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**Subject Policy for Financial Conflict of Interest (FCOI)**

**A. PURPOSE:**

The purpose of this policy is to provide the employees and associates of this business community a framework to promote objectivity in funded research or activity by establishing standards to ensure that the design, conduct or reporting of research will not be biased by any conflicting financial interests of an investigator.

**B. SCOPE:**

This Financial Conflict of Interest Policy applies to all investigators, who are in a position to affect the design, conduct, or reporting of funded research or activity, and their immediate family. This policy also applies to all BCL personnel working in a key position on a funded project. All Investigators submitting applications for funding of sponsored research or activity must disclose to the Institution any actual or potential financial conflict of interest (as defined herein).

**C. OBJECTIVES:**

Federal regulations (42 CFR 50; Subpart F) require that all Institutions have established policies and procedures to ensure that the design, conduct, or reporting of funded activity is not biased as a result of the personal financial holdings of personnel directing the activity. All institutions are mandated to manage, reduce or eliminate any actual or potential financial conflicts of interest. Before external funding proposals are submitted to the sponsor, the institution is required to obtain, from investigators and personnel, the written disclosure of any significant financial interest that could reasonably appear to affect the objectivity of their performance on the sponsor funded project.

**D. POLICY:**

Conducting high quality research and instructional activities is integral to the primary mission of BioChip Labs, Inc. Active participation by investigators and other employees in external activities that enhance their professional skills or constitute public service can be beneficial to the institution as well as the individual.

It is BioChip policy that all Investigators submitting applications for external funding of sponsored research or activity disclose to the institution any financial interests which the Investigator or the Investigator's immediate family hold, if these holdings could reasonably give the appearance that a financial conflict of interest might exist between the Investigator and the external sponsor of the research.

This policy sets forth assurances that all federal and state regulations regarding potential financial conflicts of interest will be followed and also establishes procedures that provide a process to manage, reduce, or eliminate potential financial conflicts of interest.



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## **E. DEFINITIONS:**

**Conflict of Financial Interest Classifications-** the determinations of the Research Integrity Officer (and a Financial Conflict of Interest Review Committee, if deemed necessary) issued following a review of a disclosed financial interest:

1. Not a financial conflict of interest.
2. A potential financial conflict of interest, with mandate of public disclosure.
3. A potential financial conflict of interest, with mandate of additional project oversight.
4. A potential financial conflict of interest, with mandate of divestiture of relationship with sponsor.
5. A financial conflict of interest, with mandate that the Investigator terminate involvement with the project.

**Financial Conflict of Interest** - a Significant Financial Interest as defined herein that could directly affect the design, conduct, or reporting of research or activity. Abbreviated FCOI (financial conflict of interest).

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

**Immediate family** - Spouse and dependent children of the investigator.

**Institution** - any entity or organization that is applying for or receives external research funding.

**Institutional responsibilities** - an individual's professional responsibilities on behalf of BCL. Such responsibilities include, but are not limited to: research, research consultation, professional practice, and service on committees or panels such as research ethics committees (e.g. Institutional Review Boards, Institutional Animal Care and Use Committees) and other bodies monitoring the conduct of research.

**Intellectual property** - any term used to describe the patents, copyrights, mask work protection, trade secrets, and plant variety protection certificates, which cover, or pertain to, inventions.

**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 sponsor funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

**PHS** - Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**Potential financial conflict of interest** - any outside activity, commitment or interest that may reasonably give the appearance of adversely affecting, compromising, or being incompatible with,



the institutional obligations of an Investigator.

**Related Outside Entity** - means an entity in which a person has a significant financial interest that may, or may reasonably appear to an outside observer, to influence the discharge of research, or other BCL-related responsibilities. In determining relatedness, individuals should employ a standard of common sense, and when in doubt, disclose. Examples of entities that might be related are those:

1. whose products, services or activities are related to the areas of a faculty member's or an investigator's teaching or research;
2. that fund research in a faculty member's or an investigator's area of professional interest;
3. that own or have rights to develop intellectual property that is the subject of research in which a staff member or an investigator participates;
4. that compete commercially with such an entity as described in (3);
5. that make or propose to make a gift to BCL that would support a staff member's or an investigator's research activities;
6. that furnish products or services to BCL through a contractual process in which a staff member or an investigator participates in any way;
7. that propose to enter a licensing agreement with BCL with respect to technology invented by any staff member or investigator;
8. that act as a legal or de facto agent for any outside entity engaged in any of the above activities.

**Research** - 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Resolution Plan** - an action plan agreed to by BCL and the Investigator, outlining the steps that must be taken by the Investigator and/or the Institution to manage a potential financial conflict of interest situation.

