AdvocateAuroraHealth		
Title: Conflicts of Interest in Research-Individual		**Document Number:** 2302
Document Type: ☒ Policy ☐ Procedure ☐ Guideline ☐ Other		**Last Review/Revision Date:** 02/01/2020
Content Applies to Patient Care: (Select all that apply) ☐ Adults ☐ Pediatrics (Under 18)	**Content Applies to:** (Select One) ☐ Clinical ☒ Administrative	**Next Review Date:** 02/01/2023 **Effective Date:** 01/29/2019
Scope: ☒ AAH System ☐ AAH IL Only ☐ AAH WI Only ☐ Site Only (Location Name): ☐ Department Only (Department Name):		

I. PURPOSE

Advocate Aurora Health shall establish and perform processes to ensure that any Significant Interests (SI) held by Investigators, Advocate Aurora Health Research Leaders 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. To achieve that purpose, this policy outlines requirements for the disclosure, review, management, reporting and monitoring of Significant Interests related to Research that are held by Investigators and those reviewing and approving Research involving human or animal subjects.

II. SCOPE

This policy applies to:

A. Investigators involved in Research involving human or animal subjects or participating in Public Health Service (PHS) funded Research being conducted at Advocate Aurora Health and any entity or facility owned and controlled by Advocate Aurora Health;

B. Investigators involved in Research utilizing Advocate Aurora Health's patient population or protected health information if deemed to be human subject Research;

C. Investigators involved in Research funded by or under funding received by Advocate Aurora Health or any of its entities;

D. Investigators listed on applications to Advocate Aurora Health's Institutional Review Boards (IRB) or Institutional Animal Care and Use Committees (IACUC); and

E. Advocate Aurora Health IRB and IACUC members, Research Subject Protection Program (RSPP) team members, and IRB and IACUC consultants.

F. Advocate Aurora Health Research Leaders, with respect to disclosures of SIs as is necessary for institutional conflict of interest determinations.

III. DEFINITIONS/ABBREVIATIONS

A. **Advocate Aurora Health Research Leader** means an individual responsible for direct oversight of Advocate Aurora Health's Research efforts as determined by Advocate Aurora Health's Compliance & Integrity Department. This includes individuals with Advocate Aurora Health Research administrative and supervisory responsibility (i.e., Research presidents, vice presidents, directors and managers), those with Research review/oversight responsibility (i.e., RSPP director(s), Institutional Official for Human Subject Protection, and IRB and IACUC Chairs), and others as deemed appropriate by the Compliance & Integrity Department.

B. **Conflict of Interest (COI)** in the Research context means a SI that could directly and significantly affect the design, conduct or reporting of ongoing or proposed Research, or present the appearance thereof. Appearance of a conflict will be determined by the Research Conflict of Interest Committee based on a reasonable person's assumption that a researcher would likely be unable to maintain scientific objectivity due to a competing SI.

For those reviewing Research (e.g., IRB or IACUC members), holding a SI automatically creates a COI.

C. **Conflict of Interest Management Plan** is a written and accepted plan stipulating conditions or restrictions that are agreed upon by conflicted team member(s) and Advocate Aurora Health in order to minimize or manage a Conflict of Interest.

D. **Equity Interest** includes any stock, stock options or other ownership interest. The value of equity interest is determined through reference to public prices or other reasonable measures of fair market value.

E. **Immediate Family Members** means a spouse or domestic partner, dependent child or stepchild, or other individuals who have a financially dependent relationship with the Investigator, Advocate Aurora Health Leader, IRB and/or IACUC member, RSPP team member, and IRB and/or IACUC consultant or are residing in the same household.

F. **Institutional Conflict of Interest (ICOI)** in the Research context means that a SI of Advocate Aurora Health or of an Advocate Aurora Health Research Leader could directly and significantly affect the design, conduct or reporting of ongoing or proposed Research, or present the appearance thereof.

G. **Institution of Higher Education** means a U.S. institution as defined at 20 USC 1001(a), which is 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.

H. **Institutional Responsibilities** are activities that derive or descend from one's professional standing or expertise and/or job duties/activities that are conducted on behalf of Advocate Aurora Health, or if not employed by Advocate Aurora Health, conducted on behalf of another employer.

I. **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 involving human or animal subjects or participating in Public Health Service (PHS) funded Research, including, but not limited to collaborators and consultants.

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

K. **Related to the Research** means there is a SI held that: 1) could be affected by the Research; 2) and/or is in an entity whose financial interest could be affected by the Research.

L. **Remuneration** includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, fees for participation in speakers' bureaus).

