

MACALESTER COLLEGE FINANCIAL CONFLICT OF INTEREST POLICY

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In accordance with Federal regulations, the College has a responsibility to manage conflicts of interest that arise in the course of projects funded by the U.S. government. A potential conflict of interest occurs when there is a divergence between an individual's private interests and his/her professional obligations to the College such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. The College requires that Investigators disclose Significant Financial Interests when applying for external grant funding as well as during the award period.

*** FOR INVESTIGATORS WITH PUBLIC HEALTH SERVICE (PHS)-FUNDED RESEARCH (INCLUDING NIH), refer to Section 2 of this policy.

*** FOR ALL OTHER INVESTIGATORS WITH EXTERNALLY-FUNDED RESEARCH, adhere to Section 1.

SECTION 1

Applicable to all externally-funded research, except PHS-funded research
(PHS-funded research is covered in Section 2)

Key Definitions

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 or educational activities funded by an external sponsor, or proposed for such funding.

Significant Financial Interest:

Anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interest (e.g., stocks, stock options or other ownership interests); and
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

Significant Financial Interest does not include:

1. Salary, royalties or other remuneration from the College;
2. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that, when aggregated for the investigator and the investigator's spouse or domestic partner and dependent children, meets both of the following tests:

- a. Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and
 - b. Does not represent more than a 5% ownership interest in any single entity
6. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse or domestic partner and dependent children, are not expected to exceed \$10,000 during the twelve month period.

Provided, however, that the exclusions in terms (1), (4), and (5) shall not apply if the compensation or transfer of equity interest is conditioned upon a particular outcome in an externally funded research project.

Each investigator is required to disclose the following Significant Financial Interest (including those of the investigator's spouse or domestic partner and dependent children):

- Any Significant Financial Interests of the Investigator that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by an external sponsor;
- Any Significant Financial Interests of the Investigator in entities whose financial interests would reasonably appear to be affected by such activities.

Significant Financial Interest Disclosure

Noncompliance with this policy will be investigated consistent with College policies relating to faculty and staff, or other applicable disciplinary policies.

To comply with these regulations, each Investigator shall disclose any Significant Financial Interest prior to the time of proposal submission. For the principal investigator, this disclosure will be part of the Grant Proposal Clearance form which must be returned to Foundation, Government and Corporate Relations. Any co-investigators must complete a Financial Interests Disclosure Form and return it to Foundation, Government and Corporate Relations.

Investigators must also update their financial disclosures during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained. Foundation, Government and Corporate Relations collects these disclosures on behalf of the Provost. An Investigator must report to Foundation, Government and Corporate Relations any changes in reportable Significant Financial Interests as they occur. In addition, Foundation, Government and Corporate Relations will request financial disclosure updates from investigators each year in September or October.

Management of Financial Conflicts of Interests

The Provost will perform a review of all financial disclosures to determine whether an actual or potential conflict of interest exists. An actual or potential conflict exists when the review reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project.

If the determination is made that a Significant Financial Interest exists that could affect the design, conduct or reporting of federally funded activities, then the Provost will ask the Investigator to develop a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a Significant Financial Interest.

At a minimum, the Resolution Plan shall address such issues as:

- Public disclosure of Significant Financial Interests;
- Review of research protocol by independent reviewers; and
- Monitoring of research by independent reviewers.

The Provost shall review the Resolution Plan and approve it and add conditions or restrictions, as needed, which may include the following:

- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of Significant Financial Interests; or
- Severance of relationships that create actual or potential conflicts of interest.

If the Provost determines that imposing the above referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Provost may recommend that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions.

The Provost is responsible for ensuring that actual or potential conflicts of interests are satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to expending any funds from the applicable Federal award, or they will be disclosed to the sponsoring agency for action.

The Disclosure Forms completed by Investigators will be retained by Foundation, Government and Corporate Relations until three (3) years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever comes later.

If some of the research is carried out through a subrecipient, collaborators must provide a certification that their institutions 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.

Purchasing Conflict of Interest Policy

Macalester's Purchasing function observes an additional policy regarding procurement of supplies, equipment, or services from an employee of the College or their relative(s).

Purchases from which a Macalester employee, or his/her relative(s) would benefit, are subject to public competitive bidding or special clearance by the Purchasing Manager and the Vice President for Administration & Finance. College employees who have, or whose relatives have, a substantial interest in any contract with, sale to, purchase from or service for the College are required to disclose that interest to the College in advance of the transaction.

To facilitate compliance with this policy, Purchasing will solicit competitive bids at the request of a department – or grant Investigator – so that bids or proposals from College employees and their relatives may be considered.

