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Ball State University's Policy and Procedures on Financial Conflicts of Interest in Funded Research

I. Financial Conflicts of Interest (FCOI) Policy

Ball State University (BSU) is dedicated to maintaining the public's trust and upholding the highest ethical standards in all research activities. Further, federal regulations require funded researchers to disclose potential FCOIs in order to maintain transparency and objectivity in funded research. These regulations stipulate Public Health Service (PHS) funded research project investigators and their teams must submit annual FCOI disclosures for review and, when needed, managed.

In compliance with this and other federal regulations governing FCOIs in research, all researchers (investigators) and their research teams are required to submit these disclosures for review. If required, additional detailed management plans will be developed that manage, mitigate or eliminate the disclosed conflict. This standard applies to funded research projects.

The purpose of this policy and corresponding procedures is to provide guidance for recognizing and dealing with actual or perceived conflict of interest in funded research projects. The primary goal of this policy and procedures is to manage, mitigate or eliminate actual or perceived conflicts of interests by University employees. Please note this policy only addresses funded research and does not cover, nor takes the place of, BSU's Conflict of Interest/Conflict of Commitment (COI/COC) policy.

II. Introduction

BSU is committed to providing the highest quality teaching, research, and service possible. This mission is often served by the active participation of its employees in activities outside the University. Interaction with business, government, not-for-profit groups, professional societies, academic institutions, and private individuals or organizations contributes to the professional growth of employees and to the enrichment of University programs. University employees are therefore encouraged to share their professional knowledge and expertise through outside activities that do not interfere with their University responsibilities.

While such interactions are encouraged, an employee's professional or other activities outside the University may result in a real or perceived conflict of interest or conflicts of commitment in funded research. These conflicts may affect the way in which the employee carries out his or her University responsibilities and conducts their research. These Conflicts of interest may adversely impact the University's mission, and potentially undermine public confidence in the University. It is therefore necessary to manage or eliminate conflicts of interest in funded research, so that the integrity and the interests of the University, as well as those of its employees, are protected.

This policy and procedure sets forth University-wide procedures for disclosing and managing such conflicts. This document is designed to comply with Federal Financial Conflicts of Interested regulations (42 CFR Part 50, Subpart F: *Promoting Objectivity in Research* and 45 CFR Part 94).

III. Statement of Guiding Principles and Expectations

The Public Trust

BSU is committed to upholding the highest level of public trust in education and research. As part of this commitment, BSU is dedicated to maintaining transparency in its activities, upholding the highest ethical standards of its employees and fostering the pursuit of academic and research growth. Only by upholding the highest of standards, ensuring strong ethical conduct and maintaining integrity in all of our processes can the public trust our endeavors.

External Activities

BSU recognizes the value of its employees engaging in activities outside of the university. Many of these activities foster new relationships with outside entities, help in facilitating knowledge, stimulate new and novel research, enhance education and inspire new opportunities. These activities, however, need to be tempered with managing or mitigating financial and personal interests that usually accompany these types of activities so that they do not negatively impact the endeavor, cloud judgments, influence research outcomes or endanger the public's trust in BSU.

Academic Freedom

BSU as an institution of higher education believes strongly in the tenants of academic freedom. The ability to pursue research and other scholarly activities without fear of censorship has always been a hallmark of academic institutions. However, this is not an absolute right. All members of the BSU community are expected to perform their duties in a professional and ethical manner. All research must be conducted objectively, free from financial influence or personal self-interests. Failure to do so degrades the tenants of academic freedom and erodes public trust.

Financial Conflicts of Interest (FCOI) in Human Subjects Research

BSU strives for extending the realm of knowledge and science. BSU is dedicated to the ethical conduct of human subjects research as one of these means. FCOI's involving human subjects research pose special concerns and can raise ethical dilemmas. BSU and its researchers have an ethical and moral obligation to protect the rights and safety of all persons participating in research conducted at or by BSU researchers. Financial interests held by those conducting research may compromise the fulfillment of those ethical obligations and be detrimental to the welfare of research participants, as well as the integrity of the research process. As such, any person with an unmanaged conflict of interest is prohibited from conducting or receiving approval of such research. In addition, research involving human subjects and a disclosed financial conflict of interest, may only be approved only if the design, implementation and circumstances of the research are such that there are sufficient safeguards in place that protect the participants and the objectivity of the data obtained.

