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|  | Financial Conflict of Interest Policy for Research | Doc. # | EN-FCOIP |
| | | Revision | A |
| | | CO# | 0117 |
| | | Effective Date | 2021-08-25 |

INTRODUCTION

The Eyenuk, Inc. (“Eyenuk” or “Institution”) is committed to conducting all research activities in a manner compliant with all applicable laws and regulations. This policy sets forth standards that enable Eyenuk to promote objectivity in research and prevent the bias of any conflicting interest of an Investigator in designing, conducting or reporting research in the context of grants, cooperative agreements and other relevant arrangements.

SCOPE

The Department of Health and Human Services (“HHS”) has established regulations that apply to Public Health Service (“PHS”)-sponsored Investigators regarding the disclosure and management of conflicts of interest in connection with research. These regulations require an Institution to maintain a written policy on conflict of interest (COI) disclosure as a condition for receiving PHS awards. In compliance with these federal regulations, Eyenuk has established this policy to require disclosure, identification, and management of financial conflicts of interest (FCOI) for all Investigators supported by PHS research awards and other non-federal sponsors.

All Investigators who are funded by or are seeking PHS funding shall be informed of this policy and relevant reporting requirements or be notified of where these regulations may be accessed via the web.

Applicability of Institutional Affiliate’s Conflict of Interest Policy:

For research that is subject to an institutional affiliate’s conflict of interest policy, Eyenuk will rely on that institution’s policy for a determination regarding any apparent or actual conflict of interest or commitment, unless the Institutional Official or Committee elects in its discretion to review apparent conflicts such as, but not limited to:

- Conflicts of commitment pertaining to the Investigator’s or Research Staff member’s Eyenuk responsibilities;
- Investigator or Research Staff conflicts of interest related to a potential Eyenuk conflict of interest;
- Conflicts not disclosed or reviewed pursuant to the affiliate’s conflict of interest policy;
- Conflicts that, in the discretion of the Eyenuk, were not adequately disclosed or reviewed under the affiliate’s conflict of interest policy.

DEFINITIONS

Institutional Affiliate or Affiliate means an institution that partners or collaborates with Eyenuk to conduct PHS-sponsored research. Such affiliate shall have a written conflict of interest policy in accordance with the applicable Federal PHS regulation or State regulations.

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

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Conflict of Interest (COI) refers to situations in which financial or other personal considerations compromise, or have the appearance of compromising an individual’s professional judgment in proposing, conducting or reporting research. Conflicts of interest include non-financial as well as financial conflicts.

An Investigator or Research Staff member (as broadly defined below) is considered to have a conflict of interest when he or she, or that person’s family (as defined below), possesses a financial or personal interest in an activity that involves his or her responsibilities relating to research.

Family means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

Financial Interest is defined below in the section titled “Understanding what Financial Interest Means” on page 3.

Institutional Official means the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s institutional responsibilities. Eyenuk Signing Official, Dr. Kaushal Solanki, PhD (CEO) is also the designated Institutional Official.

Institutional responsibilities means the Investigator’s professional responsibilities associated with his or her Institutional appointment or position, such as research, development, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means 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 may include engineers, or interns. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Small Business Innovation Research (SBIR) means an NIH program designed to support small business concerns conducting innovative research/research & development with potential for commercialization.

Small Business Technology Transfer (STTR) means an NIH program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution.

Subrecipient refers to subcontractors or consortium members of an awardee Institution (or a PHS recipient). In such situation, the awardee Institution must take reasonable steps to ensure compliance of the subrecipient Investigator pursuant to 42 C.F. R. § 50.604(c).

UNDERSTANDING WHAT FINANCIAL INTEREST MEANS

Financial Interest means 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.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) 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.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional 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 U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct and/or reporting of sponsored research.

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CONFLICT OF INTEREST RESPONSIBILITIES

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

Eyenuk’s designated Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

1) DISCLOSURE OF FINANCIAL INTERESTS

Investigators at Eyenuk, who are also employed by an institutional affiliate, are required to disclose their outside significant financial interests and those of the investigator’s family in accordance with the affiliate’s FCOI policy.