SECTION 2

Applicable to Public Health Service (PHS)-funded Research (All other externally-funded research is covered in Section 1)

The Public Health Service (PHS) revised the policy regarding financial conflict of interest effective September 26, 2011. In response to the amended policy, the College requires Significant Financial Interest disclosures and training for each Investigator on PHS-funded research in an effort to provide a reasonable expectation that the design, conduct, and reporting of PHS-funded research will be free from bias resulting from Investigator financial conflicts of interest. Furthermore, in compliance with the requirements of 42 CFR Part 50, Subpart F, Objectivity of Research; this policy applies to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements. The regulation applies to both prime and subrecipient institutions, domestic or foreign, and through implementation, to each Investigator who is planning to participate in, or is participating in, such research. This financial conflict of interest policy does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications / awards.

Key Definitions

Investigator: The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS Awarding Component, or proposed for such funding, which may include, for example, collaborators or consultants.

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 PHS by the College.

Institutional responsibilities: An Investigator's professional responsibilities on behalf of the College which may include, but are not limited to, research, teaching, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Interest: Anything of monetary value, whether or not that value is readily ascertained.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. Investigators (PD/PI, Senior/key personnel), including subrecipient Investigators, must disclose all financial interests received from all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (income in excess of \$5,000).

Significant Financial Interest (SFI):

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. 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); 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;
 - b. 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, domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interest in excess of \$5,000.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of \$5,000, (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, a United States 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 a United States Institution of higher education. The disclosure must include, at a minimum, a statement of the purpose of the trip, the identity of the sponsor, the destination and the duration of the trip.

Significant Financial Interest does not include:

- Salary royalties, or other remuneration paid by the College to the Investigator if the Investigator is currently employed or otherwise appointed by the College;
- Intellectual Property Rights assigned to the College and agreements to share in royalties related to such rights;
- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

Investigator Training

The College will provide training on the Financial Conflict of Interest Regulation and include the College's policy on FCOI and the Investigator's responsibilities regarding disclosure of foreign and domestic SFIs. Each Investigator doing PHS-funded research must complete the College's FCOI training:

- Prior to engaging in research related to any PHS Awarding Component funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
 - The College revises its policy in a manner that affects the Investigator;
 - An Investigator is new to the College; or
 - The College finds an Investigator is not in compliance with the College's policy or management plan.

Significant Financial Interest (SFI) Disclosure

Noncompliance with this policy will be investigated consistent with College policies relating to faculty and staff, or other applicable disciplinary policies.

The College maintains enforcement mechanisms to ensure Investigator compliance, which may include employee sanctions or other administrative actions such as letters of reprimand, mandatory additional training, restrictions on the use of award funds, or other measures consistent with College disciplinary policies.

Each Investigator must disclose their foreign and domestic SFIs at time of application. The principal investigator will include this disclosure on the Grant Proposal Clearance form which must be returned to Foundation, Government and Corporate Relations. Any co-investigators must complete a Financial Interests Disclosure Form and return it to Foundation, Government and Corporate Relations.

Investigators must also update their significant financial disclosures during the period of the award. Foundation, Government and Corporate Relations collects these disclosures on behalf of the Provost. An Investigator must report to Foundation, Government and Corporate Relations any changes in reportable Significant Financial Interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance). In addition, annually, Foundation, Government and Corporate Relations will request financial disclosure updates from investigators in September or October.

If, in the course of an on-going PHS-funded research project, an Investigator who is new to the project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the College will, within 60 days, review the SFI, determine if an FCOI exists and implement an interim management plan, if needed. If the College identifies an SFI that was not disclosed or reviewed in a timely manner, the Provost shall, within 60 days, review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.

Management of Financial Conflicts of Interest

The Provost will perform a review of all significant financial interest disclosures to determine (1) whether an Investigator's significant financial interest is related to PHS-funded research and, (2) if so, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the College, through the Provost, reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The College may involve the Investigator in the determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the College reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

If the determination is made that a Significant Financial Interest exists that could directly and significantly affect the design, conduct or reporting of PHS-funded activities, then the Provost will implement a Management Plan that details proposed steps to manage the financial conflict of interest. The College will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the project.

At a minimum, the Management Plan shall include:

- Role and principal duties of the conflicted Investigator 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 agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Conditions or restrictions, which might be part of the management plan, include the following:

- Public disclosure of financial conflicts of interest (e.g. when presenting and publishing the research);
- For research projects involving human subjects research, 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 financial conflict of interest;
- 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;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

Further, if the PHS Awarding agency or HHS decides that a particular FCOI will bias the objectivity of research, they may impose special award conditions, suspend funding or impose other enforcement mechanisms until the matter is resolved.

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the College to review or manage an FCOI, or failure to comply with the management plan, the College shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. If bias is found, the College

will complete a Mitigation report describing the impact of the bias on the research project and the College's plan of action taken to eliminate or mitigate the effect of the bias.

