

Wayne State University Research Policy

Individual and Institutional Financial Conflict of Interest and Commitment

1. Purpose

- 1.1. The purpose of this university policy is to promote objectivity in the research, scholarship and service missions of the University. The Policy establishes standards which identify and manage relationships and financial interests involving all university research (funded or non-funded) that may result in real or perceived financial conflicts of interest for WSU employees, students or immediate family members. Disclosure and management of such conflicts, or potential conflicts, protect the integrity of the employees, students, and University.
- 1.2. It is critical to maintain the highest standards of quality in research, scholarship and service to support the mission of WSU. The University and its employees are committed to conducting themselves with the highest standards of integrity and ethics. This policy will guide WSU employees in the identification, disclosure, and management of conflicts of interest.
- 1.3. This policy is applicable to employees interacting with companies and other external entities in research and Sponsored Programs. It addresses the specific combination of activities or Significant Financial Interest (SFI) that may lead to potential financial conflict of interest and/or commitment. The policy is designed
 - to guide employees in the identification of financial conflict of interest and commitment involving companies,
 - to assist employees in the management of financial conflict of interest and commitment, and
 - to establish a mechanism for disclosure and review of all relevant relationships with companies.

2. Policy Statement

- 2.1. Without prior administrative approval, WSU employees are prohibited from engaging in activities from which they, their families or their businesses will gain financially because of the employee's position at WSU or because of the use or disclosure of WSU information. Employees are required to disclose such situations, manage, and if so directed, to eliminate or avoid situations that either create financial conflicts of interest or that appear to be financial conflicts of interest.
- 2.2. Faculty members and other employees who accept employment at WSU make a commitment to WSU that includes the appropriate and responsible use of WSU information and resources. Employees must ensure that both their use of WSU information and resources and their outside obligations, financial interests, and activities do not interfere with, nor appear to interfere with, their primary obligations to WSU. It is the responsibility of the employee to disclose in writing any potential or actual financial conflict of interest. The failure of an employee to disclose a financial conflict of interest or failure to eliminate a conflict when so directed may be grounds for disciplinary action up to, and including, discharge or termination for cause.
- 2.3. Wayne State University encourages external activities that enhance an employee's value to WSU; which enhance WSU's presence in local, national, or international communities; or which provide public service. Such service to outside educational,

professional, scientific, artistic, cultural, civic, business or other organizations is permissible under the terms of this policy, as long as it does not pose a financial conflict of interest.

3. Definitions¹

- 3.1. Employee. “Employee” means:
 - (1) any person possessing either a full-time or part-time appointment at the University. These include the faculty ranks of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as “Research,” “Adjunct,” “Visiting,” or “Clinical,”) instructor, and lecturer, as well as academic professionals and postdoctoral associates.
 - (2) employees, students, and other individuals identified as key personnel on grant applications (whether salaried or not salaried) who on behalf of the University are responsible for, or in a position to influence, the design, conduct or reporting of the research or other scholarly activity.
 - (3) employees, students, and other individuals identified as key personnel, regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities related to the submission of a human or animal research protocol.
- 3.2. Equity. An interest in a business consisting of any stock, stock option or similar ownership interest in such business.
- 3.3. Disclosure of significant financial interests means an Investigator’s disclosure of significant financial interests to an Institution.
- 3.4. FCOI. The “FCOI” refers to Financial Conflict of Interest.
- 3.5. Financial Conflict of Interest (FCOI). A significant financial interest on the part of an investigator or institution that could directly and significantly affect the design, conduct, or reporting of any funded research, or research involving human participants or animals.
- 3.6. FCOI Report. An Institution’s report of a FCOI to a PHS Awarding Component.
- 3.7. Financial Interest. Anything of monetary value, whether or not the value is readily ascertainable.
- 3.8. HHS. The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- 3.9. Institutional Responsibilities. An Investigator’s professional responsibilities on behalf of the Institution which may include
 - research,
 - research consultation,
 - teaching,
 - professional practice,
 - intellectual property interest on a patent, patent application or a copyright related to the research that is or may be assigned or licensed to an outside party,
 - institutional committee memberships, and

¹ Throughout the policy, the first letter of each word being capitalized indicates terms defined in this section.