M. **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.

N. **Research Conflict of Interest Committee (RCOIC)** means the group, appointed by Advocate Aurora Health's Chief Compliance Officer, charged with: (a) establishing thresholds at which a SIs automatically is deemed to create a Conflict of Interest; (b) recommending management strategies based on various circumstances and thresholds; and (c) making final determinations when the conflicted individual, or others responsible for implementation, do not agree with COI determinations or proposed management plans.

O. **Significant Interest (SI)** in Research means any of the following held or received by an Investigator, IRB or IACUC member, IRB or IACUC consultant, RSPP team member or Research Leader and/or an Immediate Family Member of these individuals if related to the Investigator, Advocate Aurora Health Leader, or IRB and/or IACUC member, team member or consultant's Institutional Responsibilities (see exclusions at the end of this definition):

1. Equity interest in and remuneration from a <u>publicly</u> 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 (12) months preceding the disclosure, in aggregate, exceeds $5,000. See exclusions below.

2. Any amount of equity interest in a <u>non-publicly</u> traded entity

3. Remuneration from a <u>non-publicly</u> traded entity that, in aggregate, exceeds $5,000 over the twelve (12) month period preceding the disclosure. See exclusions below.

4. 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.

5. IP interests or rights held by another individual or entity when the Investigator, IRB or IACUC member, IRB or IACUC consultant, RSPP team member, or Research Leader, or any of these individuals' Immediate Family Members has received or has the potential to receive income from those interests or rights.

6. Reimbursed or sponsored travel from a single entity that, in aggregate, exceeds $5,000 over the twelve-month period preceding the disclosure. See exclusions below.

7. 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 team member, 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:

1. Compensation for services provided directly to Advocate Aurora Health

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator, IRB or IACUC member, IRB or IACUC consultant, RSPP team member, or Research Leader does not directly control the investment decisions made in these vehicles

3. Any of the following if from a U.S. federal, state or local government agency, a U.S. Institution of Higher Education, an academic teaching hospital or a medical center or a research institute that is affiliated with a U.S. Institution of Higher Education:

    a) Income from seminars, lectures or teaching engagements

    b) income from service on advisory committees or review panels

    c) reimbursed or sponsored travel

4. Travel included in a clinical trial agreement with Advocate Aurora Health

P. **Significantly** means to a degree that could potentially alter the outcome of the Research (e.g., number of subjects enrolled by a conflicted

investigator is large enough to affect overall study results, conflicted investigator is solely responsible for study design, study conduct or data analysis, etc.)

Q. **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 Advocate Aurora Health or Investigator's employer if other than Advocate Aurora Health.

IV. POLICY

A. **Prohibited Conflicts.** The following create deep-seated conflicts with an Investigator's obligation to conduct scientifically sound and ethical Research and are therefore prohibited:

1. Payment contingent upon particular Research results or tied to successful Research outcomes

2. Payment/recruitment bonuses or incentives for enrolling or referring patients to Research studies unless:

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

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

B. **Education.**

1. Advocate Aurora Health shall 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's education shall occur initially prior to engaging in human or animal subject Research or PHS-funded Research, at least every four (4) years thereafter, and immediately when any of the following circumstances apply:

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

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

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

2. Compliance & Integrity Department along with leaders responsible for the review and conduct of Research will establish education and ensure Investigator compliance with educational requirements.

C. **Required Disclosures**.

1. All Investigators and Advocate Aurora Health Research Leaders must disclose SIs annually, within the timeframe prescribed by Advocate Aurora Health's Compliance & Integrity Department. In the annual disclosure, these individuals must update information regarding previously disclosed interests.

   a) 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.

   b) Investigators planning to participate in Public Health Service (PHS) funded Research must complete their disclosure no later than the time of application for funding.

2. Compliance & Integrity Department will solicit annual disclosures from Investigators and Advocate Aurora Health Research Leaders.

3. Office(s) at Advocate Aurora Health responsible for the protection of human and animal Research subjects will develop and maintain procedures to ensure annual disclosure requirements related to IRB and IACUC review are met.

   a) All Investigators should notify appropriate reviewing bodies (i.e., IRB or IACUC) of SIs they believe are related to a project on which they are named.
   b) Office(s) at Advocate Aurora Health responsible for the protection of human and animal Research subjects shall develop and maintain procedures to query Principal Investigators, who are requesting approval of a Research project involving human or animal subjects, as to whether they have made the required annual disclosure, 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.

4. Advocate Aurora Health offices responsible for submission of Research grant applications will develop and maintain procedures to ensure annual disclosure requirements related to PHS-application submission are met. They shall develop and maintain procedures to query any key personnel planning to participate in PHS-funded Research, as to whether they have made the required annual disclosure, 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.

