ClearGazeTest, Inc.

Financial Conflict of Interest (FCOI) Policy for Public Health Service–Funded Research

Adopted 12 July 2026 · Applies to all research funded by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH) · Issued under and compliant with 42 CFR Part 50, Subpart F ("Promoting Objectivity in Research") and the NIH Grants Policy Statement §4.1.10.

1. Purpose and Scope

This Policy promotes objectivity in research by establishing standards and procedures to ensure that the design, conduct, and reporting of research funded by the PHS are not biased by any conflicting financial interest of an Investigator. It applies to each Investigator who is planning to participate in, or is participating in, PHS-funded research at ClearGazeTest, Inc. (the "Institution"), whether funded through a grant, cooperative agreement, or as a subrecipient. This Policy implements the requirements of 42 CFR Part 50, Subpart F.

2. Definitions

Investigator. The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, which may include collaborators, consultants, and subrecipient personnel.

Institutional Responsibilities. An Investigator's professional responsibilities on behalf of the Institution, including research, research consultation, and service on committees and panels related to Institution activities.

Significant Financial Interest (SFI). A financial interest of the Investigator (and the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities and consists of one or more of: (i) with regard to a publicly traded entity, remuneration received in the 12 months preceding disclosure plus the value of any equity interest as of the date of disclosure that, when aggregated, exceeds $5,000; (ii) with regard to a non-publicly traded entity, remuneration received in the preceding 12 months that exceeds $5,000, or any equity interest (stock, stock option, or other ownership interest); and (iii) intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. Investigators must also disclose the occurrence of reimbursed or sponsored travel related to their Institutional Responsibilities. SFI does NOT include: salary, royalties, or other remuneration paid by the Institution to the Investigator; income from investment vehicles (e.g., mutual funds and retirement accounts) in which the Investigator does not directly control investment decisions; or income from seminars, lectures, teaching, or service on advisory/review panels for U.S. federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or affiliated research institutes.

Financial Conflict of Interest (FCOI). An SFI that the Institution reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institutional Official / Independent Reviewer. The individual(s) designated under Section 3 responsible for the solicitation and review of SFI disclosures and the implementation of this Policy.

3. Institutional Official and Independent Review

The Chief Executive Officer of ClearGazeTest, Inc. serves as the Institutional Official responsible for implementing this Policy. Because the Institution is a small business in which the Institutional Official may also serve as an Investigator (including as PD/PI), any SFI disclosure by the Institutional Official, or by any Investigator whose disclosure the Institutional Official cannot review free of personal financial interest, shall be reviewed and, if necessary, managed by an Independent Reviewer who has no financial interest in the affected research — for example, a member of the Board of Directors, outside legal counsel, or a qualified independent consultant engaged for this purpose. This safeguard ensures that no Investigator reviews or determines the disposition of his or her own financial interests.

4. Training (42 CFR 50.604(b))

Each Investigator must complete training on this Policy and the FCOI regulation prior to engaging in PHS-funded research and at least every four years thereafter. Training must also be completed immediately when: the Institution revises this Policy in a manner that affects Investigator requirements; an Investigator is new to the Institution; or the Institution determines that an Investigator has not complied with this Policy or with a management plan. The Institution will use the NIH FCOI training module or an equivalent and will retain records of completion.

5. Disclosure of Significant Financial Interests (42 CFR 50.604(e))

Each Investigator must submit to the Institutional Official a written disclosure of all SFIs (and those of the Investigator's spouse and dependent children): (a) no later than at the time of application for PHS-funded research; (b) at least annually during the period of the award; and (c) within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Disclosures must include sufficient information for the Institution to determine whether the SFI is related to the PHS-funded research and whether it constitutes an FCOI.

6. Review of Disclosures and Determination of FCOI (42 CFR 50.604(f)–(g); 50.605(a))

The Institutional Official (or Independent Reviewer, as applicable) will review each disclosure, determine whether an SFI is related to the PHS-funded research, and, if so, determine whether it is an FCOI. An SFI is related to the research when the Institution reasonably determines the interest could be affected by the research or is in an entity whose financial interest could be affected by the research. Where an FCOI exists, the Institution will, prior to the expenditure of any PHS funds, develop and implement a written management plan and, thereafter, monitor Investigator compliance with that plan until completion of the research.