Confidentiality

BSU strongly believes in maintaining the privacy and confidentiality of all of its employees and students. Information submitted as part of a FCOI disclosure process will be protected to the fullest extent allowed by law. Information submitted will only be used for official proposes and those purposes required by law. Only authorized personnel will have access to submitted information. No information submitted will be used for personal gain or unfair advantage by any authorized personnel.

As a requirement under 42 CFR Part 50, Subpart F: *Promoting Objectivity in Research* and 45 CFR Part 94, any managed FCOI involving PHS funds needs to be publically available for review on a publically available website. Only that information required by law will be posted on a BSU public website for review. No other information will be posted.

IV. Definitions

Activities outside of the University (Outside Activities): Those activities not directly related to the research, teaching and service mission of the University. This includes any work, activity or service for an entity outside of BSU that could potentially result in a FCOI.

Authorized Personnel: Those individuals who have a legitimate right to access and/or use submitted information as part of the FCOI process. These individuals include, but may not be limited to:

- The Conflict of Interest Officer (CIO);
- Staff of the ORI;
- Directors of Sponsored Projects Administration (SPA)

- University Officials and the Board of Trustees who have a legitimate purpose in the information;
- Indiana State and Federal Officials who have a legitimate purpose in viewing the information;

Books, publications or other media: For purposes of this policy, this term includes any book, publication, and/or other media item, whether physical, electronic and/or internet based, for which there is a propriety interest, royalties associated with and/or the person has ownership interests in. This term also includes any other situation that may be governed by Indiana state or federal law.

Conflict of Interest Officer (CIO): The CIO is a BSU appointed official who will coordinate the implementation and administration of FCOI policy, maintain appropriate records, provide expertise for the identification, disclosure and resolution or management of conflicts of interest and conflicts of commitment, conduct investigation into allegations of noncompliance, and enforce or levee sanctions against violators as applicable to this policy and federal Regulations. The BSU Responsible Conduct of Research Officer has been designated as the CIO. The Director, Office of Research Integrity (ORI) will serve as the CIO for BSU when no CIO (RCR Officer) is available.

Disclosure form: The Statement of Disclosure of a Financial Conflict of Interest (FCOI) form.

Employee: Any person employed by the University. This term includes Graduate Assistants (GA's) and Research Assistants (RA's). This term does not include student employees unless classified as such by BSU Human Resources or other applicable state regulation or University policy. For compliance with the federal regulations (42 CFR Part 50, Subpart F: *Promoting Objectivity in Research*; and 45 CFR Part 94 Responsible Prospective Contractors) an employee also may be considered an investigator.

Financial conflict of interest (FCOI): A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest: Anything of monetary value, whether or not the value is readily ascertainable.

Funded Research: For purposes of this policy, "funded research" applies to any research grant awarded by PHS, National Science Foundation (NSF) and/or any other agency or organization that may require FCOI disclosures (or similar type of) as a requirement of receiving the grant award.

Institutional responsibilities: An investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution 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.

Investigator: Any University faculty and staff person that has responsibility for research design, collection of research data, reporting of research and/or the performance of any other substantive research activity(s).

This term includes any Project Director/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 or other federally funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Management Plan: A plan created by the CIO that outlines a course of action that mitigates, eliminates or otherwise manages the FCOI situation for the employee.

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).

Professional activities: Those activities related to the research, teaching and service mission of the University or to an employee's discipline, profession or craft, irrespective of whether those activities are compensated or constitute University activities.

Research: (as applicable to this policy) A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. This term encompasses basic and applied research and product development.

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.