**Significant financial interest** - a Financial Interest consisting 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 an outside observer, to influence the discharge, research, or other BCL-related responsibilities.

1. 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);



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- 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. 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).
  3. For PHS-funded projects, 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, provided; however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, an institution of higher education (i.e., a United States 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. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Exclusions from this definition:

- (a) Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- (b) Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- (c) 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;
- (d) Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency located in the United States, an institution of higher education as defined at 20 U.S.C. 1001(a) (i.e., a United States Institution of higher education), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- (e) Income from service on advisory committees or review panels for a federal, state or local government agency located in the United States, institution of higher education as defined at 20 U.S.C. 1001(a) (i.e., a United States Institution of higher education), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- (f) Biochip Labs imposes a \$5000 threshold for reimbursed or sponsored travel, anything beyond that value must be reported as SFI.

**Sponsor** - any non-BCL entity providing partial or full support of research or activity performed by BCL staff members utilizing BCL resources.

## **F. RESPONSIBILITIES:**

1. It is the responsibility of investigators to disclose any potential financial conflicts of interest truthfully and accurately to the best of their knowledge and ability and to ensure the disclosure of any potential financial conflicts of interest held by their immediate families.



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## **G. PROCEDURES:**

1. All Investigators specifically named in grant applications are required to complete the Required Agreements regarding Significant Financial Interest and provide a signature that certifies their compliance with the Institution's Financial Conflict of Interest policy. All such investigators must disclose any significant financial interests by attaching a complete Significant Financial Interest Disclosure Form and assure that a current SEC-I, "Statement of Financial Interest" disclosure form) is placed on file.
2. In the event that a significant financial interest is held by the immediate family of the Investigator, it is the responsibility of the Investigator to ensure that a separate SEC-I form is completed by the immediate family member and submitted by the Investigator as an attachment to the Investigator's own SEC- I disclosure form.
3. If the proposal is funded as an award, the Investigator must submit an SEC- I annually on May 1 of every year that an award is in active status. If the investigator or the Investigator's immediate family acquires new financial interests with potential conflict during the life of the award a new SEC-1 must be filed within 30 days of the date the interest is acquired.
4. All Investigators who are not named in submitted proposals, but who are subsequently hired as Investigators on grant proposals, are required to submit SEC-I forms to the Office of Human Resources within ten days (10) of being named to the grant funded position.
5. Each Investigator must complete training prior to engaging in sponsored projects related to any PHS-funded grant or contract and at least every four years, and immediately under any of the following circumstances: BCL FCOI policies change in a manner than affects investigator requirements; an Investigator is new to the Institution; and/or the Institution finds an Investigator non-compliant with the FCOI policy or resolution plan.
6. The Institution will accept grant awards for funded proposals but will withhold expenditure authority until all required SEC-I forms are submitted in compliance with this requirement. (The Public Health Service as research sponsor does not permit such an exception.).
7. Collaborators, subrecipients or subcontractors from other entity or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding Investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies. The determination of whether this policy or the policy of the collaborator, subrecipient, or subcontractor will apply must be incorporated as part of the written agreement between the parties and must include time periods to meet disclosure and/or FCOI reporting requirements.
8. When PHS funds are involved, subrecipient institutions that rely on their FCOI policies must



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report identified FCOI to the awardee institution in sufficient time to allow the awardee institution to report the FCOI to the PHS Awarding Component to meet reporting obligations.

9. Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service (PHS). The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding Investigator significant interest disclosure and that its portion of the project is in compliance with the subcontractor's company policies.
10. If an unmanageable financial conflict of interest situation is determined, the Institution shall take the necessary action to assure that the Investigator's relationship with the project is severed.
11. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
  - Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
  - Failure by the Institution to review or manage such a Financial Conflict of Interest; or
  - Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

BioChip Labs shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

BioChip Labs shall document the retrospective review which must include at least the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
8. Findings of the review; and
9. Conclusions of the review.

BioChip Labs will notify NIH promptly should any bias be identified and submit a mitigation report.



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## **H. DISTRIBUTION:**

All employees annually and via onboarding (updated within 60 days of any modification of the policy).

## **I. SOURCES:**

**42 CFR 50.603 (b) - Promoting Objectivity in Research Authority**

([https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50\\_1603](https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50_1603))

**42 CFR 50.604 (b) - Responsibilities of Institutions regarding Investigator financial conflicts of interest** (<https://www.law.cornell.edu/cfr/text/42/50.604>)

**42 CFR 50.604(e)(1)-(3) - Subpart F - Promoting Objectivity in Research Authority**

([https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50\\_1604](https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50_1604))