



Swiss Institute of
Bioinformatics

SIB Policy on Compliance with United States of America Regulations

(“NIH Financial Conflict of Interest Policy”)

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I. Background

SIB receives significant sums of grant funding from United States public sources, notably the Public Health Service (PHS) through the National Institutes of Health (NIH).

As of 24 August 2012, the reporting requirements imposed on PHS-funding recipients such as SIB have changed with respect to the management and disclosure of financial conflicts of interest. These changes are aimed at bringing the financial rules of this grant funding in line with general United States government policy.

The above-cited changes are mandatory for any organization or individual receiving PHS funding and are applicable to both new and existing grant funding.

Failure to apply the regulations can lead, notably, to:

- The cessation of this line of grant funding;
- Suspension or cessation of PHS funding;
- The imposition of special grant conditions, and strict compliance with any PHS-required corrective action.

II. Scope

In order to comply with applicable United States of America regulations dealing with financial conflicts of interest, SIB has implemented this Policy as an extension to its existing policies, rules, and regulations dealing with conflicts of interest for all PHS funded activity. ("Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought *and* Responsible Prospective Contractors; Final Rule" (2011) - 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, respectively).

This Policy is applicable at all SIB sites to all SIB members of the personnel meeting the definition of an Investigator (see definition in Definitions under the Requirements), sub-recipient investigators, and – with respect to the training requirements (see VI. Training Provision) – all SIB research staff.

III. Responsibilities of Investigators

Investigators (see definition in Definitions under the Requirements) are responsible for the following:

Financial Conflict of Interest Training

- Undertaking and passing the necessary Financial Conflict of Interest training within 2 months of arrival at SIB or before applying for any PHS-funded research, whichever occurs first, and updating this training as required (see VI. Training Provision);
- Providing Grants Services with a copy of the Financial Conflict of Interest training certificate prior to submission of any PHS-funded grant application.

Financial Conflict of Interest Disclosures

- Completing a Financial Conflict of Interest Annual Disclosure Form A. This form determines whether an Investigator has a Significant Financial Interest (see Definitions under the Requirements) that needs to be disclosed. This must be done no later than at the time of application for PHS-funded research. The Financial Conflict of Interest Annual Disclosure Form A is in Appendix 3 Financial Conflict of Interest Disclosure Forms;
- Ensuring that the details on such form include disclosures for both him/herself and those of any spouse and dependent children;
- Updating this Financial Conflict of Interest Annual Disclosure Form, at least, annually and within 30 days of any new reportable Significant Financial Interests being obtained or identified;
- Completing a Financial Conflict of Interest Disclosure Form B where a Significant Financial Interest exists. One Form B must be completed for each entity in which an Investigator has a Significant Financial Interest. The Financial Conflict of Interest Disclosure Form B is in Appendix 3 - Financial Conflict of Interest Disclosure Forms;
- Ensuring that the details on such form include all his or her Significant Financial Interests and those of any spouse and dependent children;
- Updating this Financial Conflict of Interest Disclosure Form B, within 30 days of a new reportable Significant Financial Interest being obtained or identified from the same entity. If a new reportable Significant Financial Interest is obtained or identified from a new entity, a new Financial Conflict of Interest Disclosure Form B must be submitted.

Financial Conflict of Interest Compliance of Other Investigators

- Ensuring that, when any PHS-sponsored program activity is initiated – and before submitting a proposal, signing a contract, or finalizing any agreement – all Key Personnel (see Definitions under the Requirements) on the proposal, contract, or agreement have completed an up-to-date Financial Conflict of Interest Annual Disclosure Form A for the current calendar year and that this is on file with Grants Services. If this identifies the existence of a Significant Financial Interest, ensuring that Financial Conflict of Interest Disclosure Form B has also been submitted and is on file with Grants Services.

Complying with Management Actions and Corrective Actions

- Complying with any management action deemed necessary by the Head of Grants Services to mitigate risks associated with any Financial Conflict of Interest, the management thereof and any corrective action to be taken;
- Remedying any case where the Investigator fails to disclose Significant Financial Interests in a timely manner by providing immediately the relevant information to Grants Services. Failure to disclose information in a timely manner is subject to the enforcement mechanisms outlined in section IX. Remedies and Enforcement;

- In addition to the other obligations imposed elsewhere in this Policy: providing, in a timely manner, all information and/or assistance that may be necessary or desirable to comply with the obligations implemented by this Policy.

