

Blackfeet Community College Financial Conflict of Interest Policy Pertaining to Sponsored Research

The Blackfeet Community College (BCC) grants office overseeing federal grant management is responsible for compliance duties related to conflicts of interest in Sponsored Research. As a Community College that receives U.S. Public Health Service (PHS) funding, including the National Institutes of Health (NIH), BCC has adopted the PHS terminology and perspective for reviewing sponsored research conflicts related to any federal funding agency.

The intent of this policy is to identify conflicts and manage them by defining the boundaries within which conflicts occur while allowing investigators to proceed with their research. The primary goal is to maintain objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by a Financial Conflict of Interest of a BCC Investigator.

Sponsored Research Definitions.

Financial Conflict of Interest (FCOI) is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

FCOI Report means an Institution's report of a FCOI to a PHS Awarding Component.

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

Immediate Family is the employee's spouse and dependent children.

Institutional Official is a BCC employee who is designated to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS funded research.

Institutional Responsibilities is the Investigator's professional responsibilities on behalf of the College including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or other institutional committees.

Investigator is the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of funded research, or proposed for such funding.

Manage is taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS means the 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.

PHS Awarding Component means the organizational unit of the PHS that funds the research.

Senior/Key Personnel is the Project Director/Principal Investigator and any other person identified as senior/key personnel by BCC in a grant application, progress report, or any other report submitted to PHS.

Significant Financial Interest (SFI) consists of one or more of the following interests of the Investigator (and the Investigator's Immediate Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities received from an entity within twelve months preceding the disclosure. For purposes of this definition, "compensation" 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:

1. For any publicly traded entity, SFI is compensation and equity interest totaling \$5,000 or greater.
2. For any non-publicly traded entity, SFI is compensation of \$5,000 or greater and/or any level of equity interest.
3. Non-College intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interest does not include:

- o Salary, royalties, or other compensation received from or through BCC if the Investigator is currently employed or otherwise appointed by BCC.
- o Income from seminars, lectures, or teaching engagements sponsored by governments, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.
- o Income from service on advisory committees or review panels for governments, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education.
- o Investments in and income from investment vehicles, such as mutual funds and retirement accounts as long as the employee does not directly control the investment decisions made in these vehicles.

Sponsored Research is creative activities, scholarship, training and instructional projects involving funds, materials, or other compensation from outside sources under agreement. Research in this context means a systematic investigation, study or experiment designed to

develop or contribute to generalizable 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). This may also include a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Travel Disclosure is a means of disclosing sponsored or reimbursed travel, as provided in this Policy. The Travel Disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official may request additional information such as a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Travel Expenses includes expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

BCC Sponsored Research FCOI Policies

Disclosure Prior to Proposal Submission.

Disclosure by Investigators shall be made to BCC before submitting a proposal for funding.

Sponsored Research Disclosure.

In Sponsored Research, all Investigators must disclose any SFIs prior to the College expenditure of funds.

Annual Disclosure

Annually, all BCC research investigators associated with a PHS grant must complete and submit a Conflict of Interest Report. The report will be submitted to the BCC Grants Office. The Investigator's completion of the report certifies that:

1. The employee does not have any interests or outside commitments which require disclosure;
2. The employee has a potential conflict of interest which has been duly disclosed previously and there has been no change which requires an updated disclosure; or
3. The employee has new interests which may create a conflict of interest or conflict of commitment and has disclosed them.

Disclosure During Sponsored Research.

For as long as the Sponsored Research continues, new Investigators and existing Investigators acquiring new interests shall disclose SFI that would reasonably appear to be related to the Investigator's Institutional Responsibilities within 30 days of discovering or acquiring (e.g.,

through purchase, marriage, or inheritance). All disclosures must be also updated on the Annual Report during the period of the award.

Disclosure Review.

The BCC Grants Office shall review all Investigator Disclosures prior to funding expenditure to determine whether the SFI is a FCOI by evaluating (1) whether the Investigator's SFI could be affected by the research or the research could affect the entity in which the Investigator has an interest, and, if so, (2) whether the interest could directly and significantly affect the design, conduct, or reporting of the research. If a FCOI exists, appropriate action to manage the conflict will be taken.

