**Northwest Prevention Science, Inc (NPS)
Financial Conflict of Interest Policy**

**Purpose**

Northwest Prevention Science, Inc (NPS) and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to conflict of interest and objectivity in research. It is the purpose of this policy to set forth the procedures for identifying a significant financial interest (SFI), determining if those interests constitute a financial conflict of interest (FCOI), and the procedures for reviewing and managing those conflicts. It is important to ensure that conflicts do not improperly affect NPS’s research and other activities. To maintain objectivity in research, NPS and its investigators and employees will completely disclose, appropriately review, and manage identified conflicts. A FCOI exists when NPS, through its COI Administrator, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of research at NPS, regardless of funding source.

The policy applies to each Investigator/employee, as defined below, who is planning to participate in or is participating in federal government funded research. NPS will conduct the following:

* Have in effect an up-to-date, written and enforced administrative process to identify and manage FCOI,
* Promote and enforce Investigator compliance with the regulation,
* Manage FCOI and provide initial and ongoing FCOI reports,
* Agree to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, personnel, upon request, and
* Fully comply with the regulation’s requirements.

**Definitions**

**COI Administrator** is the person who reviews disclosures of interests to determine whether those interests represent a financial conflict. The COI Administrator is responsible for distributing disclosure forms to those individuals in potential conflict for their completion, gathering and reviewing completed forms. Should a FCOI exist, the COI Administrator will work with the investigator/employee to develop a management plan to reduce or eliminate the conflict. The COI Administrator will be responsible for all record keeping and forwarding of documents to the funding agency, if requested. It is the responsibility of the COI Administrator to maintain FCOI disclosure forms, and to ensure that a current form is on file for all investigators/employees at the time of a new grant submission and annual progress reports as required by Federal regulations.

**Contractors/Consultants:** Anyone who is working on a project and is not employed by NPS.

**Disclosure of SFI** is required by an investigator/employee and can be completed by filling out the SFI disclosure form.

**FCOI** means a SFI that could directly and significantly affect the design, conduct, or reporting of NPS research and/or the negotiation of contracts and the purchase of supplies and services.

**FCOI Report** means NPS’s report of all identified FCOI.

**Funding agency:** Any agency that requires a COI policy as a requirement for receiving funding.

**Investigator** means 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 research funded by the federal government, or proposed for such funding, which may include, for example, collaborators or consultants. When considering who must submit a SFI disclosure, NPS considers the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

**Manage** means taking action to address a FCOI by putting together a plan that includes reducing or eliminating the FCOI, and monitoring that plan to ensure that the design, conduct, and reporting of research will be free from bias for the required duration.

**Research** means a systematic investigation, study or experiment designed to develop or 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., interventions and technology applications).

**SFI**

A. **SFI** consists of one or more of the following interests of the investigator/employee (and those of the investigator/employee’s spouse/domestic partner and dependent children) that reasonably appears to be related to their responsibilities at NPS:

1. **Publicly traded entity:** a SFI 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;

2. **Non-publicly traded entity:** a SFI 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 employee (or the investigator’s or employee’s spouse/domestic partner or dependent children) holds equity interest of any amount (e.g., stock, stock option, or other ownership interest); or Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3. **Travel:** SFI also includes occurrences of any reimbursed or sponsored travel related to an investigator’s responsibilities, the value of which is estimated to exceed $5,000. This does not apply to travel that is reimbursed or sponsored by a 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.

4. **Royalties:** Income from royalties from non-NPS owned sources could be considered a SFI if the income fits the definition of a SFI in either sections A. i. or A. ii. above. If royalties are received related to patents or copyrights owned by NPS and licensed or potentially licensed, they are considered remuneration from the applicant Institution and would not be considered a SFI of the Investigator.

B. **SFI does not include the following types of financial interests**: salary, royalties, or other remuneration paid by NPS to the investigator or employee if the individual is currently employed or otherwise appointed by NPS, including intellectual property rights assigned to NPS and agreements to share in royalties related to such rights; any ownership interest in NPS held by the individual if NPS is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

**Subrecipients:** Any institution that receives funds as part of a sub-award and has designated a PI or PD at that institution for that project. If a sub-recipient does not have a conflict of interest policy in place, they must comply with NPS’s policy.

