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Research, Sponsored Programs, and Innovation Financial Conflict of Interest in Research Policy

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Policy Type

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| <input type="checkbox"/> Entity Policy | <input checked="" type="checkbox"/> Corporate Policy |
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Policy Scope

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| <input checked="" type="checkbox"/> Summa Health (Corporate) | <input checked="" type="checkbox"/> Summa Health System (Hospitals) |
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| <input checked="" type="checkbox"/> Summa Health Medical Group | |
| <input checked="" type="checkbox"/> Summacare | <input type="checkbox"/> Department: _____ |

1.0 Purpose:

1.1 The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies

2.0 Scope:

2.1 This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research. Specific guidance and requirements regarding Public Health Service (PHS) (including other sponsors who require PHS compliance) and National Science Foundation (NSF) funded research at Summa Health are noted in Sections 5.11-5.12 of this policy. If other research sponsor requirements differ from this policy, those requirements will be followed in accordance with applicable written agreements.

This policy does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program.

If a research project involves PHS/NSF subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should PHS or NSF funds be subcontracted by Summa Health to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

3.0 Definitions:

- 3.1 **Financial Conflicts of Interest Administrator (FCOI Admin)** means the individual responsible on behalf of Summa Health for the implementation of this policy, including the solicitation and initial review of disclosures of significant financial interest from research Investigators.
- 3.2 **Conflict of Interest Management Plan** means the written plan developed to manage conflicts by mitigating, reducing or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.

- 3.3 **Entity means** any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- 3.4 **Financial Interest means** anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children whether or not the value is readily ascertainable.
- 3.5 **Financial Conflict of Interest means** a Significant Financial Interest related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.
- 3.6 **Institution means** any domestic or foreign, public, or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- 3.7 **Institutional Official means** the individual who is legally authorized to act for the institution, and on behalf of the institution.
- 3.8 **Institutional Responsibilities means** an Investigator's professional responsibilities on behalf of Summa Health including, but not limited to, activities such as research, research consultation, teaching, professional/clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Data and Safety Monitoring Boards, etc.
- 3.9 **Investigator means** the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators or consultants.
At Summa Health this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities.
- 3.10 **Management means** actions taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.11 **PD/PI means** the project director or principal investigator of a research project.
- 3.12 **Public Health Service (PHS) Awarding Component means** the organizational unit of the PHS that funds the research (e.g., National Institutes of Health).
- 3.13 **Research means** a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a PHS or NSF Awarding Component through a grant or cooperative agreement, whether authorized under the PHS, NSF, 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.**
- 3.14 **Senior/Key Personnel means** the Project Director/Principal Investigator 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 or NSF by the Institution under this subpart.
- 3.15 **Significant Financial Interest (SFI) means**

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
3. The term *significant financial interest* **does not include** the following types of non-foreign financial interests:
 - a. Salary, royalties, or other remuneration paid by Summa Health to the Investigator if the Investigator is currently employed or otherwise appointed by Summa Health, including intellectual property rights assigned to Summa Health and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
 - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- d. Travel by an Investigator 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 a research institute that is affiliated with an Institution of higher education.

3.16 **Small Business Innovation Research (SBIR) Program** - the extramural research program for small businesses established by the awarding components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public law 102-564.

4.0 Policy

Each year an Investigator who conducts externally funded research must disclose via the electronic system all significant financial interests (SFIs) that are relevant to an Investigator's institutional responsibilities, or within 30 days after he/she becomes aware of a new SFI (including a change to a prior disclosure) or after a financial conflict of interest has been eliminated. All Investigators participating in externally funded research (including NIH Programmatic activities) at Summa Health must comply with this disclosure requirement. Additionally, Summa Health Institutional Review Board (IRB) members, Research, Sponsored Programs, and Innovation Compliance Committee (RCC) members and any PHS-funded sub-recipient Investigators that have elected to follow Summa's FCOI requirements must follow these disclosure requirements as well.

Prior to submitting an application for research funding or expending awarded funds for research, the Office of Research Administration staff must ensure that all investigators have a current research significant financial interest disclosure form on file via the electronic submission system (and that it includes the financial disclosure of their spouse and dependent children) and all applicable training requirements have been met to ensure compliance with federal requirements.