IV. Responsibilities of the Head of Grants Services

The SIB Head of Grants Services, in consultation with all relevant stakeholders, is responsible for:

Review of Financial Conflict of Interest Disclosures and Determinations of Actions Required;

- Review of all Investigator Significant Financial Interest Disclosures;
- Maintaining the annual update of Financial Conflict of Interest Disclosure Forms A and B, including issuing reminders to the Investigators concerned;
- Determination as to whether any Significant Financial Interests relate to PHS-funded research;
- Determination as to whether a Financial Conflict of Interest exists (i.e. a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research);
- Development and implementation of management plans, as needed to manage Financial Conflicts of Interest with the aim of reducing or eliminating all Financial Conflicts of Interest prior to expenditure of funds;

Reporting and Disclosures to the National Institutes of Health

- Completion and delivery of all relevant reports to the NIH, and making all relevant information publicly available as required. Specifically, Financial Conflict of Interest reports provided to the NIH will include the following information relating to an Investigator:
 - Name of the Investigator with the financial conflict of interest;
 - Name of the entity with which the Investigator has a financial conflict of interest;
 - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - Value of the financial interest (dollar ranges are permissible: \$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 through reference to public prices or other reasonable measures of fair market value;
 - A description of how the financial interest relates to the PHS-funded research and the basis for SIB’s determination that the financial interest conflicts with that research.

Financial Conflict of Interest Compliance of Other Investigators

- Ensuring that subrecipients of PHS funding are compliant with Financial Conflict of Interest management and reporting requirements (see section VII. External Parties involved in PHS-funded research).

Public Disclosures

- Completion and delivery of all public disclosures following receipt of a written request for information (see section VIII. Public Accessibility).

Policy Compliance and Registry

- Completion and documentation of retrospective reviews, where necessary;
- Maintenance of records under this Policy.

V. Responsibilities of SIB Management

SIB Management will ensure that the appropriate confidentiality and security of any disclosures hereunder to SIB's designated official and relevant stakeholders are maintained.

SIB Management will also receive all incoming requests for public disclosures and coordinate responses (see section VIII. Public Accessibility).

VI. Training Provision

SIB will make available training in relation to the requirements under this Policy.

All SIB research staff to whom this Appendix applies must undertake the Financial Conflict of Interest training within 2 months of joining SIB. In addition, each such research staff member must undertake the Financial Conflict of Interest training:

- upon initial implementation of this Policy, if the Investigator is already involved in PHS-funded research;
- prior to applying for or engaging in research related to any PHS-funded grant;
- at least every 4 years;
- immediately, if:
 - SIB revises this Policy and this affects requirements of Investigators; or
 - An Investigator is not in compliance with this Policy or a management plan.

VII. External Parties involved in PHS-funded research

If SIB carries out the PHS-funded research through subrecipients (e.g. subcontractors, or consortium members), SIB – by routing all relevant written agreements through SIB Grants Services, which in turn will involve SIB Management and, where relevant, other stakeholders – will take reasonable steps to ensure that any subrecipient Investigator complies with PHS requirements implemented within SIB via this Policy by:

- Incorporating as part of a written agreement with the subrecipient, terms that establish whether this Policy or the financial conflict of interest policy of the subrecipient will apply to the subrecipient's Investigators;
- If the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the subrecipient shall certify as part of the above-referenced agreement that its policy complies with applicable PHS requirements.

If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to this Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for SIB;

- Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the above-referenced agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to SIB. Such time period(s) shall be sufficient to enable SIB to provide timely Financial Conflict of Interest reports, as necessary, to the PHS as required;
- Alternatively, if the subrecipient's Investigators must comply with this Policy, the above-referenced agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to SIB. Such time period(s) shall be sufficient to enable SIB to comply in a timely manner with its review, management, and reporting obligations;
- Providing Financial Conflict of Interest reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified Financial Conflict of Interest.

VIII. Public Accessibility

This Policy will be made publicly available on the SIB internet website.