**Sub-awards:** Organizations that receive grant funds and are paid by NPS under the terms of the award.

**Procedures**

**Training:**

Each investigator must complete training prior to engaging in research related to any NIH funded grant at least every four years, and immediately under these designated circumstances:

* NPS’ FCOI policies change in a manner that affects investigator requirements
* An investigator is new to NPS
* NPS finds an investigator noncompliant with the FCOI policy or management plan

This training will be comprised of NPS’ FCOI policy, the Investigator/employee’s disclosure responsibilities, and the federal regulation.

**Disclosure:**

**Who:** An investigator/employee who is planning to make application for funded research or planning to assume direct or indirect responsibility for purchases of supplies, services and/or contracts must disclose to the COI Administrator his or her significant financial.

**When:** Disclosure forms reflecting an investigator’s/key personnel’s current SFI must be provided prior to the submission of a grant proposal, and annually thereafter in order to continue working on the project. Updated disclosures are also required within 30 days of a change in the significant financial interest of an investigator/employee that are related to the investigator’s/key personnel’s responsibilities. Each year, within the first quarter, updated disclosure forms will be required of all investigators/key personnel.

**How:** An investigator/employee will complete the NPS SFI Disclosure Form A and sign and submit the document to the COI Administrator. By submitting this form, the investigator/employee attests in writing that he/she will comply with all provisions of NPS’ FCOI policy including the terms and conditions of a management plan, if applicable.

\*Subrecipients: NPS is responsible for ensuring any subrecipient’s compliance with the regulations and reporting identified financial conflicts of interests for subrecipient investigators/key personnel to the awarding agency. NPS must incorporate as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of NPS or that of the subrecipient will apply to subrecipient investigators/key personnel and include time periods to meet disclosure and/or FCOI reporting requirements. NPS is responsible for monitoring subrecipient’s compliance with the FCOI regulations, management plans, and for reporting all identified FCOI prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

**Review and Reporting:**

Upon receipt of all SFI Disclosure forms for a project, the COI Administrator shall review the forms and identify any significant FCOI and begin to develop a management plan.

**Initial Reporting:**

After review of all SFI disclosure forms, the COI Administrator will compile a report that includes sufficient information to enable the funding agency to understand the nature and extent of any financial conflict, and to assess the appropriateness of NPS’s management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

* Project number;
* PI or Contact PI if a multiple PI model is used;
* Name of the investigator/employee with the FCOI;
* Name of the entity with which the investigator/employee has a FCOI;
* Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
* Value of the financial interest 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 research and the basis for the institution’s determination that the financial interest conflicts with such research; and
* A description of the key elements of NPS’s management plan, including:
	+ Role and principal duties of the conflicted investigator/employee in the research project;
	+ Conditions of the management plan;
	+ How the management plan is designed to safeguard objectivity in the research project;
	+ Confirmation of the investigator’s/employees’ agreement to the management plan;
	+ How the management plan will be monitored to ensure investigator/employee compliance; and
	+ Other information as needed.

Included with the FCOI report will be a detailed management plan detailing how the investigator/employee with the FCOI will address the conflict and bring it to an acceptable level.

**Periodic Review and Reporting:**

**New Personnel:**

If a new Investigator/employee is added to a project, they must complete a SFI Disclosure form. The form will be reviewed by the COI Administrator. If a CFOI is identified, NPS shall provide to any agency requiring such a report, within sixty (60) days, an FCOI report regarding the conflict. NPS will implement a management plan that shall specify the actions that will be taken to manage the FCOI.

**Untimely disclosure:**

If NPS identifies a significant FCOI that was not disclosed timely by an investigator/employee or was not previously reviewed or managed by NPS (e.g., was not timely reviewed or reported by a subrecipient), the COI Administrator shall, within sixty (60) days: review the SFI; determine whether it is related to the research; determine whether a FCOI exists; and, if so: implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

**Remedies:**

**Overview:**

NPS will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure investigator and employee compliance as appropriate. If the failure of an investigator/employee to comply with NPS’s FCOI policy, or a management plan appears to have biased the design, conduct, or reporting of the research, NPS shall promptly notify the funding agency of the corrective action taken or to be taken. If the funding agency is subject to these regulations (e.g., an organizational component of the Public Health Service, including the Centers for Disease Control and Prevention or the National Institutes of Health) it will consider the situation and, as necessary, take appropriate action, or refer the matter to NPS for further action, which may include directions to NPS on how to maintain appropriate objectivity in the PHS-funded research project. The funding agency may, for example, require NPS to enforce any applicable corrective actions prior to a grant award or when the transfer of a grant(s) involves such an investigator/employee.