5. All Investigators and Advocate Aurora Health Research Leaders must update their annual disclosure within thirty (30) days of discovering or acquiring a new SI. Advocate Aurora Health offices responsible for the protection of human and animal Research subjects and responsible for submission of Research grant applications shall periodically remind Investigators of their obligation to update their annual disclosure within thirty (30) days of discovering or acquiring a new SI.

6. IRB and IACUC members and RSPP team members must complete a SI disclosure prior to their review of Research involving human or animal subjects and annually thereafter, within the timeframe prescribed by the office(s) responsible for administering and overseeing IRB and IACUC functions. Consultants to the IRB and IACUC must complete a SI disclosure prior to the review.

   If an IRB or IACUC member, RSPP team member, or IRB or IACUC consultant or their Immediate Family Members has a SI related to ongoing or proposed Research, or if they or an Immediate Family Member 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.

D. **Disclosure Review**

1. Relatedness Determinations.

a) Neither the individual who holds the interest nor anyone engaged in the design, conduct or reporting of the Research may make a final determination as to whether a SI is related to a specific Research activity.

b) The Chief Compliance Officer shall delegate responsibility for making relatedness determinations to an appropriately qualified individual(s) or position(s). This position may be outside of the Compliance & Integrity Department.

2. COI Determinations.

a) Neither the individual who holds the interest nor anyone engaged in the design, review, conduct or reporting of the Research may determine whether a Related SI creates a Conflict of Interest.

b) The Chief Compliance Officer shall delegate responsibility for making Conflict of Interest determinations to an appropriately qualified individual(s) or position(s) within the Compliance & Integrity Department.

c) The Research Conflict of Interest Committee (RCOIC) will be established to recommend thresholds at which a SI creates a Conflict of Interest, recommend management strategies based on various circumstances and thresholds, and serve as an appeal body.

(1) The RCOIC will be chaired by a member of the Compliance & Integrity Department (non-voting member) as appointed by the Chief Compliance Officer.

(2) At a minimum, the RCOIC will include the following voting members: an Institutional Official for Human Subject Protection Program or his/her designee, an Ethic's Program representative, a Research investigator, and a Continuing Medical Education Office representative.

(3) The System Vice President for Research or designee and IRB Administrator(s) or designee will serve on the RCOIC as non-voting members in order to address questions of the Committee or relay concerns.

(4) Membership may be revised on an ad hoc basis as deemed necessary by the Chief Compliance Officer to address member conflicts and the need for additional expertise in the review of specific interests.

d) Investigators may not change the IRB of record and review of a study based upon a COI determination made by the Compliance & Integrity Department or IRB.

E. COI Management

1. SIs of Investigators and Advocate Aurora Health Research Leaders 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.

2. Management of Investigator and Advocate Aurora Health Research Leader COIs will be documented in a formal written management plan except when management is limited to disclosure of interest(s) in publications and/or presentations. Management strategies may include, but are not limited to:

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

   b) Limitations on the conflicted Investigator's or Advocate Aurora Health Research Leader's involvement in the conduct or oversight of the Research

   c) Modification of the Research plan

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

   e) Reduction of the SI

   f) Severance of relationships that create a Conflict of Interest

3. For any 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. The

IRB or IACUC may require the addition, but not the removal, of conflict elimination/reduction strategies to the management plan. 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.

4. The Compliance & Integrity Department will assign to an appropriate individual(s) responsibility for implementation of each management plan.

F. Appeals. Individuals who disagree with determinations that a SI creates a COI or the proposed management provisions may appeal the decision to the Research COI Committee. Research COI Committee decisions may be appealed to the Chief Compliance Officer.

G. **Management Plan Monitoring.**

Monitoring will be performed by Compliance & Integrity Department and/or Advocate Aurora Health's Research Institute quality assurance program and will verify that management plans: a) have been implemented within a reasonable period of time after finalization; and b) remain in place throughout the life of the related Research project and conflicts continue to be appropriately managed. Any individual(s) conducting monitoring must not hold any individual or institutional COI related to the disclosed SI. Monitoring may include, but is not limited to, requesting reports from Research leaders or other team members, auditing records, interviewing and/or reviewing publications.

H. **Confidentiality.** Those involved in SI collection and review and COI management plan implementation and monitoring processes will protect the confidentiality of SIs obtained from Investigators and release such information on a need to know basis only and/or as required by regulation or funding agency requirements.

I. **Administrative Actions/Sanctions.**

1. Investigators and Advocate Aurora Health Research Leaders 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 Compliance Officer or his/her designee. Administrative actions/sanctions could include but are not limited to, additional training, additional monitoring, retrospective review, and removal from Research project(s) or other restrictions on Research privileges.

