1. **PURPOSE**
   To outline requirements for the disclosure, review, management, reporting and monitoring of Significant Interests related to Research that are held by Investigators and those involved in the review and approval of Research involving human or animal subjects.

2. **SCOPE**
   This policy applies to:
   a) Investigator’s involved in research being conducted at any Aurora Health Care entity or facility
   b) Investigator’s involved in research utilizing Aurora Health Care’s patient population or protected health information;
   c) Investigator’s involved in research funded by or under funding received by Aurora Health Care or any of its entities;
   d) Investigators listed on applications to Aurora Health Care’s Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC); and
   e) Aurora Health Care IRB and IACUC members, IRB and IACUC staff, and IRB and IACUC consultants.

3. **DEFINITIONS**

   3.1 **Conflict of Interest (COI)** in the Research context means the Research Conflict of Interest Committee (RCOIC) has determined that a Significant Interest could directly and significantly affect the design, conduct or reporting of ongoing or proposed Research. COI in the context of review of human or animal subject Research means the individual proposed to be involved in the review holds a Significant Interest.

   3.2 **Institution of Higher Education** means an institution as defined at 20 USC 1001(a), an educational institution that meets all of the following: (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education or the recognized equivalent; (2) is legally authorized within a state to provide a program of education beyond secondary education; (3) provides an educational program for which the institution awards a bachelor’s degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program (4) is a public or other non-profit institution; and (5) is accredited by a nationally recognized accrediting organization.
3.3 **Institutional Responsibilities** are activities that derive or descend from one’s professional standing or expertise or activities that are conducted on behalf of Aurora. These include, for example, Research, teaching, consulting or other services, professional practice, and committee or panel membership/service.

3.4 **Immediate Family Members/Partners** means a spouse, dependent child, stepchild, domestic partner or other individuals who have a financially dependent relationship with the Investigator or are residing in the same household.

3.5 **Investigator** means a project director, Principal Investigator, key personnel or any other person, regardless of title or position, involved in the design, conduct, or reporting of Research, including, but not limited to collaborators and consultants.

3.6 **Principal Investigator** means the lead researcher on a specific project.

3.7 **Related to the Research** means the Significant Interest could be affected by the Research or the Significant Interest is in an entity whose Significant Interest could be affected by the Research.

3.8 **Research** means 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. The term encompasses basic and applied research and product development.

3.9 **Research Conflict of Interest Committee (RCOIC)** means the group, appointed by Aurora’s Chief Compliance Officer, charged with confirming or refuting Conflict of Interest determinations made by the Research Compliance Officer. This group is also responsible for approving and monitoring plans necessary to manage Conflicts of Interest. The RCOIC will be chaired by the Research Compliance Officer (non-voting member) and, at a minimum, include the following voting members: Institutional Official for Aurora’s Research Subject Protection Program or his/her designee, a member of Aurora’s Legal Services team, an Investigator, and Aurora’s Policy and Ethics Officer. The Senior Vice President for Research or his/her designee will serve on the RCOIC as a non-voting member.

3.10 **Significant Interest (SI)** means any of the following held or received by an Investigator, Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)
member, IRB or IACUC consultant, or IRB or IACUC caregiver and/or an Immediate Family Members/Partners of these individuals if related to the individual’s Institutional Responsibilities (see exclusions at the end of this definition):

a) Equity interest in and remuneration from a publicly traded entity when the value of the equity interest as of the date of disclosure and the value of any remuneration received from the entity in the twelve months preceding the disclosure, in aggregate, exceeds $5,000

b) Any amount of equity interest in a non-publicly traded entity

c) Remuneration from a non-publicly traded entity that, in aggregate, exceeds $5,000 over the twelve-month period preceding the disclosure.

d) Intellectual property (IP) interests or rights (e.g., patents, copyrights) at the point a decision is made to file for protection of the IP or a proposal is being developed to test the product in animal or human subjects, whichever occurs first. In all cases, disclosure must occur prior to IRB or IACUC submission, as applicable.

e) IP rights interests or rights held by another individual or entity when the Investigator, IRB or IACUC member, IRB or IACUC consultant, or IRB or IACUC caregiver or any of these individuals’ Immediate Family Members/Partners has received or has the potential to receive income from those interests or rights.

f) Reimbursed or sponsored travel from a single entity that, in aggregate, exceeds $5,000 over the twelve-month period preceding the disclosure. This does not include travel reimbursed or sponsored by Aurora Health Care.

g) A formal or informal relationship or involvement with a sponsor of the Investigator’s Research or the sponsor of Research being reviewed by an IRB or IACUC member, IRB or IACUC caregiver, or IRB or IACUC consultant, or a relationship or involvement with an entity that has a direct or indirect financial interest in the sponsor or otherwise stands to benefit from the results of the Research. Examples include positions on sponsor’s advisory board or board of directors, service on a board of a venture capital fund that invests in a sponsor, participation on speaker’s bureaus for a sponsor and service on a sponsor’s data
safety monitoring board.