Senior/key personnel: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

Significant Financial Interest (SFI): A financial interest or anything of monetary value that reasonably appears to be related to the employee's Institutional Responsibilities including but not limited to:

- Equity interests in a publically traded company or business that **exceeds \$5,000 or 5% ownership interest** (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);
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights);
- Remuneration, including salary, consulting fees, honoraria, paid authorship, travel reimbursement, etc., received from a publicly traded company during the twelve-month period preceding the date on which an employee is making a disclosure, and/or an equity interest held in such publicly traded company, if the **aggregate** value of such remuneration, plus the value of the equity interest as of the date of disclosure, **exceeds \$5,000**;
- Remuneration, including salary, consulting fees, honoraria, paid authorship, travel reimbursement, etc., received from a non-publicly traded company during the twelve-month period preceding the date on which an employee is making a disclosure, if the remuneration **exceeds \$5,000**;
- Any Equity Interest in a non-publicly traded company or business, regardless of value; and

The term does not include:

- Salary, royalties or other remuneration from the University;
- Income from seminars, lectures or teaching engagements sponsored by a federal, state, or local government agency or an Institution of higher education;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- Income from service on panels for a federal, state or local government agency or institution of higher education (includes an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education);
- Intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;
- Any financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over the management and investments of which the employee **does not exercise control**.

*Note that this definition of "significant financial interest" differs from the definition of "pecuniary interest" under the Indiana Conflicts of Interest Law.

University: BSU, Muncie, IN.

University activities: Those activities directly related to the research, teaching and service mission of the University.

*Note: the line separating "University activities" and "activities outside of the University" for faculty is imprecise at best and may differ among disciplines and professions. One useful guideline for faculty is the question: is this an activity a faculty member would list on an annual faculty report and would expect to receive credit during the tenure, promotion, and/or salary-setting processes?

University responsibilities: Those responsibilities of a University employee to perform University activities as defined by a University or administrative unit policy or employment contract.

V. Financial Conflicts of Interests (FCOI) Disclosures

All employees and investigators are required to disclose FCOI's for any funded research projects as required by federal regulations.

All employees and investigators are also required to disclose any individual financial conflict of interest (FCOI) that could be perceived to impact their University responsibilities, decision-making, research endeavors or other official obligations to BSU. This is regardless of research funding status or current research status.

A. Regulatory Authority

42 CFR Part 50, Subpart F: *Promoting Objectivity in Research*; and
45 CFR Part 94 *Responsible Prospective Contractors*

B. Who must abide by this policy and submit FCOI disclosures

- All BSU full-time and part-time faculty involved in the design, conduct, and reporting of funded research;
- Any BSU employee (including student employees) who acts as a research investigator (Principal Investigator) on a funded research project;
- Any person involved in the design, conduct, and reporting of funded research (this includes student employees and persons that meet the definition of investigator, etc.);
- Any person serving on a research review committee (for ex. IRB, IACUC, etc.)
- Visiting faculty, scientists/scholars, consultants involved in any funded research endeavor at BSU; and/or
- Any contractor, sub-contractor, sub-awardees, etc. who does not fall under the jurisdiction of BSU are expected to have, and comply with, their own institutional policy on FCOI. If any of these parties do not have their own policy(s) on FCOI, then they must abide by the BSU policy concerning FCOI as a condition of working with, or receiving a contract from, BSU.

C. When must FCOI Disclosure be submitted

Unless noted otherwise or required by an official entity, all FCOI disclosures must be submitted within thirty (30) calendar days prior to the submission of PHS/NIH grant application being submitted, thirty (30) calendar days of the annual renewal date, and when there is a change in circumstances.

1. General

- At least annually. This should be done at least thirty (30) calendar days of the annual renewal date;
- When a new appointment begins and/or when a new faculty member starts working at BSU on a funded research project;
- When required by a federal agency;
- When required as a condition or specific term of a grant/award; or
- As may be required by law.

2. Event specific situations (events that may require a new FCOI disclosure and/or amendment of the current disclosure)

- When the situation creating the conflict changes (a material change);
- When service on a research review committee begins. If one is not already on file, then this must be filed within 15 calendar days;
- When discovering a new or previously unreported SFI. Must be filed within thirty (30) calendar days;
- When a new situation comes up that creates an actual or perceived conflict (a material change) different from one previously disclosed; or
- When applying for a new or different PHS or other funded research grant.