Sponsored Research Conflicts Management Plan.

If the Institutional Official determines the SFI constitutes an FCOI, a conflicts management plan may be implemented. The plan may employ safeguard strategies including, but not limited to, the following:

1. Public disclosure of FCOI (e.g., when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
3. 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;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

Sponsored Research Reporting and Records.

As applicable by agency, BCC will provide the Investigator's FCOI and implemented management reports to the funding agency. PHS FCOI Reports shall contain all the agency designated elements and will be submitted:

- o Prior to the expenditure of PHS funds;
- o Within 60 days of discovering or acquiring a new FCOI of an Investigator on any PHS-funded research;
- o Non-PHS-Funded Investigators are required to disclose only those SFIs that are related to their research no later than submission of an application for the related research; and

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- o Annually for ongoing, managed FCOI cases.

FCOI Report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of BCC's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- o Project number;
- o Project title;
- o PD/PI or contact PD/PI if a multiple PD/PI model is used;
- o Name of the Investigator with FCOI;
- o Name of the entity with which the Investigator has a financial conflict of interest;
- o Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- o Value of the financial interest (dollar ranges are permissible), 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;
- o A description of how the financial interest relates to the PHS-funded research and the basis for BCC's determination that the financial interest conflicts with such research; and
- o A description of the key elements of BCC's management plan, including:
 - o Role and principal duties of the conflicted Investigator in the research project;
 - o Conditions of the management plan;
 - o How the management plan is designed to safeguard objectivity in the research project;
 - o Confirmation of the Investigator's agreement to the management plan;
 - o How the management plan will be monitored to ensure Investigator compliance; and

Other information as needed.

Travel Disclosure.

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, an Institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an Institution of higher education.

PHS Public Reporting Requirements.

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BCC will make information concerning identified FCOI held by Senior/Key Personnel on PHS-funded research to any written request within five business days of a request in accordance with the requirements of the PHS FCOI regulations. Record Retention.

Records of all conflicts disclosures, travel disclosures, and conflict management plans submitted with grant proposals and records of actions related to such disclosures shall be maintained in the grant or contract file for the length of time specified by the funding agency, typically three years from the date of submission of the final expenditure report.

PHS Retrospective Review Process.

Within 120 days of a determination of noncompliance, BCC will complete a retrospective review of the Investigator's activities and the research project to determine whether any research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. BCC will document the retrospective review, retain all information, and submit a mitigation report if necessary as required by agency regulations. Such noncompliance may occur:

- o When an FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose a SFI that is determined to constitute a FCOI);
- o When there is failure by BCC to review or manage such a FCOI; or
- o When there is failure by the Investigator to comply with a Sponsored Research Conflicts Management Plan.

PHS Retrospective Review Documentation.

BCC shall document the retrospective review. Documentation shall include, but not necessarily be limited to, all of the following key elements:

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

PHS Retrospective Review Results and Remedies.

Based on the results of the retrospective review, if appropriate, BCC shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, BCC is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and BCC's plan or action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Depending on the nature of the FCOI, BCC may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of BCC's retrospective review.

Sanctions and Remedies for Violation of Policy.

If the BCC determines that a person has violated this Policy, including any failure to make a required SFI Disclosure or Travel Disclosure or comply with a requirement of a conflict management plan, the Institutional Official shall recommend appropriate sanctions consistent with BCC policies and procedures relating to faculty, employee, or other discipline. The Institutional Official is authorized to suspend, for good cause, an ongoing Research project or pending Technology Transfer Transaction to prevent any probably or continued violations of this Policy.

If the failure of an Investigator to comply with BCC's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, BCC shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

PHS Training.

Investigators active in PHS grants must complete financial conflict of interest training. This training can be met by completing the FCOI Tutorial developed by NIH and can be found at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. Training must be completed prior to engaging in research related to any PHS-funded grant and at least every four years thereafter, and immediately when any of the following circumstances apply:

1. BCC revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to BCC; or
3. BCC finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

Public access of BCC Sponsored Research FCOI Policy.

The BCC Sponsored Research FCOI Policy will be publicly available on the BCC website.