- service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- 3.10. 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 funded research, or proposed for such funding, (e.g., collaborators or consultants).
- 3.11. IRB. “IRB” refers to the one of the Institutional Review Boards at the University - reviews human participant research.
- 3.12. IACUC. “Institutional Animal Care and Use Committee” - reviews animal research.
- 3.13. Immediate Family. “Immediate Family” means the employee’s spouse or domestic partner and dependent children.
- 3.14. Institution. Any domestic or foreign, public or private, entity or organization.
- 3.15. Institutional Financial Conflict of Interest. “Institutional Financial Conflict of Interest” may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship, or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the University. The existence (or appearance) of such conflict can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the University. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations or the values of the University.² Institutional Financial Conflicts of Interest may include
- investments,
 - gifts,
 - honoraria,
 - consulting fees,
 - paid authorship,
 - stock or stock option,
 - intellectual property interest on a patent, patent application or a copyright related to the research that is or may be assigned or licensed to an outside party, and
 - position on Scientific Advisory Board
- Note: The definition does not apply to affiliated foundations if the structure of the relationship between the University and the foundation effectively eliminates any potential Financial Conflict of Interest on the part of the foundation (e.g., if the foundation simply provides financial support for a particular project through the University and does not retain any direct financial interest in the project.)
- 3.16. Manage. Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

² Task Force on Research Accountability, Report on Individual and Institutional Financial Conflict of Interest, Report and Recommendations, Association of American Universities, October 2001, p. 10.

- 3.17. PD/PI. A Project Director or Principal Investigator of a funded research project, or research protocol involving human participants or animals; the PD/PI is included in the definitions of senior/key personnel and investigator.
- 3.18. PHS. 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 (NIH).
- 3.19. PHS Awarding Component. The organizational unit of the PHS that funds the research that is subject to this policy. Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
- 3.20. Research. A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.
- 3.20.1. 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).
- 3.20.2. 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.
- 3.21. 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 a funding agency by the Institution. This also includes key personnel identified on protocols submitted to the IRB involving human participants, as well as those submitted to the IACUC for studies involving animals.
- 3.22. Significant Financial Interest.
- 3.22.1 A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
- (i) 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;
 - (ii) 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.22.2 PHS Investigators only, also must disclose the occurrence of any reimbursed or sponsored travel 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The initial disclosure must include reimbursed or sponsored travel that is received in the preceding 12 months.

- For example, travel 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 would be considered reimbursed or sponsored travel.

3.22.3. The term significant financial interest **does not** include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; 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, an 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 an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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 an Institution of higher education.

3.23. Small Business Innovation Research (SBIR) Program. The extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this policy the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

3.24. Sponsored Programs. "Sponsored Programs" means research, training, and instructional projects involving funds, materials or other compensation from outside sources under agreements that contain any of the following: The agreement binds the University to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

4. Classification of Potential Financial Conflict of Interest and Commitment

- 4.1. The following chart lists categories of activities and external relationships covered by this policy (see Table 1). For each level, depending on whether the Sponsored Program involves human participants, the requirements for disclosure and/or management are provided. A designated representative of the FCOI Committee will determine whether the relationship represents an activity requiring additional review.
- 4.2. If a Management Plan is required, certification that the management plan has been accepted and will be implemented must be provided to the FCOI **before the research project is started** (See 11.1).

HUMAN RESEARCH STUDY				
Category 1	Category 2	Category 3	Category 4	Category 5
< \$4,999	\$5,000-\$9,999	\$10,000-\$19,999	\$20,000-\$100,000	>\$100,000
No management plan	Expedited management plan	Expedited management plan	Expedited management plan	Electronic review Or full committee review
No consent language	No consent language	Possible consent language	Consent language required	Consent language required
NON-HUMAN RESEARCH PROGRAM				
Category 1	Category 2	Category 3	Category 4	Category 5
< \$4,999	\$5,000-\$9,999	\$10,000-\$19,999	\$20,000-\$100,000	>\$100,000
No management plan	No management plan	No management plan	Expedited management plan	Electronic review Or full committee review

Table 1: Categories of financial conflicts of interest.