Information on Financial Conflicts of Interest held by Investigators will be:

- made available within five calendar days of a written request;
- updated, at least annually, where relevant;
- updated, within 60 days of a newly identified Financial Conflict of Interest, where relevant;
- remain available for three years from the date the information was most recently updated.

Requests for public accessibility shall be addressed to SIB Management, who will forward such requests to the Head of Grants Services for action within five business days of a request, after consultation, where relevant.

The information that SIB makes available as a written response to any requestor within five business days of a request, will include, at least, the following:

- the Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the significant financial interest is held;
- the nature of the significant financial interest;
- and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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 through reference to public prices or other reasonable measures of fair market value.

IX. Remedies and Enforcement

SIB will notify the NIH promptly if a Financial Conflict of Interest-based bias is found with the design, conduct or reporting of NIH-funded research and will prepare and submit a mitigation report.

SIB will notify the NIH promptly and take corrective action if an Investigator fails to comply with this Policy or a Financial Conflict of Interest management plan and such failure appears to have biased the design, conduct, or reporting of the NIH-funded research.

SIB will complete and document a retrospective review within 120 days of SIB's determination of non-compliance for Significant Financial Interests not disclosed in a timely manner or whenever a Financial Conflict of Interest is not identified or managed in a timely manner.

All Investigators are required to comply fully, truthfully and in a timely manner with this Policy. Instances of proven intentional or grossly negligent breach, including failure to submit required disclosures, statements or updates thereof; failure to provide additional information requested by SIB; knowingly filing an incomplete, erroneous or misleading disclosure; knowingly violating applicable laws, regulations or this Policy; or failure to comply with prescribed conditions or restrictions that have been imposed pursuant to this Policy, may be grounds for disciplinary action being taken against the Investigator in accordance with the SIB Employee Rules and Employee Regulations.

X. Definitions under the Requirements

A. Basis of Definitions

The definitions contained in United States 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, respectively, which are available at:

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

are herewith incorporated by reference. For ease of reading, selected definitions are expressly included in this Policy and some definitions listed below have been amended to take SIB's environment into account:

B. Key Definitions

Disclosure of Significant Financial Interests means an Investigator's disclosure of Significant Financial Interests to SIB.

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of United States Public Health Service-funded research. A Financial Conflict of Interest exists when SIB, through its designated official(s), reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution means SIB.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of SIB, and as defined by SIB in this Policy, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator means the Project Director or Principal Investigator (PD or PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. For the purposes of this Policy, as a minimum, group or team leaders and staff scientists who are involved in NIH grants or applications are considered to be Investigators.

Related is where SIB, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research. SIB may involve the Investigator, or other stakeholders, in the designated official's/officials' determination of whether a Significant Financial Interest is related to the PHS-funded research.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by SIB in the grant application, progress report, or any other report submitted to the PHS by SIB.

Significant Financial Interest

(1) A Significant Financial Interest consists of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (i) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) with regard to intellectual property rights and interests (e.g., patents, copyrights), a Significant Financial Interest exists if any income related to remuneration for such rights and interests received in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.

(2) Investigators also must disclose the occurrence of **any** reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to

their Institutional responsibilities, **which is not paid for by SIB**. Investigators also **do not** need to record and disclose any travel that is reimbursed or sponsored by the following **US** institutions (Federal or state government departments, local government agencies, institutions of higher education, academic teaching hospitals, medical centres, or research institutes affiliated with an institution of higher education).

Travel paid directly through or reimbursed by SIB is not subject to disclosure. However, travel paid by Non-US institutions (such as, for example, a European University or research institute) is unlikely to benefit from the disclosure exemption outlined in the definition, and therefore must be disclosed.

Investigators shall disclose all details providing a true, fair and full view of reimbursed or sponsored travel, containing at least: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration, along with an itemized monetary value of the travel, category of transportation (coach, business, first) and category of accommodation.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by SIB to the Investigator if the Investigator is currently employed or otherwise appointed by SIB, including intellectual property rights assigned to SIB and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, income from service on advisory committees or review panels or teaching engagements sponsored by the following US institutions (Federal or state government departments, local government agencies, institutions of higher education, academic teaching hospitals, medical centres, or research institutes affiliated with an institution of higher education).