D. Requirement for research approval

1. Any PI and Co-PI and all research team members (including student employees) submitting a federally funded research protocol to a research review committee (for ex. IRB, IACUC, etc.) must have current and valid FCOI disclosure(s) on record with the Office of Research Integrity (ORI) before final protocol approval is granted.
2. Having a current and valid FCOI disclosure on record will also be a requirement before submitting any federal research grant applications through the SPA.

E. What must be disclosed by the investigator

- Any Significant Financial Interest (SFI);
- Any relationship (financial interests, stock options, consulting fees, etc.) with the same entity where the aggregate amount is greater than **\$5,000**.

F. Required Training

All persons subject to this policy and receiving, or plan on receiving, PHS funds must complete an approved FCOI training once every four (4) years and when any of the following occurs:

- BSU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- An investigator is new to BSU; or
- When BSU finds that an investigator is not in compliance with the institution's FCOI policy or management plan.

Additional training(s) may be required. Information about approved trainings is available on the ORI website and may be subject to changes.

BSU currently uses the Collaborative Institutional Training Institute (CITI) Conflicts of Interest Course to meet the basic training requirement for those persons with FCOI's and involving PHS funds. Taking the [NIH FCOI Tutorial](#) also meets the basic training requirement for those persons with FCOI's and involving PHS/NIH funds.

In person training is provided when needed to support an applicable PHS/NIH-funded research project or applicable federally funded training awards (ex. NIH). Arrangements can be made by contacting the BSU's RCR (CIO) Officer or their designee.

G. Reporting Financial Conflicts of Interest (FCOI) to PHS Authorities.

Prior to the expenditure of any PHS funds under an award, BSU will report to the funding agency the existence of any FCOI found along with an assurance that the conflict has been managed, mitigated, or eliminated. When the research project involves PHS funds the reporting requirements will be in accordance with federal regulations. Any FCOI identified after the release of research funds will be reported and managed within sixty (60) calendar days of identification. To the extent required by law, BSU will make available to the appropriate governmental agency(s) information regarding all identified FCOI and their management, reduction, or elimination.

If the investigator fails to meet their obligations under this policy and has biased the research (up to, and including, possible research misconduct as defined in the BSU's Policy for Responding to Allegations of Research Misconduct), BSU will promptly notify the funding agency (in the case of PHS, the PHS awarding component) of the corrective action taken or to be taken.

When BSU determines that an FCOI exists, it must be reported to the NIH awarding Institute or Center through the submission of an initial (original) and annual FCOI report using the eRA Commons FCOI Module. When reporting a FCOI, the following information must be included:

- The name of the investigator with the FCOI
- The name of the entity with which the investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
 - \$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000 or a statement that a value cannot be readily determined

- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the institution's management plan, including:
 - 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.

1. Discovery of an undisclosed Significant Financial Interest.

a. If BSU identifies a FCOI that was not previously disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by BSU during an ongoing funded research project, the CIO will within 60 sixty days:

- i. Review the significant financial interest;
- ii. Determine whether it is related to funded research;
- iii. Determine whether a financial conflict of interest exists; and,
- iv. If possible, implement an interim management plan that will specify the actions to be taken to manage such financial conflict of interest going forward.

b. If any FCOI is not identified or managed in a timely manner, BSU will, within one hundred twenty (120) calendar days of the Institution's determination of noncompliance, complete a retrospective review of the investigator's activities and the funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research (up to, and including, possible research misconduct as defined in the BSU's Policy for Responding to Allegations of Research Misconduct). Such activities include, but are not limited to:

- Failure by the investigator to disclose a significant financial interest that is determined by BSU to constitute a FCOI;
- Failure by BSU to review or manage such a FCOI; or
- Failure by the investigator to comply with a FCOI management plan,

In such cases, BSU will document the retrospective review. Retrospective reviews will include, but not necessarily be limited to, all of the following key elements:

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

c. If a FCOI involves PHS-funded research, based on the results of the retrospective review, BSU will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found (up to, and including, possible research misconduct as defined in the BSU's Policy for Responding to Allegations of Research Misconduct), BSU will notify the relevant funding agency promptly and submit a mitigation report to the PHS awarding component when required. The mitigation report will 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 BSU's plan of 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).