Table 1 Definitions:

Consent Language. Language that discloses the investigator(s) financial conflict in the research informed consent document that requires approval by Institutional Review Board.

Electronic Review. FCOI-ER Subcommittee appoints two FCOI Committee reviewers; recommendation is sent to full committee by e-mail and objections are requested within a specified time period.

Expedited Management Plan. The Financial Conflict of Interest Expedited Review (FCOI-ER) Subcommittee (AVP or VP or Chair, and Conflict of Interest Coordinator)..

Full Committee Review. Full FCOI Committee develops management plan or disapproves proposal, discussion and voting by teleconference or at regularly scheduled meeting.

5. Students

- 5.1. The following applies to employees assigning students, postdoctoral fellows or other trainees to a Sponsored Program with a company, or a research protocol involving human participants or animals, in which the employee or the immediate family may be entitled to receive significant financial interest.

6. Appointment of and Responsibilities for a Financial Conflict of Interest Committee

- 6.1. The Vice President for Research shall appoint members of a FCOI Committee. While membership should come from the faculty and administration, a majority of the voting members of the committee shall represent the faculty.
- 6.2. The responsibilities of the FCOI Committee are to:
 - 6.2.1. Formulate guidelines applicable to employees that determine whether an investigator's SFI is related to the funded research and, if so related, whether the SFI is an FCOI;
 - 6.2.2. Develop procedures to obtain and review information supplied by employees;
 - 6.2.3. Conduct the review of all disclosures via an expedited or full committee review process, recommend an appropriate management plan and, when appropriate, recommend the elimination of FCOI. The employee and/or WSU administration will not implement a Sponsored Program, human participant protocol or animal protocol until a management plan, approved by the FCOI Committee, has been implemented or the FCOI has been eliminated.
 - 6.2.4. Communicate with the SPA, the IRB, the IACUC, and other administrative units regarding identification and management of employee relationships that may constitute a potential FCOI.
- 6.3. The Office of the Vice President for Research shall provide administrative support for the FCOI Committee. A representative from that office shall staff the committee and provide education and advice to employees concerning their responsibilities under this policy. That representative shall also oversee and coordinate compliance with the recommendations of the committee.

7. Disclosure and Review Process

- 7.1. Disclosure to the FCOI Committee
 - 7.1.1. An employee must disclose to the FCOI Committee significant financial interests related to an investigator's funded or unfunded institutional responsibilities. Potential FCOI must be disclosed at the time that a Sponsored Program proposal is submitted, at least annually during the award period, and within 30 days of discovering or acquiring a new SFI with any sponsor in which the employee or immediate family member has a SFI as determined through reference to public prices or other reasonable measures of fair market value.

Funding for the Sponsored Program will not be available to the employee until the disclosure of financial interest is reviewed and approved by the FCOI Committee. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the FCOI Committee shall provide to the Sponsored Program Administration, an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting with certification that an appropriate Management Plan has been developed and implemented.

- 7.1.2. If unrelated to proposals for funding, at the time of submission of human or animal protocols if financial relationships related to the research exist.
 - 7.1.3. Potential FCOI involving University royalty entitlements shall be disclosed by the employee to the FCOI Committee.
 - 7.1.4. The employee is required to update his/her disclosure to the FCOI Committee on an annual basis, or within 30 days of such time as new reportable SFIs are obtained.
 - 7.1.5. When there is no potential for FCOI and/or commitment for any member of the research team, the Principal Investigator may certify no FCOI.
- 7.2. Sub-recipient organizations are required to comply with federal regulations on FCOI. WSU will allow sub-recipient to rely on its own FCOI policy if it can be demonstrated to WSU that this policy complies with the new rule. In addition, the sub-recipient must agree to report its identified FCOI's in a time frame that allows WSU to report these to PHS sponsor as required by regulations.
- 7.3. Disclosure to other Committees, Offices, and Outside Organizations
- 7.3.1. Employees must disclose their relationships with company or temporarily excuse themselves from any University Committee or review process that is considering a position.
 - 7.3.2. If a company is proposing to sponsor research, an employee must disclose SFI to that company.
 - 7.3.3. Employees proposing a Material Transfer Agreement (MTA) under which the University will provide materials to, or receive materials from, a company in which the employee or their immediate family has a SFI, must first disclose the proposed arrangement to the University's Technology Transfer Office.
 - 7.3.4. Employees must disclose their relationships with companies in all written or oral communications about the results of the Sponsored Program. The disclosure includes communication with professional groups and information to news media.
- 7.4. Correspondence with Financial Conflict of Interest Committee
- 7.4.1. Employees may choose to accept and return the management plan received from the committee, or may communicate questions, concerns, or disagreements about the management plan directly to the committee. All correspondence must be in writing.
 - 7.4.2. Employees must respond to the committee in writing within 30 days of receipt of a management plan. After that time, a new disclosure form may have to be submitted for consideration by the Committee.

