

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Promoting Objectivity in Research		SOP #: RSP.015.01
Effective Date	09/04/2020	
Last Revision/Review	11/30/2021	

1. Purpose

The purpose of this procedure relates to the Burrell College of Osteopathic Medicine Policy B-1041 and how the College enforces the policy to ensure compliance with 42 CFR 50 Subpart F and 45 CFR 94 or other sponsor requirements for reporting and managing Conflict of Interest.

2. Related Policy/Authority

College Policy B-1041 – Conflict of Interest

Burrell College SOP HR.021

[42 CFR 50 Subpart F](#) - Responsibility of Applicants in Promoting Objectivity in Research for Which PHS Funding is Sought

[45 CFR 94](#) – Responsible Prospective Contractors

3. Faculty/Staff Responsibilities

President

Vice-President of Finance

Assistant and Associate Deans, Department Chairs and Directors

Burrell College Faculty, Staff, and students seeking extramural sponsorship of College activities including research, creative scholarship and programmatic funding.

4. Definitions/Abbreviations

Significant Financial Interest (SFI) – means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees, or honoraria; equity interests (e.g. stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). SFI does not include: (1) Salary royalties, or other remuneration from the applicant institution; (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR 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 non-profit entities; (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse 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 interest in an any single entity; or (6) Salary, royalties, or other payments that when aggregated for the Investigator and the Investigator's Spouse and dependent children over the next twelve months are not expected to exceed \$10,000.

Investigator or Senior/Key Personnel – means any individual, regardless of title or position who is responsible for the design, conduct, or reporting of outcomes that are relevant to the extramurally

funded project. At Burrell College this includes: Professional Faculty & Staff; Research Associates, Postdoctoral Fellows & Visiting Scholars, Medical Residents, Any individual listed by name on the PHS grant or subaward contact or any other individual responsible for design, conduct, reporting, or oversight of College research activities.

Consultant or Contractor – An individual who provides professional advice or services for a fee, but normally not as an employee of the College. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services.

Sponsored Program – research, creative scholarship, public service training, and instructional projects conducted by covered persons involving funds, materials, or other compensation from outside sources through grants, contracts, or cooperative agreements.

Sponsor – the entity providing the funds that support the research, creative scholarship, public service training, and instructional projects conducted by investigators.

Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

5. Procedural Steps

- 5.1 All Burrell College employees are required to complete a conflict of interest disclosure as defined in Burrell College Policy B-1041 and SOP # HR.021. Investigators or Senior/Key Personnel are required at the time of grant application to verify that the COI disclosure is current and that no changes and/or amendments to the disclosure on file are necessary.
- 5.2 Process for Informing Investigator of COI Policy
 - 5.2.1 The Burrell College Conflict of Interest Policy is publicly available on the Burrell College website. The Office of Human Resources also informs employees of COI disclosure requirements.
 - 5.2.2 The Office of Human Resources requires all employees to submit a COI disclosure on an annual basis (SOP # HR.021).
 - 5.2.3 The Office of Research and Sponsored Programs requires that a proposal transmittal form accompany all new proposals through the routing pathway for all new extramurally sponsored research grants. Verification of COI disclosure by the Investigator(s) and/or Senior/Key Personnel is one component of the transmittal process. Grant submission delays or disallowance may result in situations where COI disclosures and management plans are not current or not complete.
 - 5.2.4 Links to the Federal Regulations provided through published College Policies, Standard Operating Procedures, and Office of Research & Sponsored Programs website.

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5.3 Conflict of Interest Training

- 5.3.1 The College uses CITI Program Conflict of Interest training modules for Investigator/Key Personnel training. Investigators must complete the training module once every three (3) years. Investigators and/or Senior/Key Personnel shall not be allowed to engage sponsored projects if they are not current on COI training.

5.4 Disclosure, Review, and Monitoring of Conflict of Interest

- 5.4.1 College Employees and Investigators are required to submit a COI Disclosure to the Office of Human Resources on an annual basis and update any changes as they occur.
- 5.4.2 Investigators certify and the Office of Research Sponsored Programs verifies investigator compliance at the time of new proposal submission and at intervals consistent with sponsor requirements.
- 5.4.3 The Office of Human Resources or a designated institutional officer reviews the disclosures as part of the proposal transmittal process, informs the Authorized Institutional Official for Research of Conflicts of Interest, and indicates whether an institutional management plan has been established. The I.O. for Research will inform sponsor of Conflict of Interest in accordance with Sponsor requirements.
- 5.4.4 Employees and investigators are required to update COI disclosures annually or at more frequently intervals should a significant financial conflict of interest arise. The institutional officer responsible for reviewing financial conflict of interest will inform the I.O. for Research of any significant COI or changes in COI for all investigators named in sponsored awards.
 - 5.4.4.1 An appropriate management plan will be developed and the COI reported as required by sponsor policy or regulations.

5.5 Reporting COI to Sponsor

- 5.5.1 The Office of Research and Sponsored Programs request regular updates on COI from from all investigators on externally sponsored projects. The I.O. for Research Will notify NIH/PHS within 60 calendar days of COI identification for all NIH sponsored projects. For none -NIH sponsored projects, the I.O. Will notify the sponsor in accordance with the requirements of the sponsor.

5.6 Non-Compliance with COI Requirements

- 5.6.1 All College employees and investigators or key personnel named on sponsored awards shall comply with the COI disclosure requirements. Failure to comply with College policies and procedures can result in sanctions.
- 5.6.2 Matters of non-compliance will be reported to the sponsor in accordance with sponsor requirements.

5.7 Maintenance of COI Records

- 5.7.1 COI disclosures from investigators or key personnel will be kept on file for at least three (3) years after the final expenditure report is submitted to the sponsor.

5.8 Enforcement of Conflict of Interest Policy

- 5.8.1 Enforcement of the College Conflict of Interest Policy is accomplished via the development of a Conflict of Interest Management Plan as detailed in SOP HR 021. The purpose of the COI management plan is to assist the employee and College in mitigating conflicts that exist or may develop.

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5.9 Subrecipient Requirements

5.9.1 Subrecipients of awards managed through the ORSP are required to certify that they have NIH/PHS compliant policies in place or that they agree to comply with existing College policies for the purpose of the subaward.

5.10 Public Accessibility Requirements

5.10.1 The College COI policy is published on the College website.

6. Reports/Charts/Forms/Attachments/Cross References

Identify if any reports are required to include data elements.

7. Maintenance

Reviewed annually by ORSP.

8. Signature

Signature on File

12.6.2021

Assistant Dean for Research

Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
1	[e.g., 3.1]			