2. 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. RSPP team member failure to comply with disclosure requirements will be handled in accordance with Advocate Aurora Health human resource performance improvement processes.

J. **Record Retention.** Records related to any aspect of disclosure, disclosure review, COI management, COI management plan monitoring, and all other actions taken under this policy will be maintained in accordance with Advocate Aurora Health record retention policies and any federal agency or other sponsor requirements.

K. **Public Health Service Funded Research.** Advocate Aurora Health 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.

V. PROCEDURE

A. Disclosure Review.

1. Upon receipt of annual disclosures, a determination of whether any disclosed SIs are related to ongoing or proposed Research will be made by the individual(s) or position(s) appointed by the Chief Compliance Officer.

2. Review of proposed Research by the IRB or IACUC will be held until SIs related to proposed Research have been evaluated and a determination made.

3. Compliance & Integrity Department will utilize Research COI Committee guidelines to evaluate SIs determined to be related to the Research and will make a determination as to whether they create a COI with ongoing or proposed Research and if so, utilize Research COI Committee guidelines to create a management plan. No formal management plan will be required when the COI's management is limited to disclosure of interest(s) in publications and/or presentations. In these cases, Compliance & Integrity Department will send a notification to the conflicted individual of his or her obligation to disclose.

4. If Compliance & Integrity Department determines that a SI creates a COI, the Investigator holding the SI and an appropriate leader will

be informed of the results of the evaluation and the management plan. Each management plan will specifically name the position(s) or individual responsible for the plan's implementation.

5. If the COI is related to human or animal subject Research:

   a) Compliance & Integrity Department will inform the applicable IRB or IACUC of the COI determination;

   b) The IRB or IACUC, as applicable, has final authority to decide whether the COI and its management plan allow the Research to be approved;

   c) The IRB or IACUC may require the addition, but not the removal, of conflict elimination/reduction strategies to the management plan;

   d) 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;

   e) The IRB or IACUC will be asked to inform Compliance & Integrity of the result of the IRB or IACUC review of the management plan; and

   f) The IRB or IACUC will inform Compliance & Integrity Department of significant changes/amendments to studies involving a COI and significant changes to disclosures so that existing management plans can be re-evaluated to determine whether adjustments to the management plan are necessary.

B. **COI Management**

1. After any IRB or IACUC review, if applicable, Compliance & Integrity Department will forward the final management plan to the conflicted individual and the appropriate leader. The conflicted individual must acknowledge understanding of management plan or appeal the decision or management provision(s) to the Research COI Committee. The leader must acknowledge responsibility for implementation of the management plan by accepting the plan or provide explanation for declining.

2. The leader will make the conflicted individual's direct report aware of the management plan and request their assistance with

implementation if necessary.

C. **Appeals**

1. Any appeal of a COI determination or proposed management provisions must be submitted in writing to the Chair of the Research COI Committee as soon as possible but no later than fifteen (15) working days of receipt of notice from the Compliance & Integrity Department that a SI creates a conflict and communication of the COI management plan. The appeal must be based on the belief and include justification as to why the conflicted individual does not believe the SI meets the definition of a COI and/or why specific management provision(s) are not appropriate.

2. The Research COI Committee will review the appeal request. The individual holding the SI will be informed of the outcome of the review. The leader assigned to implementing the management plan and the IRB or IACUC as applicable will be informed of the RCOIC's decision in regard to the appeal if it changes the determination or management plan.

3. Appeal of the RCOIC's determination must be submitted in writing to the Chief Compliance Officer within fifteen (15) working days of receipt of the RCOIC's decision and include justification as to why the conflicted individual does not believe the SI meets the definition of a COI and/or why specific management provision(s) are not appropriate. The individual holding the SI will be informed of the outcome of the review. The leader assigned to implementing the management plan and the IRB or IACUC as applicable will be informed of the RCOIC's decision in regard to the appeal if it changes the determination or management plan.

D. 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 Small Business Innovative Research Program Phase I applications. Additional requirements and related procedures are in regard to:

1. Disclosure Review and Management

2. Reporting

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

4. Public Accessibility

5. Sub-recipients

VI. CROSS REFERENCES

- Conflicts of Interest – Team Member
- Conflicts of Interest in Research-Institutional

VII. RESOURCES AND 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)
- AAMC Report on Institutional Approaches to Implementing the Final NIH Rule on Financial Conflicts of Interest (March, 2012)
- Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research PDF (A report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008)

VIII. APPENDICES

Appendix A-Additional Requirements/Procedures Related to PHS-Funded Research