8. Public Accessibility

- 8.1. The research policy will be available on the WSU's research website. Investigators will be directed there by appropriate representatives of the Office of the Vice President for Research.
- 8.2. WSU will ensure public accessibility of information concerning any FCOI associated with that project. Information concerning identified FCOI's held by investigators will be made available within 5 business days of a written request. The information may be requested by completing the Request for Information form available at <https://research.wayne.edu/integrity/pdf/request-for-information-form.pdf>. This

information will remain available for three years from the date that it was most recently updated. The required elements will be provided:

- 8.2.1. Investigator's name;
- 8.2.2. Investigator's title and role with respect to the project;
- 8.2.3. Name of the entity in which SFI is held;
- 8.2.4. Nature of the SFI; and
- 8.2.5. Approximate dollar value of the SFI, 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.

9. Training

- 9.1. Investigators must complete training before engaging in the research and at least every four years. Additionally, they must take required training immediately if the institution revises its FCOI policy such that requirements for investigators are changed, if an investigator is new to the institution, or if an investigator is found not to be in compliance with this policy and procedure including any management plan.
- 9.2. Investigators will be informed of the FCOI training requirements and how to access the training materials via the Research website, periodic emails, and in-person educational sessions.

10. Institutional Financial Conflict of Interest

- 10.1. Institutional Financial Conflict of Interest consists of two major types:
 - 10.1.1. Potential Conflict of Interest involving University equity holdings or a royalty arrangement related to Sponsored Programs, and
 - 10.2.1. Potential Conflict of Interest involving University officials who make decisions with institutional-wide implications, which can include department heads and centers and institutes directors, in addition to senior management.
- 10.2. Institutional Financial Conflict of Interest involving equity holding or royalty arrangements shall be covered by this policy and Institutional Financial Conflict of Interest involving University officials shall be covered by a separate Board of Governors policy (Currently Executive Order 89-3).
- 10.3. Department Chairs, Deans, Directors, and employees within the Office of the Vice President for Research who review, approve, and/or manage Sponsored Programs with companies shall disclose to the FCOI Committee all relationships with those companies in which they are involved.
- 10.4. The Assistant Vice President for Technology Commercialization shall disclose to the FCOI Committee all technology transfer agreements in which the University is proposing an equity position in the company.
- 10.5. All affiliated organizations, affiliated practice plans, and investment subsidiaries must disclose equity holding in technology resulting from Sponsored Programs conducted at the University.

11. Enforcement

- 11.1. Monitoring Plan: The research project may only begin after the actions described in the Management Plan have been implemented or, in the case of actions that occur

during the research project, an implementation plan for the actions is in place. Adherence to the Management Plan must be recertified in the annual SFI disclosure and when revisions to the SFI disclosure are submitted (see 7.1.4). Select research projects in which Management Plans have been implemented will be audited to assure compliance.