EXCLUSIONS:

i) Compensation for services provided directly to Aurora Health Care

ii) 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

iii) Any of the following if from a Federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital or a medical center or a research institute that is affiliated with an Institution of Higher Education:
   (1) Income from seminars, lectures or teaching engagements
   (2) income from service on advisory committees or review panels
   (3) reimbursed or sponsored travel

3.11 **Significantly** means to a degree that could potentially alter the outcome of the Research

3.12 **Sponsored Travel** means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. Does not include travel sponsored by Aurora Health Care or Investigator’s employer if other than Aurora Health Care.

4. **POLICY**

4.1 **General.** Aurora Health Care will develop processes to ensure that any Significant Interests (SI) held by Investigators and those involved in the review and approval of Research involving human or animal subjects do not create unmanaged conflicts with their primary obligation to design, conduct, review and/or report scientifically sound and ethical Research.

4.2 **Prohibited Conflicts.** The following create deep-seated conflicts with an Investigator’s obligation to conduct scientifically sound and ethical Research and are therefore prohibited:
a) Payment contingent upon particular Research results or tied to successful Research outcomes

b) Payment/recruitment bonuses or incentives for enrolling or referring patients to Research studies unless:

i) the payment is intended to cover expenses related to recruitment efforts and documented as such; and

ii) the payment is commensurate with the work being performed.

4.3 **Education.** Aurora Health Care will educate Investigators on the requirements of this policy, their responsibilities regarding disclosure of SIs, and, when an Investigator is engaged in Public Health Service (PHS) funded Research, the regulation related to objectivity in research. Investigator education will occur prior to engaging in human or animal subject Research or PHS-funded Research, at least every four years thereafter, and immediately when any of the following circumstances apply:

a) Aurora Health Care revises its policies on COI in a manner that affects the requirements of Investigators;

b) an Investigator is new to Aurora and plans to apply or participate in Research; or

c) an Investigator is found to be out of compliance with this policy or an executed and accepted COI Management Plan.

4.4 **Required Disclosures.**

a) All Investigators must disclose SIs annually, within the timeframe prescribed by Aurora’s Compliance Department. The annual disclosure will include updated information regarding previously disclosed interests.

i) Investigators named on a Research project involving human or animal subjects must complete their annual disclosure no later than the time of Institutional Review Board (IRB) or Institutional Animal Care Committee (IACUC) review, as applicable.
ii) Investigators planning to participate in Public Health Service (PHS) funded Research must complete their disclosure no later than the time of application for funding.

b) All Investigators must update their annual disclosure within 30 days of discovering or acquiring a new SI.

c) All Investigators have an obligation to notify appropriate reviewing bodies and funding agencies of SIs they believe are related to a project on which they are named.

d) IRB and IACUC Members and IRB and IACUC caregivers must complete a SI disclosure prior to their review of Research involving human or animal subjects and annually thereafter, within the timeframe prescribed by Aurora’s Research Subject Protection Program (RSPP). Consultants to the IRB and IACUC must complete a SI disclosure prior to the review of each project.

If an IRB or IACUC member, IRB or IACUC caregiver, or IRB or IACUC consultant or their Immediate Family Members/Partners has a SI related to ongoing or proposed Research, or if they or an Immediate Family Member/Partner is named as Key Personnel on an IRB or IACUC application, they will automatically be deemed to hold a Conflict of Interest and not be allowed to participate in the review, discussion or vote on the proposed or ongoing Research except to provide information requested by the IRB or IACUC.

4.5 Disclosure Review and COI Determinations. The Research Compliance Officer (RCO) is authorized to evaluate and determine whether SIs of Investigators create a COI. Any determination that a SI creates a COI will be confirmed by the Research COI Committee (RCOIC).