All individuals subject to this policy (see above) must complete the initial online conflict of interest training and renew that training at least once every four years to be approved to participate in research and research oversight at Summa Health.

5.0 Procedure

5.1 Investigator Responsibilities

Investigators are responsible for:

- 5.1.1 Disclosing all significant financial interests and providing updates to disclosed information as needed

- 5.1.2 If acting as the PI/PD, providing a list of individuals who meet the definition of “investigator” (see 3.9) within the required disclosure timeline
- 5.1.3 Completing all required training and education
- 5.1.4 Completing the annual disclosure form even if they have no financial interests to report.
- 5.1.5 Ensuring that an updated disclosure information is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals, as well as at the time of grant submission.

5.2 Financial Conflicts of Interest

A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

- 5.2.1 Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's Summa Health-based research;
- 5.2.2 Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research;
- 5.2.3 Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

This policy addresses individual financial conflicts of interest; however, Summa Health may also have conflicts of interest in research whenever the financial interests of Summa Health, or of a Summa Health official acting within his or her authority on behalf of Summa Health, might affect—or reasonably appear to affect—Summa Health processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

5.3 Review of FCOIs

The Financial Conflicts of Interest Administrator (FCOI Admin) conducts an initial review of all disclosures. If necessary, the FCOI Admin obtains additional information from the Investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or newly funded sponsored project or program. The FCOI Admin then formally identifies cases that require further review and refers such cases to the RCC.

The RCC will review the collected information in accordance with its Charter to determine whether a financial conflict of interest exists by considering the following:

- 5.3.1 Impact on integrity of research data;
- 5.3.2 Risks to rights and safety of animal and/or human research subjects;
- 5.3.3 Risks to the rights of students and trainees participating in research; and
- 5.3.4 Appearance of conflict of interest.

If a financial conflict of interest is identified, the RCC will determine whether the research can be

undertaken with appropriate management.

5.4 Management of FCOIs

For cases that require management, a Management Plan will be developed by the FCOI Admin and RCC. The Management Plan will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

- 5.4.1 Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate;
- 5.4.2 Disclosure of significant financial interests directly to subjects involved in human research;
- 5.4.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- 5.4.4 Modification of research plan;
- 5.4.5 Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- 5.4.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- 5.4.7 Severance of relationships that create the actual or potential conflict of interest;
- 5.4.8 If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

A draft Management Plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the final RCC-approved plan to acknowledge their agreement to comply.

If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim Management Plan will be implemented when necessary.

5.5 Monitoring

Investigator compliance with Management Plans will be monitored by Summa Health officials. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

5.6 Research Involving Vulnerable Populations

Special consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique

Investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by the Vice President, Research, Sponsored Programs & Innovation, FCOI Admin and RCC. If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implementation of a Management Plan to ensure the safety of human subjects and the integrity of the research. The IRB of Record must review the research with consideration given to the requirements of the Management Plan developed by the RCC. The IRB of Record may require additional safeguards to be implemented but may not determine less stringent financial conflict of interest management requirements.

5.7 Appeals

Investigators may appeal RCC decisions in writing within 15 days of receipt of the finalized Management Plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to the committee's decision. The Institutional Official (IO) will review the appeal and make a final determination. Alternatively, the IO also can convene an Appeals Committee to review the SFI information, the Management Plan, and previous meeting minutes to make a final decision.

In either situation, the Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 90 days from the date requested by the Investigator. The decision of the IO/Appeals Committee is final and binding.

5.8 Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel (see Section 5.11.4).

5.9 Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or Summa Health.

5.10 Policy Revision

Summa Health may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The RCC will have five business days to review and comment on any proposed revisions.

Summa's Vice President, Research, Sponsored Programs & Innovation is responsible for granting final approval. He/she will review all proposed revisions, in collaboration with his/her staff, and will consider the committee's feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.

5.11 Additional Requirements for PHS-Funded Research

The following **additional** requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component, including the NIH.