All other Eyenuk Investigators are required to disclose their outside significant financial interests and those of the Investigator’s family to the Institutional Official, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests (and those of the Investigator’s spouse and dependent children) that are related to the investigator’s institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms (Attachment A) should be submitted to the Institutional Official or designee.

b) Ad Hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests (and those of the Investigator’s spouse and dependent children) to the Institution, through the Institutional Official:

- within 30 days of their initial appointment or employment.
- prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.
- when any Significant Financial Interest is acquired or discovered during the course of

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the year within thirty (30) days of discovery or acquisition.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined under Financial Interest and Significant Financial 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 Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator’s research.

2) REVIEW OF DISCLOSURES AND MANAGEMENT PLAN BY THE INSTITUTIONAL OFFICIAL

With each PHS proposal, progress report, incremental funding or extension, Investigators’ Significant Financial Interests disclosures will be reviewed by the designated Institutional Official to determine whether there are any Significant Financial Interests that would reasonably appear to be related to the PHS-funded research activity. The value of the Financial Interest or a statement that a value cannot be readily determined should be provided. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest exists when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The management plan shall be implemented prior to the expenditure of PHS funds awarded for the research project, specify the actions that are required to manage the Financial Conflict of Interest, and include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the investigator’s agreement to the plan; and
- How the plan will be monitored.

At a minimum, the management plan must contain these elements and comply with funding source regulations, and any applicable Affiliate Institutional policies:

- Public disclosure of all relevant information, including disclosure when submitting

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- proposals, publications and manuscripts, making oral presentations or presenting abstracts,
- Informed consent when enrolling human subjects in research must disclose all relevant information including sources of funding and financial or management interests,

The same review process shall take place when an Investigator reports a new Significant Financial Interest.

Institution Official will review and determine if a COI exists and recommend an appropriate management plan to address the COI.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity, to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan and with the funding source guidelines.

3) REPORTING TO PHS

Pursuant to 42 C.F.R. §§ 50.604(h) and 50.605(a)-(b), Eyenuk will promptly report conflicts of interest or non-compliance to the PHS awarding component in accordance with PHS regulations and take corrective action. Such reports shall be made via eRA Commons module if NIH funded or as outlined in 42 C.F.R. § 50.605(b)(3) and/or as instructed by the funding source.

- prior to the expenditure of any funds
- within 60 days of any subsequently identified financial conflict of interest
- at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project and
- following a retrospective review to update a previously submitted report, if appropriate.
- if bias is found with the design, conduct or reporting of NIH-funded research and will submit a Mitigation Report in accordance with PHS regulations.
- if an investigator fails to comply with the FCOI policy
- if a FCOI management plan appears to have biased the design, conduct or reporting of NIH funded research.

Investigators participating in Phase I application for STTR and SBIR are excluded from the PHS FCOI policy (Title 42 CFR Part 50, Subpart F).

4) INVESTIGATOR NON-COMPLIANCE AND ENFORCEMENT

Enforcement mechanisms, remedies, and non-compliance procedures shall comply with HHS regulations pursuant to 42 C.F.R. §§ 50.604(j), 50.605(a)(3), and 50.606(c).

a) Monitoring

The management plan to be implemented by the Institutional Official shall specify the way in which the Investigator's compliance with the management plan will be monitored on an

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ongoing basis until completion of the PHS-funded research project.

b) Disciplinary Action

In the event of an Investigator’s failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional 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 Institutional Official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or failure to comply with any conditions or restrictions, including failure to cooperate with designated monitoring bodies, will be grounds for discipline pursuant to the applicable employee or Affiliate disciplinary policies. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations.

c) Retrospective Review

If a Significant Financial Interest identified in the course of an ongoing PHS research was not disclosed in a timely manner by an Investigator or was not previously reviewed, the Institutional Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and, if necessary, implement a management plan on an interim basis.

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator’s failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator’s activities and the PHS-sponsored research project within 120 days of the determination of non-compliance to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review,

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detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a Mitigation Report in accordance with the PHS 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.

d) Cooperation with HHS Inquiries

Investigators and all other Eyenuk personnel shall cooperate with any inquiries initiated by HHS regarding conflicting financial interests in PHS-funded research compliant with 42 C.F.R. § 50.606(b). If HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by regulations, the Institution shall require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

5) TRAINING

Each Investigator, including collaborators, consultants or subcontractors, must complete training about this Policy and the PHS financial conflicts of interest policy regarding the investigator’s responsibilities and disclosure requirements prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by the Institution in accordance with HHS regulations.