7. Management Plans (42 CFR 50.605(a)(4)–(6))

A management plan will specify the actions taken to manage the FCOI. Examples include: public disclosure of the FCOI; independent review or verification of research data; modification of the research plan; change of personnel or personnel responsibilities; disqualification from participation in all or a portion of the research; reduction or elimination of the financial interest; or severance of relationships that create the conflict. The plan will identify the conflicting interest, the conditions of management, how the plan is designed to safeguard objectivity, confirmation of the Investigator's agreement, and the monitoring approach.

8. Retrospective Review and Mitigation (42 CFR 50.605(a)(3))

Whenever an FCOI is not identified or managed in a timely manner — including failure by an Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure by an Investigator to comply with a management plan — the Institution will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the research was biased. If bias is found, the Institution will notify NIH promptly and submit a mitigation report in accordance with the regulation.

9. Reporting to NIH/PHS (42 CFR 50.604(h); 50.605(b); 50.606(a))

Prior to the Institution's expenditure of any PHS funds, and for any FCOI identified during the period of award (within sixty (60) days of identification), the Institution will provide NIH with an FCOI report containing the elements required by 42 CFR 50.605(b), including the project number, PD/PI, name of the Investigator with the FCOI, name of the entity, nature and approximate dollar value (or a statement that the value cannot be readily determined) of the financial interest, and a description of how the interest relates to the research and the key elements of the management plan. The Institution will submit annual FCOI reports for the duration of the award and revised reports as required following any retrospective review.

10. Public Accessibility (42 CFR 50.605(a)(5))

Prior to the expenditure of PHS funds, the Institution will ensure public accessibility of information concerning any identified FCOI held by senior/key personnel. The Institution will respond in writing within five (5) business days of a request, providing the Investigator's name, title and role, the name of the entity, the nature of the interest, and the approximate dollar value in the ranges specified by the regulation ($0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined. Such information will remain available for at least three years from the date it is first provided.

11. Subrecipients (42 CFR 50.604(c); NIH GPS 15.2.1)

Where the Institution carries out PHS-funded research through a subrecipient, the Institution will incorporate, as a term of the subaward, terms that establish whether the FCOI policy of the Institution or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's policy applies, the subrecipient will certify that its policy complies with the regulation and will provide FCOI reports to the Institution in sufficient time (no later than 45 days) to enable the Institution to report to NIH as required.

12. Enforcement, Remedies, and Noncompliance (42 CFR 50.604(j))

Investigators who fail to comply with this Policy or an applicable management plan are subject to remedies and sanctions up to and including suspension or termination of participation in the research and other disciplinary action consistent with Institution policy and applicable law. Failure to comply may also trigger the retrospective review and reporting obligations described above.

13. Recordkeeping (42 CFR 50.604(i))

The Institution will maintain records relating to Investigator disclosures, the Institution's review of and response to such disclosures, and all actions under this Policy, for at least three years from the date of submission of the final expenditure report or, where applicable, from other dates specified in 45 CFR 75.361.

14. Clinical Research (42 CFR 50.606(c))

If the Institution maintains an FCOI management plan for research that constitutes a clinical research project whose results are intended to be, or are being, presented in a public forum, and it is later determined that the FCOI was not managed or reported as required, the Institution will require the Investigator to disclose the FCOI in each public presentation of the results and to request an addendum to previously published presentations.

15. Effective Date, Public Posting, and Review

This Policy is effective as of the date of adoption stated above, is posted on a publicly accessible website maintained by the Institution as required by the NIH Grants Policy Statement §4.1.10, and will be reviewed periodically and updated as necessary to maintain compliance with 42 CFR Part 50, Subpart F.

Institutional Official: Dr. Michael D. Duplessie, FRCS (Ophth., Glasgow), Chief Executive Officer, ClearGazeTest, Inc. · Contact: doctor@cleargazetest.com