4.6 COI Management.

a) SIs of Investigators that are determined to create a COI must be managed to the extent that the SI no longer directly and significantly affects the design, conduct or reporting of the Research. If management to this extent is not possible, the interest must be eliminated.
b) Management of Investigator COIs will be documented in a formal written management plan approved by the RCOIC. Management strategies may include, but are not limited to:

i) Disclosure of interest(s) to study participants, others conducting the Research and/or in presentations and publications

ii) Limitations on the conflicted Investigators’ involvement in the conduct of the Research

iii) Modification of the Research plan

iv) Appointment of an independent monitor or research intermediary capable of taking measures to protect design, conduct and reporting of the Research

v) Reduction or elimination of the SI

vi) Severance of relationships that create a Conflict of Interest

c) If an Investigator COI is related to Research involving human or animal subjects, the IRB or IACUC, as applicable, has final authority to decide whether the COI and its management plan allow the Research to be approved.

4.7 Appeals. Determinations that an Investigator SI creates a COI may be appealed to the Chief Compliance Officer.

4.8 Management Plan Monitoring. The RCOIC will monitor Investigator COI management plan compliance. The RCOIC may delegate monitoring responsibility to the RCO or others.

4.9 Administrative Actions/Sanctions. Investigator failure to complete required training, failure to respond to a request for a SI disclosure statement or update SIs, and/or failure to adhere to a management plan may result in administrative actions and sanction as deemed appropriate by the Chief Medical Officer. Administrative actions/sanctions could include but are not limited to, additional training, additional monitoring, retrospective review, and restrictions on Research privileges.
IRB or IACUC members who fail to respond to requests for SI disclosure statements or update Sis will have membership privileges revoked until disclosures are complete. IRB or IACUC caregiver failure to comply with disclosure requirements will be handled under AHC Policy #4 – Caregiver Accountability.

4.10 Record Retention. Records related to any aspect of disclosure, disclosure review, COI management and all other actions taken under this policy will be maintained in accordance with AHC Policy No. 223 - Record Retention, Storage and Destruction.

4.11 Public Health Service Funded Research. Aurora Health Care will comply with all requirements for applicants and recipients of Public Health Service funds as detailed at 42 CFR 50 and 45 CFR 94, and any other funding agency or accreditation requirements regarding the disclosure, review, management and reporting of interests.

5. PROCEDURE

5.1 Education. The Compliance Department, Research Subject Protection Program (RSPP) and Aurora Research Institute (ARI) will partner to establish education and ensure Investigator compliance with educational requirements as required in section 4.3. In addition to other educational requirements, all Investigators will be informed of requirements of and/or changes to this policy at the time an annual disclosure is requested.

5.2 Disclosures.

a) The Compliance Department will solicit annual disclosures from Investigators. Disclosures will meet the requirement for an annual disclosure as noted in this policy if received within 30 days of the request. If the disclosure is found to be incomplete upon review by the Compliance Department, the requirement for an annual disclosure will be considered met as long as the Investigator is responding in a timely fashion to requests for additional information. The Compliance Department will notify the Chief Medical Officer, RSPP and/or ARI as applicable, of delinquent disclosures.

b) RSPP will develop and maintain procedures to ensure annual disclosure requirements related to IRB and IACUC review, as noted at 4.4.a)i) and 4.4.d. are met.
c) ARI will develop and maintain procedures to ensure annual disclosure requirements related to PHS-application submission, as noted at 4.4.a)ii) are met.

d) RSPP and ARI will develop and maintain procedures to ensure that Principal Investigators requesting approval of a Research project involving human or animal subjects or any key personnel planning to participate in PHS-funded Research certify that they have made the required annual disclosure within the prescribed timeframe, their disclosure is up to date, and either: (1) they do not believe any disclosed interests are related to the proposed Research; or (2) identify any disclosed interests they believe are related to the proposed Research.

e) ARI and RSPP will periodically remind Investigators of their obligation to update their annual disclosure within 30 days of discovering or acquiring a new SI.

