

POLICY ON CONFLICT OF INTEREST IN RESEARCH

I. SUMMARY OF INTENT

It is the policy of the Buck that all activities conducted at the Institute must be conducted with integrity. To this end, standards shall be established and enforced to provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest. In carrying out this policy, the Institute will comply with all federal and state rules and regulations governing objectivity in research.

II. APPLICABILITY

This policy applies to all institutional research activities and to all employees, interns, and volunteers engaged in the conduct or oversight of research (“Investigators”) regardless of title, position, or source of funding (although travel reporting requirements apply only to PHS-funded research). By Buck policy, noncompliance with this policy may be grounds for dismissal; by PHS regulation, it may be reportable to the National Institutes of Health.

III. SCOPE

The intent of this policy is not to preclude outside activities, but instead to identify and manage financial conflicts of interest that could create bias – or the perception of bias – in the design, conduct, or reporting of research. We therefore need to know:

- (1) if you, your spouse, or your children (collectively referred to in this Section III as “you” or “Investigator”) stands to gain financially from research performed at the Buck, directly or through participation in a business entity with which you are affiliated; or
- (2) if you serve in a management, board, or advisory capacity for any entity which conducts, reports, or benefits from scientific research; or
- (3) if you own or will receive financial or securities remuneration of any kind for services which overlap with your expertise or the expertise of the Buck Institute; or
- (4) if your travel has been supported by a for-profit entity or a non-profit not affiliated with an educational institution (for PHS-funded Investigators only).

To illustrate, you must disclose all of your financial relationships with:

- sponsors of your research;
- competitors of your research sponsors;
- any member of an industry, trade, or advocacy group that directly funds your research or funds a sponsor of your research;
- any entity that manufactures, commercializes, or is developing a product that is being used, evaluated, or further developed by your research;
- subcontractors, suppliers, and lessors of goods, equipment, materials, proprietary information, services, or facilities used in your research;

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For additional information see:

Conflict of Interest in Research Procedures

- conversely, any entity that will receive materials, data, or other information from your research; and
- any others who could directly or indirectly benefit financially from your research, including for example pharmaceutical companies, trade groups, and litigants for whom you act as an expert.

For each such entity, you must disclose:

- (1) *any compensation* received or anticipated to be received from such entity –
 - regardless of whether the compensation is paid to you as an employee, consultant, advisor, director, or in any other capacity; and
 - regardless of whether the compensation is paid to you in cash or in other property, such as intellectual property rights.
- (2) *any equity* held or anticipated to be received in such entity, including stock, options, warrants, and other ownership interests; and
- (3) *any gifts, loans, or sponsored travel* received or anticipated.

Exceptions – for purposes of disclosure, you may disregard:

- any compensation that originated from the Buck Institute;
- income from and ownership of stocks, bonds, mutual funds, *etc.* where your relationship to the entity in question is no different from the general public's;
- income from seminars, lectures, teaching engagements, or travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education; and
- income from service on advisory committees or review panels for a federal, state, or local government agency or institution of higher education.

IV. PROCEDURES

The following is a summary of procedures; please also reference the more comprehensive information contained in the Institute's *Conflict of Interest in Research Procedures*.

A. Training

Every investigator is required to complete the Institute's required coursework on objectivity in research within 30 days of hire (but, for future hires, prior to engaging in research on any PHS-funded grant) and every four years thereafter. Buck offers this required training as a web-based tutorial through the Collaborative Institutional Training Initiative (CITI Program): <http://www.citiprogram.org>.

B. Disclosures

Disclosures must be submitted:

- at time of hire and annually thereafter;
- within thirty (30) days of discovering or acquiring a new reportable financial interest (*i.e.*, through purchase, marriage, business formation, entering into consulting agreements, *etc.*);
- when submitting any application, progress report, agreement, or contract for a sponsored research project; and
- for PHS-funded researchers, within one month of sponsored travel – *i.e.*, where any travel costs related to your institutional duties have been paid by a for-profit entity or a non-profit not affiliated with an educational institute.

C. Initial Review

Prior to the expenditure of any grant funds, the Institute’s COI Officer will review financial disclosures to determine whether a disclosed financial interest relates to government-funded research and also constitutes a “Financial Conflict of Interest” as defined in Public Health Service regulations. If such determination is made, the disclosed information will be forwarded to the Institute’s Conflict of Interest Committee.