BSU will submit FCOI reports annually as required under federal regulations. Depending on the nature of the FCOI, BSU may determine that additional interim measures are necessary with regard to the investigator's participation in the externally funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the Institution's retrospective review.

2. New Investigator with a SFI or FCOI.

If in the course of an ongoing externally funded research project, an investigator who is new to participating in the research project discloses an SFI or an existing investigator discloses a new SFI to the CIO will within sixty (60) calendar days:

- i. Review the disclosure of the significant financial interest;
- ii. Determine whether it is related to PHS-funded research;
- iii. Determine whether a FCOI exists; and,
- iv. If yes, implement, on at least an interim basis, a management plan that will specify the actions to be taken to manage such FCOI going forward.

Depending on the nature of the significant financial interest, BSU may determine that additional interim measures are necessary with regard to the investigator's participation in the externally funded research project between the date of disclosure and the completion of the review.

3. Drugs, medical devices, and treatments

If a PHS/NIH-funded 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 conflicting interest that was not disclosed or managed as required by 42 CFR 50 Subpart F or 45 CFR 94, BSU requires that the investigator(s) involved disclose the conflicting interest in each public presentation of the results of the research and to request an addendum to previously published presentations. Such requirements will be made to the investigator in writing.

4. Disciplinary Action

- a. Discovery of a previously undisclosed FCOI will be reviewed by the CIO in accordance with current BSU FCOI policies and federal regulation. If it is determined that a significant financial interest exists that would potentially be considered a violation of this or other BSU policy(s) or otherwise be considered an actionable offense, the matter will be referred to BSU Human Resources, the Provost's Office, the Office of the President and/or other university official as may be required under university disciplinary policies.
- b. Failure to file an annual FCOI disclosure statement in a timely manner, report information accurately, provide relevant details, disclose in an open and honest manner and/or any other action that would be construed as dishonest, will be grounds for possible disciplinary action.

H. Public Accessibility (PHS Funded Research)

1. For PHS-funded research, BSU will ensure public accessibility by written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to BSU that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by 42 CFR 50, Subpart F and 45 CFR 94 and BSU policy;

- ii. BSU determines that the significant financial interest is related to the PHS- funded research; and
- iii. BSU determines that the significant financial interest is a FCOI.

2. After review of the request by the Office of General Council, the information BSU makes available via written response to any requestor within five (5) business days of a request, shall include, at a minimum, the following:

- i. The investigator's name;
- ii. The investigator's title and role with respect to the research project;
- iii. The name of the entity in which the significant financial interest is held;
- iv. The nature of the significant financial interest; and
- v. The approximate dollar value of the significant financial interest. Dollar ranges will be used as follows:
 - a. \$0–\$4,999;
 - b. \$5,000–\$9,999;
 - c. \$10,000–\$19,999;
 - d. Amounts between \$20,000–\$100,000 by increments of \$20,000; and
 - e. Amounts above \$100,000 by increments of \$50,000; **or**
 - f. 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.

3. BSU will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) calendar days of the BSU's identification of a new FCOI, which should be requested subsequently by the requestor.

4. Information concerning the significant financial interests of an individual determined to be a FCOI under this policy will remain available, for responses to written requests for at least three (3) years from the date that the information was most recently updated.

I. FCOI and Human Subjects Research

Any disclosed FCOI that meets the requirements of this policy or requires a management plan must be disclosed to all participants in the investigator's research. This disclosure must be part of the informed consent form and part of the consenting process. Investigators must disclose, at a minimum:

- A brief description of the conflict and how it is being managed;
- Name of company, group, individual, etc. with which the conflict involves; and
- Contact information for the CIO.

J. Sub-recipient Institutions/Investigators and Reporting of Identified FCOIs

When BSU carries out PHS/NIH funded research through a sub-recipient (e.g., subcontractors, consultant, etc.), BSU will ensure that the sub-recipient follows their institutional policies and agrees to any BSU policies that are more restrictive/comprehensive. This will be done by:

1. Incorporating as part of a written agreement with the sub-recipient terms that establish whether the BSU policies or that of the sub-recipient will apply to the sub-recipient's investigators; and
2. Certifying as part of the agreement that the sub-recipient's policies comply with the regulations.