5.3 Disclosure Review.

a) Upon receipt of annual Investigator disclosures, a determination of whether any disclosed SIs are related to ongoing or proposed Research will be made by RSPP or the RCO.

b) The RCO will evaluate related SIs that are Related to the Research and make an initial determination as to whether they create a COI with ongoing or proposed Research. For any COI identified, the RCO will create a draft management plan. The RCO will recuse him/herself from evaluation of interests in which she/he has a conflict. These evaluations will be performed by the Policy and Ethics Officer.

c) If the RCO determines that a SI creates a COI, the RCO will inform the Investigator holding the SI of the results of the evaluation and the proposed management plan. The RCO may make adjustments to the evaluation, initial determination, and/or draft management plan based on feedback and additional information provided by the Investigator holding the SI.

d) For any initial COI determination made by the RCO, the evaluation and draft management plan will be submitted to the RCOIC for a final determination as to
whether the SIs creates a COI, as well as approval or modification of the proposed management plan.

e) The RCO will also inform the RSPP of initial COI determinations. IRB and IACUC review of proposed projects related to the SI will not go forward until RCOIC review is complete. The IRB and IACUC may decide to implement interim measures to protect the rights and welfare of human or animal subjects in ongoing projects Related to the Research.

5.4 COI Management.

a) If the RCOIC confirms a COI determination, and the COI is related to human or animal subject Research, the RCO will forward a summary of the SI interest along with the proposed management plan to the IRB or IACUC, as applicable, for review. The IRB or IACUC may require the addition, but not the removal, of conflict elimination/reduction strategies to the management plan. RSPP will inform the RCO of the result of the IRB or IACUC review.

b) The RCO will forward RCOIC and IRB/IACUC approved management plans to the conflicted Investigator for acknowledgement and implementation.

5.5 Appeals. Any appeal of a RCOIC determination must be submitted in writing to the RCO within 10 working days of receipt of RCOIC’s decision and the final management plan. The RCO will submit the appeal request, SI evaluation and RCOIC documentation to the Chief Compliance Officer for review. The Investigator holding the SI and the RCOIC will be informed of the Chief Compliance Officer’s decision in regard to the appeal.

5.6 Management Plan Monitoring.

a) At a minimum, the RCOIC will, on at least an annual basis, require the conflicted Investigator to: (1) confirm implementation and/or certify compliance with the management plan; and (2) reassess the adequacy of the management plan. Monitoring will occur through completion of the Research related to the COI.

b) The necessity of additional monitoring activity will be determined by the RCOIC and may include but is not limited to auditing study records, interviewing or requesting reports from department leaders and caregivers, reviewing publications, and requiring reports from the conflicted Investigator.
5.7 Additional Requirements for Public Health Services (PHS) Funded Research and Investigators.

Requirements and procedures contained within Appendix A will be followed in addition to those noted above when the interest is related to proposed or awarded PHS funding for Research by means of a grant or cooperative agreement, with the exclusion of SBIR Program Phase I applications. Additional requirements and related procedures are in regard to:

a) Disclosure Review and Management

b) Reporting

c) Interests not Disclosed, Reviewed or Managed in Timely Manner

d) Public Accessibility

e) Subrecipients

CROSS REFERENCES:

AHC System Policy No. 80 – Conflicts of Interest

AHC System Policy No. 270 - Conflicts of Interest in Research-Institutional

AHC System Policy No. 130 – Vendor Gifts and Gratuities

AHC System Policy No. 208 - Interactions with Industry

AHC System Policy No. 4 – Caregiver Accountability

OWNER: SVP/Chief Compliance Officer

REFERENCES:

42 CFR Part 50, Subpart F (Promoting Objectivity in Research)

45 CFR Part 94 (Objectivity in Research for Responsible Prospective Contractors)

45 CFR 46.107(e) (Protection of Human Subjects; IRB Membership)

Association for the Accreditation of Human Research Protection Programs,
Element I.6.B

Frequently Asked Questions, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations), National Institutes of Health, Q&A E.9.,


Association of American Medical Colleges, Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research, December 2001


Conflicts of Interest in Medical Education, Research and Practice, Bernard Lo and Marilyn J. Field, Editors; Committee on Conflict of Interest in Medical Research, Education, and Practice; Institute of Medicine, 2009, National Academy of Sciences (http://www.ncbi.nlm.nih.gov/books/NBK22937/)
Appendix A

to AHC Policy No. 269 - Conflicts of Interest in Research-Individual

ADDITIONAL REQUIREMENTS/PROCEDURES RELATED TO PHS FUNDED RESEARCH

1. Definitions

   With the exception of the following, all definitions remain consistent with those contained with the Definitions Section of Policy No. 269:

   Investigator, for purposes of this appendix, means 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 research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

2. Disclosure Review and Management.

   a. The Research Compliance Officer (RCO) and Research Conflict of Interest Committee (RCOIC), with the assistance of Aurora Research Institute (ARI), will work to ensure that review of Investigator interests, as well as the development and implementation of any needed management plans, occur prior to expenditure of Public Health Service (PHS) funds for the related research project.

   b. ARI will notify the RCO of any Investigator new to participating in PHS-funded research, or of an existing PHS-funded Investigator disclosing a new Significant Interest. The RCO will ensure that the solicitation and review of a disclosure is completed promptly. If applicable, the RCO will work with ARI to ensure development and implementation of at least an interim Management Plan within sixty days of the disclosure.

