



Financial Conflict of Interest Policy

I. PURPOSE

TwinStrand Biosciences, Inc. (TSB) strives to create a research climate that promotes objectivity in research. The purpose of this policy is to establish standards to ensure that the design, conduct and reporting of Public Health Service (PHS)-funded research (including research funded by the National Institutes of Health (NIH) and other governmental and governmentally-funded organizations) is free from bias resulting from financial conflict of interest (FCOI) in accordance with 42 CFR Part 50 Subpart F.

II. POLICY

TwinStrand Biosciences strives to create a research climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of PHS-funded research is free from bias resulting from FCOI.

This policy is applicable to any TSB employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds. It will be understood that any reference to “employee” herein also refers to consultants and other non-employees performing research under contract with TSB. Each employee engaged in PHS-funded research must:

- **Disclose** his or her significant financial interests (SFI) in non-TSB entities which might be affected by, are related to, or could appear to be related to, the employee’s activities or responsibilities on behalf of TSB;
- **Comply** with a FCOI management plan, if a FCOI is identified; and
- **Undergo** FCOI training, at least once every four (4) years.

Disclosure of SFI is essential for TwinStrand to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with a FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.

III. DEFINITIONS

1. “*Financial conflict of interest (FCOI)*” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research.
2. “*Public Health Service (PHS)-Funded Research*” means research funded in whole or in part by the National Institutes of Health (NIH) and other governmental and governmentally-funded organizations, whether U.S. or foreign.
3. *Significant Financial Interest (SFI)* exists if (i) the employee, or the employee’s spouse, parents, or dependent children, receives remuneration from a non-TSB entity which is related to, could appear to be related to, the Employee’s TSB Responsibilities (defined below); and (ii) the value of remuneration received from the non-TSB entity exceeds or potentially could exceed \$5,000;

A. Such remuneration includes:

- i. Salary or other payments for services (e.g., consulting fees or honoraria) received in the twelve (12) months preceding disclosure or otherwise committed to the employee;
 - ii. Equity interests (e.g., stocks, stock options or other ownership interests) in the non-TSB entity or any related entity. Any equity interest in a non-publicly traded entity, regardless of the amount, constitutes an SFI; and
 - iii. Income, including royalties and other payments of any kind, from intellectual property rights owned by the employee.
- B. Such remuneration excludes:
 - i. Salary, royalties, stock options or other remuneration from TwinStrand Biosciences;
 - ii. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, derived from excluded sources (as defined below);
 - iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions; and,
 - iv. Unlicensed intellectual property owned by the employee that does not generate income.
- C. SFI disclosure also includes travel which is funded, reimbursed, or sponsored by a non-TSB entity that is related to, or could appear to be related to, the Employee's TSB Responsibilities. Such travel must be disclosed, no matter the amount, except when the expenses are funded or reimbursed by an excluded source (defined below).
- D. "*Employee's TSB Responsibilities*" means any of the employee's duties and activities as an employee of TSB, including conducting research, submitting patent applications, publication, technical committee membership, speaking and presenting at conferences and meetings, and teaching as adjunct faculty at an institution of higher education.
- E. *An excluded source means a source of remuneration that is excluded from disclosure. With reference to the SFI, excluded sources include any federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.*