POLICY

Financial Conflict of Interest Policy

Applicable to Public Health Service (PHS)-funded research, including NIH SBIR/STTR awards
Effective date: [EFFECTIVE DATE] · Last reviewed: [REVIEW DATE] · Version [1.0]
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> DRAFT — placeholder text for review by Litmus Analytical leadership and counsel before publication.

1. Purpose and Scope

Litmus Analytical Inc. ("Litmus") is committed to conducting research with objectivity and integrity. This policy implements the PHS regulation at 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research," and applies to every Investigator who is planning to participate in, or is participating in, research funded or proposed for funding by PHS, including NIH, and by any other agency that adopts these requirements.

2. Definitions

- **Investigator:** the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, including collaborators and consultants.
- **Institutional responsibilities:** an Investigator's professional duties on behalf of Litmus, such as research, product development, and service on company committees.
- **Significant Financial Interest (SFI):** a financial interest of the Investigator (and spouse and dependent children) that reasonably appears related to the Investigator's institutional responsibilities and meets the thresholds defined in 42 CFR 50.603, including remuneration and equity interests, intellectual property rights and income, and certain reimbursed or sponsored travel.
- **Financial Conflict of Interest (FCOI):** an SFI that Litmus determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **Designated Official:** the person Litmus appoints to administer this policy. [NAME, TITLE]

3. Training

Each Investigator must complete FCOI training before engaging in PHS-funded research, at least every four years thereafter, and promptly when this policy changes materially, when the Investigator is new to Litmus, or when the Investigator is found to be out of compliance.

4. Disclosure Requirements

Investigators must disclose all SFIs to the Designated Official:

- no later than the time of application for PHS-funded research;
- at least annually during the award period;
- within 30 days of discovering or acquiring a new SFI.

5. Review and Determination

The Designated Official reviews each disclosure, determines whether the SFI is related to PHS-funded research and, if so, whether it constitutes an FCOI. Determinations are made before the expenditure of any award funds and within 60 days of any new disclosure during an ongoing award.

6. Management of Financial Conflicts of Interest

When an FCOI exists, Litmus will develop and implement a written management plan, which may include:

- public disclosure of the FCOI in presentations and publications;
- disclosure to research participants where applicable;
- appointment of an independent monitor;
- modification of the research plan;
- changes to personnel or their responsibilities;
- reduction or elimination of the financial interest; or
- severance of relationships that create the conflict.

Litmus will monitor Investigator compliance with each management plan until the completion of the research project.

7. Reporting to the Funding Agency

Litmus will report identified FCOIs to the PHS awarding component (for NIH, through the eRA Commons FCOI Module) before spending award funds, within 60 days of any subsequently identified FCOI, and annually for the duration of the award, in accordance with 42 CFR 50.605(b).

8. Public Accessibility

This policy is publicly available on this website. Before spending funds under a PHS-funded award, Litmus will ensure that information about any identified FCOI held by senior/key personnel is available within five business days of a written request, including the Investigator's name, title and role, the entity in which the SFI is held, the nature of the SFI, and its approximate dollar value range, as required by 42 CFR 50.605(a)(5).

9. Subrecipients

When PHS-funded research is carried out through a subrecipient, Litmus will establish in a written agreement whether the subrecipient's FCOI policy or this policy applies, and set timelines for subrecipient reporting to Litmus.

10. Noncompliance and Retrospective Review

If an FCOI was not identified or managed in a timely manner, Litmus will complete a retrospective review within 120 days, determine whether research was biased, update any reports to the funding agency, and implement a mitigation report where required. Failure to comply with this policy may result in disciplinary action, up to and including termination of employment or other relationships with Litmus.

11. Records

Litmus will retain all disclosures, reviews, determinations and management plans for at least three years from the date the final expenditure report is submitted, or longer where required by the awarding agency.

12. Contact

Questions about this policy, or requests for FCOI information, may be sent to the Designated Official at info@litmusanalytical.com, Litmus Analytical Inc., 400 S Wakara Way, Salt Lake City, UT

84108.

References

- 42 CFR Part 50, Subpart F — Promoting Objectivity in Research
- NIH Financial Conflict of Interest resources and FAQs: grants.nih.gov/policy-and-compliance/fcoi