3. Reporting.

   a. Prior to expenditure of any PHS research funds, ARI will provide the PHS awarding agency a report of any identified Investigator Conflicts of Interests, including Conflicts of Interests of subinvestigators, and ensure that no expenditure of the PHS research award occurs until the Conflict of Interest Management Plan has been implemented.

   b. For any Conflict of Interest previously reported to PHS, the ARI will provide to the PHS awarding agency an annual report that addresses the status of the Conflict of Interest and any changes to the Management Plan for the duration of the PHS-funded project.
c. For any Conflict of Interest identified subsequent to ARI’s initial report during an ongoing PHS-funded research project, ARI will provide to the PHS funding agency, within sixty days, a report that contains at a minimum the elements required at 45 CFR 50.605(b)(3) or 42 CFR 94.5(b)(3), as applicable.

d. No report will be submitted to the PHS funding agency in cases where a Conflict of Interest is identified and eliminated prior to expenditure of funds.

4. Interests not Disclosed, Reviewed or Managed in Timely Manner

a. In the event Aurora identifies an Investigator Significant Interest related to PHS-funded research that was not disclosed or managed in accordance with this policy, the RCO will, within 60 days, review the interest, determine whether it is related to ongoing PHS-funded research, determine whether a Conflict of Interest exists, and if so, implement, on at least an interim basis a management plan that specifies actions that have been or will be taken to manage the interest. RCOIC and Institutional Review Board (IRB) or Institutional Animal Care Committee (IACUC), as appropriate, will be notified of the ongoing review and receive a copy of the interim management plan for review and subsequent determinations and monitoring as required by this policy.

b. In addition, if an interest held by an Investigator that was not disclosed or managed in accordance with this policy is determined to be a Conflict of Interest related to PHS-funded research, the RCO will within 120 days, complete a retrospective review of the Investigator’s activities and the research to determine whether any research conducted during the time period of the noncompliance was biased in design, conduct or reporting. Documentation of the retrospective review will include, at a minimum, the elements required by 42 CFR 50.605(a)(3)(ii)(B) or 42 CFR 94.5(a)(3)(ii)(B), as applicable.

c. The RCO will share the results of the retrospective review with the ARI, RCOIC, and IRB or IACUC, as applicable.

d. ARI will be responsible for updating the submitted Conflict of Interest report, specifying actions to be taken moving forward, and if bias is found, promptly notifying and creating and submitting a mitigation report to the relevant PHS awarding agency. The mitigation report will, at a minimum, include the elements required by 42 CFR 50.605(a)(3)(iii) or 45 CFR 94.5(a)(3)(iii), as applicable.

5. Public Accessibility. Compliance will ensure that a current version of this policy is maintained on a publicly accessible website. Upon request, and within five days of receipt of the request within the Compliance Department, information concerning a specific Conflict of Interest related to PHS-funded research will be made available to the requestor if the Significant Interest is still held by the
The information provided will, at a minimum, include information as required by 42 CFR 50.605(a)(5)(ii) or 45 CFR 94.605(a)(5)(ii).

6. **Sub-recipients.** ARI will incorporate, as part of a written agreement with PHS subrecipients, terms that establish whether the subrecipient must comply with this policy or their own policy on disclosure, review and management of interests.

   a. If complying with its own policy, subrecipient will certify in the agreement that its policy complies with 42 CFR 50, Subpart F or 45 CFR 94, as applicable, and the agreement will specify timeframes in which subrecipient shall report identified Conflicts of Interest to Aurora. Timeframes will be sufficient to enable Aurora to comply with PHS reporting requirements.

   b. If subrecipients comply with this policy, the agreement will specify timeframes under which subrecipient must submit disclosures of Significant Interests. Timeframes will be sufficient to enable Aurora to comply with PHS requirements for review, management and reporting of interests.