

Creative Bio-Peptides, Inc. Financial Conflicts of Interest (FCOI) Policy

Purpose:

Creative Bio-Peptides, Inc. (CBP) is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. The purpose of this policy is to establish standards that provide reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children).

This policy, implemented to prevent, identify, manage and/or eliminate financial conflicts of interest, complies with the following federal regulations: Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research, applicable to PHS grants and cooperative agreements, e.g. SBIR/STTR Phase II programs.

Scope:

This policy applies to investigators participating in design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH), and requires that each investigator, collaborator or subrecipient (i.e. subgrantees, subawardees, or subcontractors) be in compliance for all Federal agency grant and contract efforts. Each subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations, or a written agreement stating that this FCOI policy shall apply to the subrecipient. When necessary, procedures will be developed or modified to implement this policy.

Definitions:

For the purposes of this policy, the following definitions shall apply:

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Financial Conflict of Interest means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

PHS means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

Public Health Service Act, or PHS Act means the statute codified at 42 U.S.C. 201 et seq. Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

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., a diagnostic test or drug). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's CBP project responsibilities, including:

1. With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
2. With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's CBP project responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.

The term *significant financial interest* **does not include** the following types of financial interests:

- Salary, consulting fees or other remuneration paid by CBP (or a subrecipient as applicable)

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to the Investigator if the Investigator is currently employed or otherwise appointed by CBP, including that paid for intellectual property rights assigned or licensed to CBP and agreements to share in royalties related to such gifts.

- Ownership interest in CBP (or a subrecipient as applicable) held by the Investigator.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local 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.
- Income from service on advisory committees or review panels for 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.
- Travel by a PHS-funded Investigator 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.

Disclosure of FCOIs and Investigator Responsibilities:

Investigators who conduct research on a CBP project will be informed of their obligations under this policy to:

- Provide CBP with a Significant Financial Interest Disclosure (SFID) Form, which will be made readily available to all Investigators.
- The information reported on the SFID Form includes the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.
- Provide updates to disclosed information as needed.
- Completing all required training and education.
- Completing an annual disclosure form even if they have no financial interests to report.
- Disclosures shall include any new information that was not previously disclosed; any change in information previously disclosed; within 30 days of discovery or acquisition.
- Investigators participating in, or planning to participate in the design, conduct, or reporting of including Public Health Service (PHS) or National Institute of Health (NIH) funded research with CBP have the authority and responsibility for the activities in this policy.

Review, Management and Monitoring of FCOIs:

CBP will conduct an initial review of all disclosures, and if necessary, obtain additional

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information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. Identified cases that require further review by management who shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest could be either affected *by* the research or could have any possible impact *on* integrity of research data.

If CBP determines that a financial conflict of interest exists, a management plan will be implemented and monitored on a case-by-case basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. Such a plan could include some/all of the following, and/or other means, as deemed appropriate:

- Disclosure to research participants or the public of significant financial interests if appropriate; (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest;
- Disclosure of significant financial interests directly to subjects involved in human research; or
- Severance of relationships that create actual or potential conflicts.

A draft of the plan of action will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.

Investigator compliance with plans of action will be monitored in an ongoing basis by CBP Management.

Enforcement:

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or CBP.

Reporting Requirements to NIH and Retrospective Review:

CBP will disclose financial conflicts of interest as required by applicable laws or regulations.

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CBP will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that CBP has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, CBP will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict.

If an SFI that was not disclosed or reviewed in a timely manner is identified, CBP will initiate a retrospective review process and an interim plan of action will be implemented. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict.

If bias is found, CBP will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, CBP will provide HHS with information relating to any investigation or disclosure of significant financial interests; CBP's review of, and response to, such disclosure; and whether the disclosure resulted in CBP's determination of a financial conflict of interest.

Confidentiality:

CBP will, to the extent possible, protect the confidentiality of disclosures. In every instance, CBP will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to CBP staff only on a need-to-know basis and will not be disclosed outside of CBP unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator Noncompliance:

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), CBP may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflict of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, CBP shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- CBP will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts.

Subrecipients:

CBP will take reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subawardees, subcontractors, or collaborators) fully comply with this policy or provide CBP with sufficient assurances to enable CBP's compliance with all applicable laws or regulations.

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, CBP requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the CBP in sufficient time to allow the CBP to report the FCOI to the PHS Awarding component.

If CBP's policy will apply to the subrecipient Investigators, CBP will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations. The written agreement terms required by CBP will contain a provision that subrecipients will report to CBP any identified FCOI in sufficient time to allow CBP to report and manage the FCOI and meet the reporting obligations as described.

Public Accessibility:

CBP will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. This information may be requested by emailing grosner@creativebiopeptides.com.

Maintenance of Records:

CBP will maintain all records related to the implementation of this policy, whether or not they result in a reporting obligation, for at least 3 years following:

- the date of submission;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report;
- the date of final resolution of any investigation, audit, or similar action involving the records;
- final payment on the contract or, where applicable from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

Training Requirements:

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site.

Training must also be completed *as soon as reasonably possible* under the following circumstances:

- CBP revises its financial conflicts of interest policy or procedures in any manner that a subrecipient and will be working on PHS-funded research; or
- An Investigator is new CBP; or
- An Investigator is found to be noncompliant with this policy or a financial conflicts of interest management plan.

Clinical Research:

If HHS determines that a clinical PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was neither disclosed nor managed, CBP shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.