other relevant oversight institutions.

13. Sanctions for non-compliance

Non-compliance with this policy may result in suspension of research privileges, removal from research projects, and institutional disciplinary action consistent with UGHE policies.

14. Effective Date and Review

This policy is effective 2 October 2026 and will be reviewed every three years, or earlier if regulatory or institutional needs require.

Approved by	Name	Signature	Date
Academic Commission Chair	Prof Abebe Bekele		October 21, 2026
Vice Chancellor	Prof Philip Cotton		October 21, 2026

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Appendices

Appendix A – Investigator Financial Conflict of Interest Disclosure Form (Template)

University of Global Health Equity (UGHE)

Conflict of Interest Disclosure Form Investigator

Information

- Name: _____
- Department/Unit: _____
- Position/Title: _____
- Project Title: _____
- Sponsor/Funding Source: _____

Section 1: Financial Interests

For purposes of this form, disclose all domestic and foreign financial interests that reasonably appear to be related to your UGHE institutional responsibilities, whether or not you believe the interest is related to a particular research project. UGHE will determine whether a disclosed SFI is related to PHS/NIH-funded research and whether it constitutes an FCOI.

1. Publicly traded entities.

- Do you, your spouse/partner, or dependent children have financial interests in a publicly traded entity where the aggregate value of remuneration received from the entity during the preceding 12 months plus the value of any equity interest in the entity as of the date of disclosure exceeds US\$ 5,000, and the interest reasonably appears to be related to your institutional responsibilities?
- ☐ Yes ☐ No

If Yes, please describe: entity name; person holding the interest; type of remuneration; remuneration received during the preceding 12 months; type and current value of equity interest; and related institutional responsibility.

2. Non-publicly traded entities.

- Do you, your spouse/partner, or dependent children have either: (a) remuneration exceeding USD 5,000 from a non-publicly traded entity during the preceding 12 months; or (b) any equity interest in a non-publicly traded entity, regardless of value, where the interest reasonably appears to be related to your institutional responsibilities?
- ☐ Yes ☐ No

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If Yes, please describe: entity name; person holding the interest; type and amount of remuneration; and/or nature of the equity interest.

3. Other compensation and financial interests

Have you received consulting fees, honoraria, paid authorship, or other compensation that meets the applicable SFI criteria above and reasonably appears to be related to your institutional responsibilities?

- ☐ Yes ☐ No

If Yes, please describe: _____

4. Reimbursed or sponsored travel

Have you received any reimbursed or sponsored travel related to your institutional responsibilities that is required to be disclosed under this policy?

- ☐ Yes ☐ No

If Yes, please describe (for travel, at a minimum describe the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration, and the relationship to institutional responsibilities): _____

Section 2: Intellectual Property

Have you, your spouse/partner, or dependent children received income related to intellectual property rights or interests, including patents or copyrights, that reasonably appears to be related to your institutional responsibilities?

- ☐ Yes ☐ No If Yes, please describe: _____

Section 3: External Commitments

Do you have leadership, board, or advisory roles in organizations that may be related to or affected by your institutional responsibilities or research?

- ☐ Yes ☐ No If Yes, please describe: _____

Section 4: Relationships

Do you have close personal or professional relationships (e.g., spouse, relative, business partner) that may influence or be influenced by your research?

- ☐ Yes ☐ No If Yes, please describe: _____

Certification

I hereby declare that the above information is true and complete to the best of my knowledge. I understand that I am required to submit an updated disclosure at least annually and within 30 days of discovering or acquiring a new Significant Financial Interest as required under this policy.

Signature: _____ **Date:** _____

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Appendix B – Examples of Potential Conflicts of Interest

- **Financial Conflicts**

- Receiving consulting fees or honoraria from a pharmaceutical company whose products are being studied.
 - Holding stock in a biotech start-up that stands to benefit from the research outcomes.

- **Professional Conflicts**

- Serving on the advisory board of an NGO involved in a related clinical trial.
 - Supervising a student while simultaneously serving on the board of the company funding the student's project.

- **Personal Conflicts**

- Having a spouse or family member employed by a sponsor organization.
 - Co-authoring with close relatives without disclosure of the relationship.

- **Institutional Conflicts**

- UGHE having equity interests in a partner organization that funds a project.

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Appendix C – FCOI Review and Management Workflow

Step 1: Disclosure

The investigator submits a FCOI Disclosure Form to the Office of Research Administration (ORA) at onboarding, before application for funding, annually thereafter, or within 30 days of acquiring a new interest.

Example: Dr. A, a UGHE principal investigator on a diabetic retinopathy screening study, discloses that she holds \$8,000 in equity in a company developing an AI-based retinal screening device — the same technology category her study is evaluating.