The documented retrospective review will include, at a minimum, the following key elements: the project number; the project title; the PD/PI (or contact PD/PI if a multiple-PD/PI model is used); the name of the Investigator with the Financial Conflict of Interest; the name of the entity with which the Investigator has the Financial Conflict of Interest; the reasons for the retrospective review; the detailed methodology used for the retrospective review (e.g., the review process, the composition of the review panel, and the documentation reviewed); the findings of the review; and the conclusions of the review. Where bias is found, the Mitigation report submitted to the PHS Awarding Component will include the key elements of the retrospective review described above, together with a description of the impact of the bias on the research project and the College's plan of action — the actions that have been or will be taken — to eliminate or mitigate the effect of the bias. If new information is discovered following completion of a retrospective review, the College will promptly update any previously submitted FCOI report accordingly.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded research project of clinical research 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 not managed or reported by the College as required, the College will require the Investigator involved to (a) disclose the Financial Conflict of Interest in each public presentation of the results of the research, and (b) request an addendum to previously published presentations to disclose the Financial Conflict of Interest.

Financial Conflict of Interest (FCOI) Reporting

Prior to the expenditure of funds, the College will provide a FCOI report to the PHS Awarding Component and ensure that a management plan is implemented. If a FCOI is obtained during the project or an Investigator new to the project has a FCOI, the College will provide a report to the PHS Awarding Component within 60 days of identification and ensure that a management plan is implemented.

Each FCOI report provided to the PHS Awarding Component will include, at a minimum: the grant or project number; the name of the PD/PI; the name of the Investigator with the Financial Conflict of Interest; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; the approximate dollar value of the Significant Financial Interest in the ranges set forth below, or a statement that the value cannot be readily determined; a description of how the financial interest relates to the PHS-funded research and the basis for the College's determination that the interest conflicts with such research; and the key elements of the College's management plan as described in the "Management of Financial Conflicts of Interest" section above. Annual FCOI reports submitted during the project period will report the status of the FCOI and any changes to the management plan, and will be submitted for as long as the Significant Financial Interest is held or until the College reports that the FCOI no longer exists.

- If the SFI report was not disclosed or reviewed in a timely manner, a retrospective review will be required. The Provost will notify the PHS Awarding Component if bias is found and will complete a mitigation report for the project.

The status of previously identified FCOI(s) will be updated annually by the College including any changes in the management plan. This update will be submitted at the same time as annual report submission.

FCOI Public Accessibility

Prior to the expenditure of any funds under a PHS-funded research project, the College will ensure that information concerning identified Financial Conflicts of Interest held by senior/key personnel is publicly accessible by written response to any requestor within five (5) business days of a request. This requirement applies to a Significant Financial Interest that:

- a) was disclosed and is still held by the senior/key personnel;
- b) the College has determined is related to the PHS-funded research; and
- c) the College has determined it is a Financial Conflict of Interest.

The information made available will include, at a minimum: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest in the following ranges — \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000 and \$100,000 by increments of \$20,000; and 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.

The College responds to written requests, each written response will note that the information 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 the College's identification of a new Financial Conflict of Interest, which the requester should subsequently request.

Information concerning the Significant Financial Interests of senior/key personnel subject to this section will remain available for response to written requests — for at least three (3) years from the date the information was most recently updated.

All records of Investigator disclosures of financial interests and the College's review of, and response to, such disclosures (whether or not a disclosure resulted in the College's determination of FCOI) and all actions under the College's policy or retrospective review, will be retained for at least three years from the date of submission of the final expenditures report or the resolution of any government action involving those records, whichever comes later.

Subrecipients and Significant Financial Interest

If a subrecipient relationship is established, terms will be included in the written agreement to establish whether the College's FCOI policy or that of the subrecipient's institution will apply to subrecipient Investigators. Subrecipients using their own policy must agree to specific time to report all identified conflicts of interest to College, provide a certification that their institutions 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. In either case, the College will report any Financial Conflicts of Interest on the part of the subrecipient to the PHS Awarding Agency.

Purchasing Conflict of Interest Policy

Macalester's Purchasing function observes an additional policy regarding procurement of supplies, equipment, or services from an employee of the College or their relative(s).

Purchases from which a Macalester employee, or his/her relative(s) would benefit, are subject to public competitive bidding or special clearance by the Purchasing Manager and the Vice President for Administration & Finance. College employees who have, or whose relatives have, a substantial interest in any contract with, sale to, purchase from or service for the College are required to disclose that interest to the College in advance of the transaction.

To facilitate compliance with this policy, Purchasing will solicit competitive bids at the request of a department – or grant Investigator – so that bids or proposals from College employees and their relatives may be considered.