The agreement will specify a time period for the sub-recipient to report all identified financial conflicts of interest to BSU. In no case will the period of time exceed ninety (90) calendar days.

Any contractor, sub-contractor, sub-awardee, etc. who does not fall under the jurisdiction of BSU are expected to have, and comply with, their own policy on FCOI. If any of these parties do not have their own policy(s) on FCOI, then they must abide by the BSU policy concerning FCOI as a condition of working with, or receiving a contract from, BSU.

K. Annual Renewal and Amendments

All persons subject to this policy must submit an annual renewal of their FCOI disclosure.

If at any time during the current disclosure year and before the period for annual renewal begins, if anything changes that effects the current FCOI discloser and/or management plan, then the effected person must submit a FCOI Amendment form, through channels, to the CIO within thirty (30) calendar days. This Amendment will then become part of the official record.

L. FCOI Information

Information about BSU's current policies and procedures, forms, and other related information will be publicly available on the ORI's website and in other places as applicable.

VI. FCOI Administration

A. General Administration

Administration of the FCOI program will be housed within the Office of Research Integrity (ORI). Administration of the FCOI program by the ORI includes:

- Coordinating and collecting annual and event-based disclosures;
- Conducting preliminary reviews of disclosures to assess completeness and accuracy of the disclosure. This can include interacting with the submitting person in order to obtain additional information, clarifications, etc.;
- Facilitating Institutional Review Board (IRB) Expedited and Full Committee review of disclosures requiring management plans as they apply to the review of human subjects research protections;
- Assisting in creating, maintaining and updating educational and resource materials;
- Assisting the CIO in creating and monitoring management plans;
- Assisting the CIO in reviewing changes in FCOI disclosures or management plans;
- Providing support to the CIO (RCR Officer); and
- Assisting and advising BSU employees, research personnel, departments, university management, and others on the current policies, how to submit disclosures, understanding management plans, and so forth.

B. CIO Assignment

The BSU Conflict of Interest Officer (CIO) is the Responsible Conduct of Research (RCR) Officer. The Director, ORI will serve as the CIO when no CIO (RCR Officer) is available. The CIO has full authority to act on any official matter involving the FCOI programs. The duties and authority of the CIO include:

- Designating an alternate CIO (CIO-A);
- Reviewing all disclosures of possible FCOIs;
- Reviewing changes in FCOI disclosures or management plans;
- Initiating any necessary inquiries into possible violations of this policy, procedures, noncompliance, failure to follow prescribed management plans and any other needed action as may be required by law;
- Enforcement of approved management plans;

- Conducting an assessment into allegations of noncompliance and/or failure to follow this policy; and
- Filing any required reports with applicable State and Federal Agencies and University Officials.

C. Recordkeeping

All FCOI records will be kept by the ORI for a minimum of three (3) years following the date of submission of the final expenditures report to the external funding agency.

All individuals must keep copies of all FCOI submissions, management plans and official correspondences for a minimum of three (3) years following the date of submission of the final expenditures report to the external funding agency.

D. FCOI Submission Process

All FCOI disclosures will follow a similar submission process. The basic process is as follows:

- a. The individual fills out the FCOI disclosure form and signs where required.
- b. The form is then submitted to the CIO via the ORI.
- c. If the disclosure meets any of the required FCOI definitions, then the disclosure will be submitted to the COI review.
- d. If a FCOI is indeed determined and a management plan is warranted, the COI will craft the plan and inform all required parties as to final decisions and actions.

E. Disclosures by the CIO and VPR

In the unlikely situation where the CIO may have a potential FCOI, FCOI disclosures by the CIO will be submitted directly to the Vice Provost for Research (VPR) or their official designee(s) for formal review.

Potential disclosures by the VPR will be submitted directly to the Provost for review.

F. Enforcement

Investigators and/or employees who violate this policy by failing to make a required disclosure of a FCOI in a timely manner or failing to comply with conditions/restrictions of a management plan will be subject to disciplinary action and appropriate sanctions in accordance with current University policies, IN State law and/or federal law.