Step 2: Initial Review

ORA receives and administratively screens the disclosure for completeness. The UGHE Director IGHER, as designated FCOI Institutional Official, makes all determinations of relatedness and FCOI. The Investigator may provide information relevant to the determination; however, the final determination rests with UGHE's designated institutional official.

Example: ORA notes that Dr. A's equity interest exceeds the \$5,000 significant financial interest (SFI) threshold and that the company's technology overlaps directly with her current study's subject matter, this is flagged as a potential COI and escalated to the the Director IGHER rather than simply archived.

Step 3: Assessment

The IGHER Director meets with ORA and reviews the disclosed SFI through the following sequential determinations:

1. **Relatedness:** Whether the SFI is related to the PHS/NIH-funded research. An SFI is related when UGHE reasonably determines that the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.
2. **FCOI determination:** If the SFI is related to the research, whether it constitutes an FCOI. An FCOI exists when UGHE reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

The outcome shall therefore be documented as one of the following:

- SFI not related to the PHS/NIH-funded research – no FCOI
- SFI related to the PHS/NIH-funded research but does not constitute an FCOI; or
- FCOI identified management is required. UGHE shall determine whether the FCOI can be appropriately managed or whether participation must be restricted or prohibited.

The IGHER Director is recused where the Director has a conflict involving the matter under review. In such

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cases, the determination shall be made by the alternate designated institutional official identified by UGHE under this policy.

Example: The IGHHER Director determines Dr. A's equity interest is directly related to her research and could reasonably bias study design or reported outcomes (e.g., favorable results could increase the company's valuation)- but concludes the conflict is manageable given her essential clinical expertise to the study, rather than unmanageable.

Step 4: Management Plan

If an FCOI is identified, the IGHHER Director develops and implements a tailored management plan prior to UGHE's expenditure of any funds under the PHS/NIH-funded research project and ensures public accessibility of FCOI information for qualifying senior/key personnel as required under this policy.

Common management measures include:

- Public disclosure in publications, conference presentations, and grant/donor reports.
- Independent monitor appointed to oversee data collection and analysis, so Dr. A is not solely responsible for outcome interpretation.
- Role reassignment — removing the conflicted investigator from specific functions (e.g., data analysis, patient recruitment, or authorship of conclusions) where bias risk is highest
- Divestment of the financial interest, if feasible and proportionate to the conflict.

Example: The IGHHER Director's management plan for Dr. A includes: (1) disclosure of her equity interest in every publication and presentation from the study; (2) appointment of a co-investigator with no financial interest to independently review and sign off on all outcome data before analysis is finalized; and (3) removal of Dr. A from any role in selecting which screening results get reported as "positive" cases. Divestment isn't required in this case, since the independent monitoring and disclosure measures are judged sufficiently.

Step 5: Monitoring and Compliance

Where an FCOI report is required, the report shall be submitted to the applicable PHS Awarding Component before expenditure of PHS/NIH funds. ORA shall actively monitor Investigator compliance with the management plan on an ongoing basis until completion of the PHS/NIH-funded research project.

Example: ORA schedules a mid-study compliance check confirming the independent co-investigator is signing off on data as required, and Dr. A submits her annual COI update confirming her equity stake and its value are unchanged (or flags any change, such as the company being acquired).

Step 6: Reporting

ORA ensures that the FCOI and its management are reported to all relevant external parties as required. For PHS/NIH-funded research, ORA shall submit initial, annual, revised, and mitigation reports in accordance with Section 8 of this policy.

For each previously reported FCOI involving an ongoing PHS/NIH-funded project, ORA shall submit an

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annual FCOI report addressing the status of the FCOI and any changes to the management plan, including whether the FCOI continues to be managed or the reason it no longer exists.

For a newly disclosed or newly identified SFI, UGHE shall complete the required review within 60 days. Where an FCOI was not identified or managed in a timely manner, UGHE shall complete the required retrospective review within 120 days of determining noncompliance and, if bias is found, promptly notify the applicable PHS Awarding Component and submit a mitigation report.

Example: Since the study is funded by an international donor with its own FCOI reporting obligations, ORA includes Dr. A's disclosed interest and management plan in the annual donor report and confirms the study's IRB approval documentation reflects the conflict and its mitigation since REC continuing review typically requires updated COI status. For NIH funded projects, ORA submits an annual NIH FCOI report and completes review for a new SFI within 60 days. If FCOI is not identified or managed in a timely manner, ORA completes a 120-day retrospective review and submits a mitigation report if bias is identified. Records are retained for ≥3 years.