D. Management and Monitoring

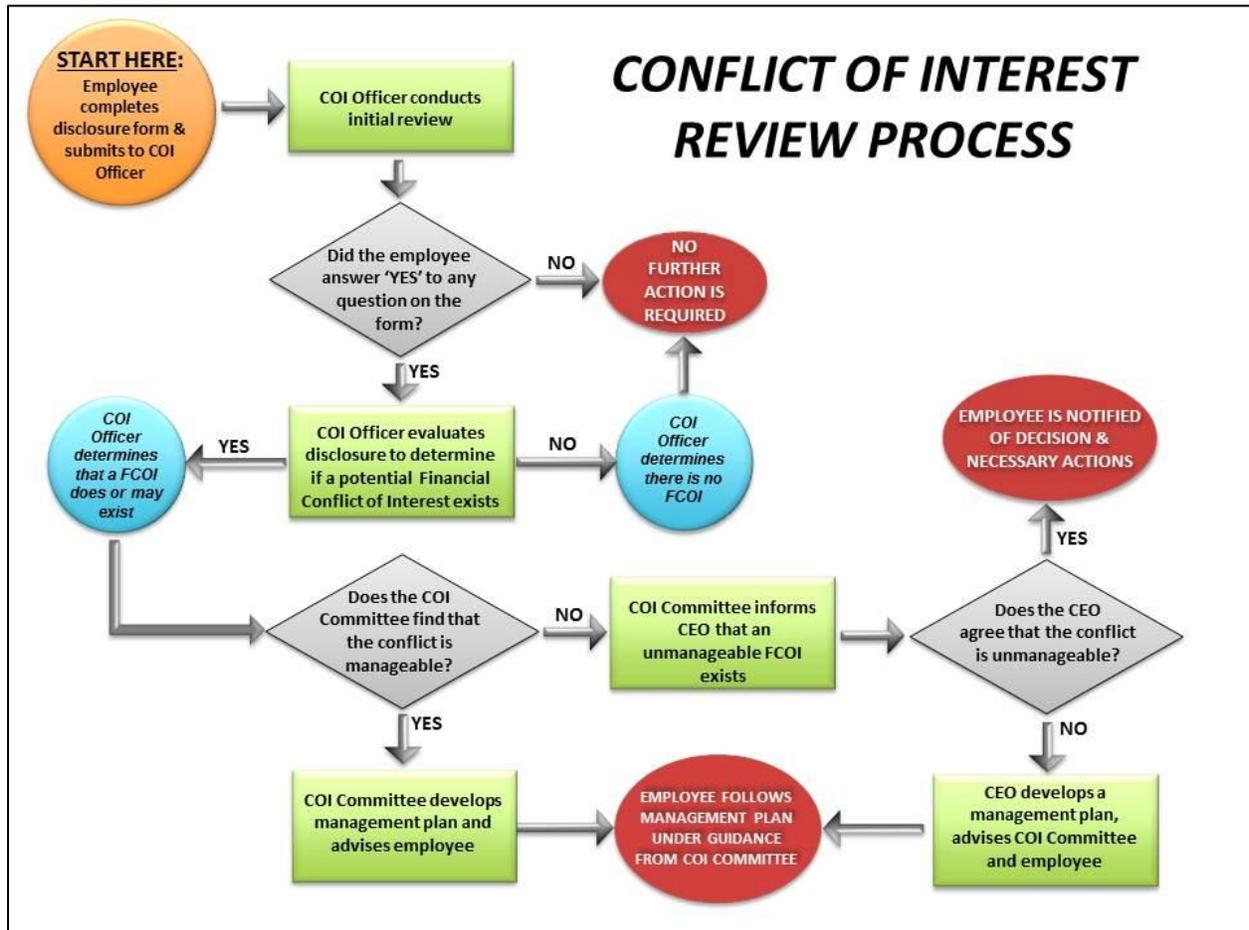
The Institute’s Conflict of Interest Committee will evaluate the FCOI to ascertain if and how it should be managed to avoid the reality or appearance of bias in research. The Conflict of Interest Committee has the right and obligation to adopt, and to require compliance with, Conflict Management Plans. These Plans will include any requirements the Committee deems necessary to eliminate or manage the conflict – including but not limited to:

- requiring disclosure of the FCOI in publications and grant applications, as well as on a publicly-accessible website as required by PHS regulations;
- requiring that publications and grant applications be reviewed by an institutional official prior to submission, or that research protocols be reviewed prior to implementation;
- precluding an Investigator’s participation in contract negotiations;
- requiring divestiture of the financial interest;
- recommending to the CEO that the Institute not accept a grant, agreement, contract, gift, or purchase giving rise to an FCOI that cannot be eliminated or appropriately managed.

In carrying out its responsibilities, the Committee may need to further disseminate disclosed information to ensure evaluation and transparency of financial interests related to research activities. An Investigator who disagrees with a decision regarding existence of a

financial conflict or the elements of a Conflicts Management Plan may submit a written appeal to the Institute’s CEO.

All Conflicts Management Plans will be regularly monitored to ensure Investigator compliance. In the event of noncompliance, the Conflict of Interest Committee will make a recommendation to the CEO concerning appropriate sanctions.



V. SANCTIONS FOR POLICY NON-COMPLIANCE

These policies are mandated by the federal government, and failure to comply may lead to dismissal. If an Investigator is found to be out of compliance with this policy or with a Conflicts Management Plan, and fails to come into compliance when requested, the Institute is required to and will report such noncompliance to the NIH and take corrective action. (In addition, per regulation, the Investigator is required to repeat FCOI training coursework.)

Regardless of compliance with the Institute’s policy and procedures, if actual financial bias in research is discovered, the NIH will be promptly notified and a Mitigation Report submitted in accord with federal regulations.

VI. CONFLICT OF INTEREST OFFICER

The Institute's COI Officer is responsible for overseeing the implementation of this *Policy* and all *Conflict of Interest in Research Procedures* – including:

- responding to inquiries concerning *Conflict of Interest in Research Policy and Procedures*;
- posting this policy on the Institute's public website and ensuring compliance with other requirements of public access to FCOI-related information;
- conducting initial reviews of financial disclosures;
- providing staff support to the Conflict of Interest Committee;
- maintaining FCOI records for at least three years from the date of the final expenditures report or as otherwise required by regulation;
- completing and documenting retrospective reviews within 120 days of determination of FCOI policy noncompliance;
- obtaining certification and agreement from subrecipients that their FCOI policy complies with PHS regulations and that relevant FCOIs will be timely disclosed to the Institute.

VII. REFERENCES & ADDITIONAL RESOURCES

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 CFR Part 50 Subpart F](#)) applicable to grants and cooperative agreements (2011 Revised Regulations).

CIRM Grants Administration Policy for Academic and Non-Profit Institutions ([Section III. C. Public Policy Requirements, 2. Conflict of Interest](#)) applicable to grants and contracts awarded by the California Institute for Regenerative Medicine (CIRM)