The funding agency may inquire at any time before, during, or after award into any investigator/employees disclosure of financial interests and NPS’ review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in NPS’s determination of a FCOI. NPS is required to submit, or permit on-site review of, all records pertinent to compliance with the regulations. To the extent permitted by law, the funding agency will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the funding agency may decide that a particular FCOI will bias the objectivity of the research to such an extent that further corrective action is needed or that NPS has not managed the FCOI in accordance with the regulations. The funding agency may determine that imposition of special award conditions, or suspension of funding or other enforcement action until the matter is resolved.

**Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:**

* Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
* For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
* Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
* Modification of the research plan;
* Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research or purchasing duties;
* Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
* Severance of relationships that create financial conflicts.

**Noncompliance and Retrospective Review:**

Whenever a FCOI is not identified, such as:

* Failure by the investigator/employee to disclose a SFI that is Determined by NPS to constitute a FCOI;
* Failure by NPS to review or manage such a FCOI; or
* Failure by the investigator/employee to comply with a FCOI management plan.

Within one hundred twenty (120) days of NPS’s determination of noncompliance, NPS shall complete a retrospective review of the investigator’s/employees’ activities and the project and/or purchasing responsibilities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, to determine bias in the design, conduct, or reporting of such research. Such retrospective review shall be completed by a review committee comprised of members selected by the Board of Directors.

NPS’s documentation of the retrospective review shall include, but not necessarily be limited to, all of the following key elements:

* Project number;
* Project title;
* PI or contact PI if a multiple PI model is used;
* Name of the investigator/employee with the FCOI;
* Name of the entity with which the investigator/employee has a FCOI;
* Reason(s) for the retrospective review;
* Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
* Findings of the review; and
* Conclusions of the review.

Based on the results of the retrospective review, if appropriate, NPS shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, NPS is required to notify any funding agency subject to these regulations promptly and submit a mitigation report to the funding agency. The mitigation report must include, at a minimum:

* The key elements documented in the retrospective review above,
* A description of the impact of the bias on the research project, and
* NPS’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Thereafter, NPS will submit FCOI reports annually. Depending on the nature of the FCOI, NPS may determine that additional interim measures are necessary with regard to the investigator’s/employees’ participation in the research project between the date that the FCOI or the investigator’s /key person’s noncompliance is determined and the completion of NPS’s retrospective review.

**Administrative Requirements:**

**Grant submission**

NPS will certify, in each application for funding to which the regulations apply, that NPS has in effect this FCOI policy, i.e., an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received.

**Public Accessibility**

NPS will post its FCOI policy on its public website. Prior to NPS’s expenditure of any funds under a research project, NPS shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any SFI disclosed to NPS that meets the following three criteria:

* The SFI was disclosed and is still held by the investigator/employee as defined by this policy;
* NPS determines that the SFI is related to the research; and
* NPS determines that the SFI is a FCOI.

The information shall include, at a minimum, the following:

* The investigator’s/employees’ name;
* The investigator’s/employees’ title and role with respect to NPS and/or the research project;
* The name of the entity in which the SFI is held;
* The nature of the SFI; and
* The approximate dollar value of the SFI (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.

NPS will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of NPS’s identification of a new FCOI, which should be requested subsequently by the requestor

**Annual Reporting:**

For any FCOI previously reported by NPS with regard to an ongoing research project, NPS shall provide to any funding agency requiring such a report an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.

FCOI reports to the funding agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the funding agency.

**Maintenance of Records:**

NPS will maintain records relating to all investigator and key person disclosures of financial interests and NPS’s review of, and response to, such disclosures (whether or not a disclosure resulted in NPS’s determination of a FCOI) and all actions under NPS’s policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the funding agency or, where applicable, from other dates for different situations.