- 11.2. Breaches of this policy include, but are not limited to failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form or failure to provide additional information as required by the FCOI Committee. Violation of this policy may be the basis for discipline of the employee in accordance with other applicable Board of Governors and administrative policies and procedures. The potential sanctions may include, but are not limited to,
- Letter of admonition;
 - Ineligibility of the employee to participate in Sponsored Program;
 - Ineligibility of the employee to participate in HIC or IACUC protocols;
 - Ineligibility of the employee to supervise graduate students;
 - Suspension;
 - Nonrenewal of appointment; or
 - Dismissal.
- 11.3. While the FCOI Committee will have the authority to send letters of admonition to the employee, all other forms of disciplinary action are advisory to the Vice President for Research who will coordinate and implement the recommendation with the appropriate administrative unit.
- 11.4. If an employee who is involved in Sponsored Programs fails to comply with this policy, then the Dean of the academic unit or other individual who may become aware of the failure to comply must promptly inform the Office of the Vice President for Research of the violation.
- 11.5. To the extent required by sponsor or government agencies, the Office of the Vice President for Research will notify the sponsoring or government agency of the violation and any corrective action taken or scheduled to be taken.
- 11.6. If the failure of the investigator to comply with the institutional policies on FCOI has biased the design, conduct, or reporting of PHS-funded research, corrective action will be taken by the FCOI Committee and/or the Vice President for Research. The Institution will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. Corrective actions are designed to maintain appropriate objectivity in the funded project.
- 11.7. In any case in which the Department of Health and Human Services determines that a PHS-funded clinical research project, 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 in accordance with this policy, the investigator is required to disclose the conflicting interest in each public presentation of the results of the research. This requirement will be communicated to the investigator through the FCOI Committee, which may audit the investigator's records to assure compliance with such requirement.

- 11.8. **Retrospective Reviews** – Whenever the Financial Conflict of Interest Committee identifies a significant financial interest that was not disclosed within a designated time by an Investigator or, was not previously reviewed by the Institution during an ongoing PHS-funded research project, the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:
- 11.8.1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
 - 11.8.2. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the FCOI Committee to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the FCOI Committee shall, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - 11.8.3. The FCOI Committee is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
 - Project number
 - Project title
 - 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 financial conflict of interest
 - 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

12. Reporting

- 12.1. Annual Report – For any financial conflict of interest previously reported by the Wayne State University with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict of interest is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

13. Record Retention

- 13.1. Records of financial disclosures and all actions taken by the Institution with respect to each conflicting interest will be retained for at least three years from the date of submission of the final expenditures report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.
- 13.2. If any litigation, claim, financial management review, or audit is started before the expiration of the retention period described in Section 11.1 of this policy, the records shall be retained until all findings related to these activities are resolved and final action has been taken.

14. Compliance with Relevant Policies and Laws

- 14.1. Applicable University Policies
 - 14.1.1. WSU Code Annotated 2.41.03 CONFLICT OF INTEREST; CONTRACTS.
 - 14.1.2. WSU Executive Order 89-3 Conflict of Interest Disclosure (Management), September 22, 1989.
 - 14.1.3. WSU Executive Order 96-2 Investigator Disclosure, April 1, 1996.
NOTE: This "Research Policy" further defines the procedures for disclosure and management of conflicts outlined in the Executive Order.
- 14.2. Institutional policies on Financial Conflict of Interest and Commitment were developed to encourage employees to be in compliance with all applicable federal and state laws and regulations involving Financial Conflict of Interest and Commitment. These include, but are not limited to:
 - 14.2.1. Public Health Service Regulation: 42 CFR Part 50 and 45 CFR Part 94 Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.
 - 14.2.2. National Science Foundation: "Investigator Financial Disclosure Policy," 60 Federal Register 132 35809, effective July 11, 1995.
 - 14.2.3. Food and Drug Administration Regulation: "Financial Disclosure by Clinical Investigators," 21 CFR pt. 54 and applicable portions of part 312, 314, 320, 330, 601, 807, 812, 814, and 860, effective February 2, 1999.
 - 14.4.4. State of Michigan Conflict of Interest Law: "Contracts of Public Servants with Public Entities" Public Act 317 of 1968, as amended by Public Act 81 of 1984.
 - 14.4.5. In accordance with 42 CFR 50.604(g)(2), Wayne State University has a responsibility to report to the PHS Awarding Component that the Investigator has made a disclosure of a conflict of interest that requires management, reduction, or elimination. Similarly, WSU must report any subsequently identified conflict(s) of interest, and assurance that these have been managed, reduced or eliminated, within 60 days of their identification