For new PHS-funded Investigators or Investigators who are joining an ongoing PHS research activity, the Institution shall establish a reasonable timeframe when Investigators must complete the required training. Training will also be provided immediately if this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

6) RECORD RETENTION

Pursuant to 42 C.F.R. § 50.604(i), the Institutional Official will retain all disclosure forms, conflict management plans, and related documents, whether or not a disclosure resulted in the Institution’s determination of a Financial Conflict of Interest, for a period of three years from the date the final expenditure report is submitted to the PHS or to the primary PHS awardee, or for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, or as otherwise required under 45 C.F.R. § 74.53(b) and 92.42(b)

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(pertaining to pending litigation and audits, or where real property and equipment purchased under the award are retained beyond 3 years, when records are transferred to or maintained by the HHS awarding agency, or indirect cost proposals and cost allocation plans).

7) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8) PUBLIC ACCESSIBILITY

Pursuant to 42 C.F.R. § 50.604(a), the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following three criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation. Disclosure forms, Disclosure Update forms, and Management Plans, including determinations of Financial Conflicts of Interest under this policy, are public records open to public inspection, as required under federal and state law.

9) REGULATORY AUTHORITY

This policy implements the requirements of 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

10) SUBRECIPIENT RESPONSIBILITIES

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from an Institution awardee of PHS funding are expected to comply with the policies and procedures for disclosure and review of Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with the HHS regulations, they must comply with Eyenuk’s policy and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards.

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Subawards issued by Eyenuk will require the subrecipient institution to certify that its policy is in compliance with HHS conflict of interest regulations, and unless the subrecipient does not have an HHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators. If a Financial Conflict of Interest is identified, the recipient organization is also responsible for sending Eyenuk notification of the conflict and of the subrecipient institution’s plan to manage, reduce or eliminate the identified conflicts, in accordance with the HHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by Eyenuk should be identified as Investigators by the Principal Investigator and should complete the Eyenuk disclosure forms. If, upon review, Eyenuk determines that these financial interests could significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the management plans put in place to eliminate, reduce or manage the identified conflicts of interest.

The Institution awardee shall incorporate as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators pursuant to 42 CFR § 50.604(c).

If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the regulation.

- a) If the subrecipient cannot provide the certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing SFIs that are directly related to the subrecipient's work for the awardee Institution;
- b) The agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to the awardee Institution's FCOI policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply with its review, management, and reporting obligations under the regulation. For NIH subawards, the awardee Institution is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH through the eRA Commons FCOI Module.

For questions regarding FCOI or this policy, email administrator@eyenuk.com



Financial Interests Report (Attachment A to Financial Conflict of Interest Policy for Research)

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Name: _____

I am reporting on activities: for the year _____
 as an addendum to my most recent report

| | | |
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| <input type="checkbox"/> yes | <input type="checkbox"/> no | 1. Compensation (including travel expenses). Have you or a member of your Family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like? If yes, furnish information on an additional page. |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity? If yes, furnish information on an additional page. |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the Eyenuk. If yes, furnish information on an additional page. |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by the Eyenuk. If yes, furnish information on an additional page. |



Financial Interests Report (Attachment A to Financial Conflict of Interest Policy for Research)

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Certification:

I have read and understand the Eyenuk's policy on Conflict of Interest and have completed this report to the best of my knowledge and belief. If required, I will comply with any conditions or restrictions imposed by the Eyenuk to manage any realor perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

Additional page(s) attached yes no

Signature Printed Name Date

Addition to Financial Interests Report of: (name)
Dated: _____

Reporting for: self family member (name) _____
relationship _____

Name of External Entity: _____
Address of External Entity: _____

Type of external relationship: (check all that apply)

- Consultant
- Speaker
- Advisory Board or Committee
- Equity Holdings
- Governing Board or Officer
- Intellectual Property Rights
- Royalty Income
- Other (describe below)

Amount of compensation or financial interest in reporting period: \$ _____

If travel paid by entity:
Destination _____
Amount \$ _____



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Comments or explanatory information: