

FINANCIAL CONFLICT OF INTEREST POLICY

INTRODUCTION

This Financial Conflict of Interest (“FCOI”) policy applies to all Calvin College (“College”) Investigators and to funded Research as stated below, including Research funded by Government agencies that require the College to adopt a Financial Conflict of Interest policy. Nothing in this policy limits the requirement of employees to also comply with the College’s general Conflict of Interest and Disclosure Policy for Employees. (See Conflict of Interest and Disclosure Policy for Employees.)

Reason for Policy:

When a College Investigator involved in scientific Research has Financial Interests in a company, organization, or institution external to the College, or receives compensation, funding, or other assistance from entities that can be affected by the Investigator’s research, there is the potential for a conflict of interest or the appearance of a conflict. Conflicts of interest can arise in grant Research projects, for example, when personal financial interests are held by Investigators in a company either sponsoring the Research or potentially benefiting from the results of the Research. Again, for example, they may occur should the College subcontract with a company owned by the Investigator or a member of his or her family. Thus, it would violate the College’s FCOI policy for an Investigator to influence the College’s business decisions in ways that could lead to personal gain or give improper advantage to members of his or her families or to associates.

Calvin College is committed to conducting Research that reflects its Christian identity and mission. Therefore, it is committed to Research that is free of outside conflicts of interest that might compromise—or even give the appearance of compromising—the sound professional judgment of its Investigators. Government regulations also require that institutions applying for research grants from certain federal agencies maintain a policy on financial conflicts of interest and require that Investigators disclose any potential Financial Conflicts of Interest when applying for support for their Research.

Policy Oversight and Enforcement:

The College Conflict of Interest Committee is responsible for ensuring implementation of this policy and may recommend that all relevant activities be suspended until the Financial Conflict of Interest is resolved or other action deemed appropriate by the Committee is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to the College’s policy.

DEFINITIONS

- a. *Disclosure of Significant Financial Interests*: an Investigator's disclosure of Significant Financial Interests to the College.
- b. *Family*: any member of the Investigator's immediate family, specifically, any dependent children and spouse.
- c. *Financial Conflict of Interest (FCOI)*: a Significant Financial Interest (or, where the Committee requires - or an Investigator elects - disclosure of other Financial Interests, a Financial Interest) that the Committee reasonably determines could directly and significantly affect the design, conduct or reporting of College Research.
- d. *FCOI Report*: the College's report of a financial conflict of interest to a Government Awarding Component.
- e. *Financial Interest*: anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial Interest does NOT include:

- i. salary, royalties, or other remuneration from the College;
- ii. income from the authorship of academic or scholarly works;
- iii. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

- iv. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

Significant Financial Interest: a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- i. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
 - ii. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
 - iii. if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
 - iv. is income related to intellectual property rights and interests not reimbursed through the Institution.
- f. *Institutional Responsibilities or College Responsibilities:* an Investigator's professional responsibilities on behalf of the College, and as defined by the College in its policy on Financial Conflicts of Interest, which may include for example: 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.
- g. *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 Research funded by the Government or other funding entity, or proposed for such funding, which may include, for example, collaborators or consultants. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postgraduate associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.
- h. *Manage:* taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- i. *PD/PI:* a project director or principal Investigator of a government-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this Rule.

- j. *Government*: Any state or federal government agency that requires this Financial Conflict of Interest Policy, including but not limited to the Public Health Service (PHS) 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).
- k. *Government Awarding Component*: the organizational unit of the Government that funds the Research or project that is subject to this policy.
- l. *Public Health Service Act or PHS Act*: the statute codified at 42 U.S.C. 201 et seq.
- m. *Research*: a systematic investigation, study or experiment designed to develop or contribute to generalized knowledge. 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 Government Awarding Component (that requires compliance with this policy) 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.
- n. *Senior/key personnel*: the PD/PI and any other person identified as senior/key personnel by the College in the grant application, progress report, or any other report submitted to the Government by the Institution under this subpart.
- o. *Conflict of Interest Committee (“Committee”)*: Team from College named by the President and charged with reviewing and managing the requirements of this policy, initially consisting of the College’s Vice President Finance or designee, the General Legal Counsel or designee, the Director of Grants and Foundation Relations or designee and Dean for Research and Scholarship or designee (“Dean”).

PROCEDURE AND GUIDELINES

1. Disclosure of Financial Interests

All Investigators are required to disclose their outside Financial Interests to the College annually and upon certain events as described below. (See Disclosure Form attached as Exhibit 1.) The Committee or its designee is responsible for the distribution, receipt, processing, review, and retention of the Disclosure Forms.

Regardless of the disclosure requirements, any Investigator who reasonably concludes or reasonably should conclude that his/her Research presents or appears to present a Financial Conflict of Interest must disclose the fact to the Committee, and Investigators are encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

- a) *Annual Disclosures:* All Investigators must disclose their Significant Financial Interests to the College, through the Committee or its designee, on an annual basis. All forms should be submitted to the Committee or its designee by March 1 for the previous calendar year or as determined by the Committee.
- b) *Other Disclosures:* In addition to annual disclosure, certain situations require other disclosures.
 - i. All Investigators must disclose their Significant Financial Interests to the Committee or its designee, within 30 days of their initial appointment or employment.
 - ii. Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Committee or its designee an updated disclosure of his or her Significant Financial Interests with the outside entity. The College will not submit a Research proposal unless the Investigator(s) have submitted such disclosures.
 - iii. In addition, all Investigators must submit to the Committee or its designee a disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.
- c) *Travel:* Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Committee or its designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to

determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2. Review and Decision of Committee

If the Disclosure Form reveals a Significant Financial Interest, it will be reviewed promptly by the Committee or its designee in a closed session for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Committee or its designee will take action to eliminate, reduce, or manage the conflict, as appropriate. If the Committee or its designee determines that there is a Financial Conflict of Interest that can be managed, it must require and approve a written management plan before any related research goes forward. The affected Investigator and the Committee is responsible for developing and submitting a proposed management plan. Any management action shall be taken after consideration of such factors as the nature of the Research, the nature and size of the interest, the degree to which the conflict is related to the Research, the extent to which the interest could be affected by the Research, and any management strategies that would mitigate or eliminate the conflict. Management strategies may include, but are not limited to:

- public disclosure of Significant Financial Interests
- monitoring of Research by independent reviewers
- modification of the Research plan to avoid conflicts of interest
- disqualification of Investigators from the portion of the funded Research that could create conflicts of interest
- require divestiture of Significant Financial Interests
- require severance of relationships that create conflicts of interest.

The Committee or its designee will also notify the Provost or its designee of the existence of the Financial Conflict of Interest in the event he/she does not support, or no longer supports, the Research.

No member of the Committee who holds a Significant Financial Interest in a project considered under this section may participate in the review or development of a management plan for the project

A Financial Conflict of Interest will exist when the Committee or its designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of Government-supported research.

To address complex situations, an additional oversight committee may be established by the Committee or its designee to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and post-graduate appointees), to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the management plan.

3. Reporting to Government

Should any reported conflict or non-compliance require reporting to Government agencies such as PHS, the Committee or its designee will report in accordance with PHS or other applicable Government regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

4. Subgrantees

- a) Subgrantee (sometimes also referred to as “subrecipients”) (e.g., subcontractors or consortium members) Investigators who are not employed by or otherwise affiliated with the College also must be in compliance with this Policy. Any College agreement with such subgrantee Investigator or its employer must contain written terms that establish whether the Financial Conflict of Interest policy of the College or that of the subrecipient (or its employer) will apply to the subrecipient's Investigators. Subgrantee Investigators can comply in two ways:
 - i. Subgrantee Investigator may have his or her conflicts resolved through the College process under this policy for identifying and resolving Financial Conflicts of Interest; or,
 - ii. If the subgrantee Investigator is employed by an institution that has enacted a Financial Conflict of Interest policy that is in compliance with applicable federal regulations, including 42 CFR § 50.604, the subgrantee's employer may provide assurances to the College that any conflicts related to the project under consideration have been managed, reduced or eliminated pursuant to the employer’s policy. Additionally, if the subrecipient's Investigators must comply with the subrecipient's or its employer Financial Conflicts of Interest policy, the agreement referenced above shall specify time period(s) for the subrecipient Investigator to report all identified Financial Conflicts of Interests to the College. Such time period(s) shall be sufficient to enable the awardee College to provide timely FCOI reports, as necessary, to the Government as required by this policy;
- b) The appropriate assurances can be provided by having the subgrantee Investigator or its employer complete the Subgrantee Assurance Form (See Exhibit 2). The subgrantee Investigator must also provide FCOI reports to the Government Awarding Component regarding all Financial Conflicts of Interest of all subrecipient Investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

- c) If the subgrantee Investigator chooses to comply through providing assurances, the assurance form must be submitted with the Investigator's conflict-of-interest form. If the subgrantee Investigator does not have a policy or is not employed by an institution that has enacted a policy in compliance with applicable federal rules and regulations, he or she must submit to follow the College Financial Conflict of Interest Policy and also follow the College's policy for managing, reducing or otherwise eliminating any conflicts

5. Investigator non-compliance

- a) *Disciplinary Action:* In the event of an Investigator's failure to comply with this Policy, the Committee or its designee shall report the matter to the Provost, who may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Committee or its designee is implemented.

The Provost's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Committee or its designee, will be described in a written explanation of the decision to the Investigator, Committee and, where applicable, other College officials, and will notify the individual of the right to appeal the decision.

- b) *Retrospective Review:* In addition, if the Committee or its designee determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Committee or its designee will complete a retrospective review of the Investigator's activities and the Research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Committee or its designee will update any previously submitted report to the Government or PHS or the prime PHS-awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the relevant Government regulations (such as PHS regulations), including a

description of the impact of the bias on the Research project and the plan of action to eliminate or mitigate the effect of the bias.

6. Training

Each Investigator must complete training on this policy prior to engaging in Research funded by PHS, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Committee or its designee in the event that this policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

7. Records

The Committee or its designee will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, and in accord with applicable Government regulations.

8. Confidentiality

To the extent permitted by law, all Disclosure Forms, conflict management plans, and related information will be confidential. However, the College may make such information available to an agency funding research of the faculty member, to a requestor of information concerning a Financial Conflict of Interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested and required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9. Public Accessibility

Prior to the expenditure of funds, the College will respond to any requestor within five business days of the request by making available information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded Research; and

- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulations.

10. Appeal

Any Investigator may appeal the decision of the Committee regarding management of a financial conflict of interest in writing to the Provost who will consult with the Investigator and Committee as the Provost deems necessary and appropriate to the particular circumstance. The decision of the Provost shall be final.

11. Regulatory Authority

This policy implements the requirements of 42 CFR Part 50, Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Cabinet – Approved, August 22, 2012

EXHIBIT 1

Disclosure Statement

Name _____

Title/Rank _____ Department _____

Title of Sponsored Project _____

Name of Funding Sponsor _____ Project Period _____

CERTIFICATION: I have read and understand the Calvin College Research Financial Conflict of Interest Policy.

1. Are you or any member of your immediate family (spouse, children, or dependents) an officer, director, partner, trustee, employee, advisory board member, or agent of the external organization funding this sponsored project or of any organization from which goods and services will be obtained under the sponsored project?

___ Yes (if so, describe in detail the nature and extent of the affiliation on an attached sheet).

___ No.

2. Are you or any immediate family member the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of the external organization funding this sponsored project or any external organization from which goods and services will be obtained under this sponsored project?

___ Yes (if so, describe in detail the nature and extent of the equity interest on an attached sheet).

___ No.

3. Have you or any member of your immediate family derived income within the past year or do you or any member of your immediate family anticipate deriving income exceeding \$5,000 per year from the external organization funding this sponsored project or any external organization from which goods and services will be obtained under this sponsored project.

___ Yes (if so, describe on an attached page the amount of the income and the reason for which it was or will be derived).

___ No.

4. Do you have any affiliation with the external organization that would diminish your ability to fulfill your paramount obligations to your students, your colleagues, or the College; or have you involved any graduate student in any capacity with the external organization?

___ Yes (if so, describe on an attached page the nature of the affiliation and the amount of time per week you dedicate to it).

___ No.

Signature of Investigator _____ Date _____

Important Note: The Investigator must also ensure that those responsible for the design, conduct, or reporting of project work will also complete and submit disclosures and updates as may be necessary.

EXHIBIT 2

Subgrantee Assurance Form

I certify that I or my employer have enacted a Financial Conflict of Interest policy that is in compliance with applicable federal regulations, including 42 CFR § 50.604. I or my employer provide assurances to the College that any conflicts related to the project under consideration have been managed, reduced or eliminated pursuant to my or my employer's policy. Additionally, I and my employer agree to comply with my or my employer's Financial Conflicts of Interest policy. I attach to this Assurance Form my or my employer's Financial Conflict of Interest Form.

Name

Date