If the violation involves a government-funded sponsored program or project, the University may be obligated under federal, state, or local law to report any violations of this policy and any corrective action(s) taken.

G. Annual Renewal and Amendments of FCOI

All persons subject to this policy must submit an annual renewal of their FCOI disclosure.

If at any time during the current disclosure year and the period for annual renewal, anything changes that effects the current FCOI discloser and/or management plan, then the effected person must submit a FCOI Amendment form, through channels, to the CIO within thirty (30) calendar days. This Amendment will then become part of the official record.

H. Management Plans

Management plans can cover issues involving FCOI. The purpose of the management plan is to minimize, mitigate or eliminate a FCOI. The CIO will work with the individual in question, the applicable

grant manager, and when applicable, the department Chairperson, on a plan that minimizes and/or mitigates the disclosed FCOI. Once a plan has been finalized, it will be written up and signed by the person with the FCOI, the CIO, the department Chairperson (if applicable), and the college Dean.

All required management plans for a previously undisclosed or unknown FCOIs need to be implemented within sixty (60) calendar days from the time of a conflict being disclosed.

1. As part of the disclosure process, Deans, Department Heads, Supervisors and Department Chairs can offer management recommendations for consideration by the COI. These recommendations must comply with current university policies and departmental procedures/policies.

2. Management plans can include, but are not limited to:

- Public disclosure of financial conflicts of interest involving PHS funded research;
- For research projects involving human subjects research, disclosure of financial conflicts of interest and/or conflicts of commitment 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);
- Severance of relationships that create financial conflicts;
- Assignment of a disinterested party to serve as final decision;
- Monitoring program(s);
- Time frame for continuing review;
- Incorporation of recommendations submitted by Deans, Department Heads, Supervisors and Department Chairs.
- Submission of supplemental documentation as needed.

3. Appeal of COI decision(s) and management plan.

Investigators and employees may appeal a COI decisions and/or management plan by submitting a formal written notice to the Provost (or their designee) or the unit's Vice President (or their designee) within ten (10) calendar days of receipt of a COI action notice.

The appeal is confined to presenting evidence of a viable resolution procedure that was not previously discussed or upon a clear and convincing showing of bias against the individual in question by the COI. The burden of evidence is upon the individual bringing forth the appeal request.

The Provost (or their designee) or the unit's Vice President (or their designee) will meet with the COI and either accept or decline the appeal in writing to the investigator within ten (10) calendar days. If the appeal is accepted, a revised strategy for management, mitigation and/or elimination will be provided to the investigator in writing within thirty (30) calendar days. A declined appeal is final.

Issues involving new information, changing circumstances, etc. should be brought to the COI via an amended disclosure form.

4. Continuing Review.

Any investigator or employee with a management plan will need periodic re-review in order to determine if the current management plan is sufficient to address the FCOI. If needed, adjustments can be made at this time.

It is the responsibility of the individual with the management plan to ensure that any necessary continuing review materials are submitted in a timely manner. The COI will monitor any implemented management plan on an ongoing basis for compliance until the completion of the research project or the duration of the identified conflict. Monitoring can include but not limited to:

- Requiring periodic reports and updates;
- Surprise follow-ups; and/or
- Meeting with the CIO on a periodic basis.

At a minimum, continuing review of established FCOI's will be conducted annually.

Investigators and employees are still required to amend their FCOI disclosure when situations and/or circumstances change and not to wait until the continuing review period.

F. Management, Mitigation and Elimination Advice

Any University employee or investigator may contact the CIO for advice about a potential FCOI. Employees or investigators are not required to disclose their name(s) or identifying details of the potential conflict, though sufficient details about the nature of the conflict will need to be provided in order for advice to be viable. The advice discussed does not constitute the providing of legal advice. The advice provided must, by its nature, be limited to options on how to manage, mitigate and/or eliminate potential conflicts.

Any University department or unit may request advice about a potential FCOI from the CIO provided that no more identifying information than necessary is disclosed unless required by law or University policy. The advice discussed does not constitute the providing of legal advice. The advice provided must, by its nature, be limited to options on how to manage, mitigate and/or eliminate potential conflicts.