5.11.1 Reporting

Summa Health will provide to the PHS Awarding Component a FCOI report as outlined in the regulations.

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. Summa Health will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Project Number
- PD/PI or Contact PD/PI if a multiple PD/PI model is used
- Name of Investigator with FCOI
- Name of the entity with which the Investigator has a conflict of interest
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honorarium)
- Value of the financial interest 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the Management Plan, including 1) role and principal duties of the conflicted Investigator in the research project, 2) conditions of the management plan and 3) how the management plan is designed to safeguard objectivity in the research project, 4) confirmation of the Investigator's agreement to the management plan, 5) how the management plan will be monitored to ensure Investigator compliance, and 6) other information as needed.

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI

- Justification if FCOI no longer exists
- Changes to the Management Plan

If an Investigator fails to comply with this policy or a financial conflict of interest management plan and that non-compliance appears to have biased the design, conduct, or reporting of the PHS-funded research, Summa Health will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Summa Health for further action, which may include directions to Summa Health on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Summa Health employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

5.11.2 Subrecipients

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, Summa Health will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements and certify, when applicable, that the subrecipient's policy complies with applicable PHS regulations

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interest to Summa Health within seven calendar days of their FCOI determination to allow the awardee Institution to report the FCOI to the PHS Awarding component in a timely manner.

Subrecipients who do not have such a conflict of interest policy will be required to follow the requirements of this policy. A subrecipient's failure to promptly comply with the Summa Health policy will be considered grounds for immediate termination by Summa Health of any applicable subcontract or subaward. The written agreement terms required by Summa Health will contain a provision that subrecipients will report to Summa Health as the awardee Institution, any identified FCOI in sufficient time to allow Summa Health to report and manage the FCOI to meet the reporting obligations described above.

5.11.3 Travel Disclosure

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, **regardless of the value**. At a minimum, the travel disclosure must include:

- Purpose of the trip
- Identity of the sponsor/organizer

- Destination
- Length
- Monetary value, if known

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- 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

Travel disclosures will be reviewed by the FCOI Admin and be referred to the RCC as appropriate, to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip.

5.11.4 **Public Accessibility**

This policy will be posted on the Summa Health public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the FCOI Admin receives the request. This information may be requested by calling **Summa Health at (330)375-4045** or emailing research@summahealth.org

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined
- Language that states that the information is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of Summa Health's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

This information will remain available for three years from the date the information was most recently updated.

5.11.5 **Training Requirements**

PHS-funded Investigators must complete FCOI training prior to engaging in research

related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to Summa Health and will be working on PHS-funded research
- An Investigator is found to be noncompliant with this policy or their approved Management Plan

5.11.6 Investigator/Institutional Non-Compliance

If an SFI is not disclosed to or reviewed by Summa Health in a timely manner, Summa Health will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether a FCOI exists, and if so:

- Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan
- Complete a retrospective review of Investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report.

If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the Investigator's Indirect Cost Allocation portion, the Investigator's Department, or directly billed to the Investigator. If 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 managed or reported by Summa Health, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

Summa Health's documentation of the retrospective review will include, but is not limited to, all of the following key elements:

- Project Title
- Project Number
- 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

Based on the results of the retrospective review, if appropriate, Summa Health will 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, Summa Health will 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 the Institution'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).

Thereafter, Summa Health will submit FCOI reports annually, as specified in Section 5.11.1. Depending on the nature of the financial conflict of interest, Summa Health 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 financial conflict of interest or the Investigator's noncompliance is determined and the completion of Summa Health's retrospective review.

5.12 NSF Reporting Requirements

If Summa Health is unable to satisfactorily manage a conflict of interest involving NSF funding, it will appropriately notify NSF's Office of the General Counsel.

6.0 Responsibilities and Authorities:

Investigators participating in, or planning to participate in the design, conduct, or reporting of externally funded research are subject to this policy. Summa Health's Office of Research Administration has the authority and responsibility for ensuring the activities in this policy.

7.0 Records

Summa Health will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

8.0 References:

- 8.1 Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- 8.2 Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- 8.3 National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies
- 8.4 Summa Health Project-Specific Disclosure for Human Subject Research Policy

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