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Ascension Wisconsin

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Financial Conflicts of Interest in Research, AW

Scope

This policy applies to staff, residents, students or other affiliates who propose, conduct or review research on behalf of Ascension Wisconsin. This policy applies to all sponsored projects, including government and non-government funded projects (such as industry or foundation sponsors), university funded projects, gift funded projects and unfunded projects, unless where noted below.

Purpose/Rationale

Ascension Wisconsin ensures the objectivity of human subject research, and to avoid actual or perceived conflicts of interest in such research by defining the process for identifying, reporting, evaluating and managing conflicts of interest. In addition, this document establishes standards to ensure that there is no reasonable expectation that the design, conduct or report of research funded under Public Health Service grants, cooperative agreements or PHS contracts will not be biased by financial conflict interest.

Definitions

Conflict of Interest: A conflict of interest is defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing or reporting research.

Conflict of Interest Official: Ascension Wisconsin has designated the Vice President of Corporate Responsibility to oversee system-wide implementation and management of the COI program.

Covered Individual: Any associate or medical staff member who has the authority to make independent decisions related to the design, conduct, or reporting of an Ascension Wisconsin research project, but not including individuals who perform only incidental or isolated tasks related to the project. Examples include a principal investigator, co-investigator, research nurse, associate, or administrator who participates in research, personnel whose resume is provided to a sponsor, personnel listed on study budgets or on an FDA 1572 Form, individuals who are likely to be authors on publications of research findings.

Covered Family Member: An individual who is the spouse, child, sibling, parent, grandparent,

great-grandparent,, grandchild, or great-grandchild, by blood, marriage, or adoption, of a Covered Individual. Please include other family members (such as cousins, nephews, aunts or uncles by blood, marriage, or adoption) if, in your judgment, your relationship is such that a transaction involving them may give rise to a potential conflict of interest for you.

Financial Conflict of Interest (FCOI). A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.

Financial Conflict of Interest in Research Committee (FCOI-R Committee): A person or persons appointed by the Institutional Official to provide an appropriate review of disclosed SFI(s), make a determination of the SFI relationship of the Covered Person and the research (reasonable belief of a FCOI) and devise an appropriate management plan for all instances in which a Conflict of Interest has been determined to exist. Ascension Wisconsin has designated the Director of Research Integrity and Protection and the Institutional review Board as FCOI-R committee members.

Financial Interest. Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities. A Covered Individual's professional responsibilities on behalf of Ascension Wisconsin, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and or service on panels such as the IRB or Data and Safety Monitoring Boards.

Significant Financial Interest (SFI). A financial interest consisting of one or more of the following interests of a Covered Individual or Covered Family Member that reasonably appears to be related to the Covered Individual's institutional responsibilities:

- Funding and Compensation Payments for services (other than for conducting the research) from a sponsor funding the investigator or close relation's research, or any organization or individual having an economic interest in the research that total \$5000 or more when aggregated over a 12-month period.

These payments may include:

- paid authorship
- payments for lectures and similar public appearances
- honoraria
- payments for service on a board, advisory committee or review panel, including scientific or technical appointments, except as stated below
- consulting arrangements

- Equity Interests

A **private equity interest** (e.g., stocks, stock options or other ownership interests not publicly traded) in a research sponsor, or in a company having an economic interest in the research, regardless of the value of such equity interest.

A **publicly traded equity interest** of \$5000 or more (except when the ownership interest is maintained in an investment vehicle, such as mutual funds and retirement accounts where the investigator, research personnel or close

relation does not directly control the investment decisions made) in a research sponsor or in a company having an economic interest in the research.

- Intellectual Property Rights and Interest Requires description of intellectual property rights held (e.g., patents, copyrights) and any agreements to share in royalties related to those rights including the amount and source of licensing or royalty income that a Covered Individual or covered family member received or had the right to receive in the 12 months preceding disclosure.
- Travel Sponsored travel or reimbursement of expenses associated with travel and provision of services that total \$5,000 or more over a 12-month period is also considered a conflict of interest to the extent the sponsorship/reimbursement is not reasonable. Unreasonable sponsored/reimbursed travel may include, for example, travel paid for or reimbursed for the investigator's family.
- Gifts The value and source of a single gift that exceeds \$5000 in value, or multiple gifts from a single entity that in aggregate exceed \$5000 in value, received in the 12 months preceding disclosure.
- Fiduciary Positions A fiduciary position held in a for-profit or nonprofit entity in the 12 months preceding disclosure, for which the individual received any form of remuneration for expenses.
- Other Any other financial interest that the Covered Individual believes conflicts with his or her ability to protect research subjects.
- Significant Financial Interest (SFI) does not include:
 - Salary, royalties, or other remuneration paid by Ascension to the Covered Individual if the Covered Individual is employed or otherwise appointed by Ascension Wisconsin, including intellectual property rights assigned to Ascension Wisconsin and agreements to share in royalties related to such rights
 - The following income from a Federal, state or local government agency, or an institution of higher education (20.U.S.C.1001(a))
 - Income from seminars, lectures or teaching engagements sponsored by any of the above.
 - Income from service on advisory committees or review panels for any of the above.
 - Travel reimbursed or sponsored by any of the above.
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles

Policy

N/A

Procedure

A. Responsibility of Covered Individuals

1. Training. All Covered Individuals must complete general research conflict of interest training *prior to* engaging in research at Ascension Wisconsin and at least every three years thereafter, as part of the required human subject training requirements. Researchers working on studies required to meet Public Health Service (PHS) regulations also complete Financial Conflict of Interest specific training. In addition, training may be required when there is a change in institutional policies or there is a case of noncompliance.
2. Disclosure of Significant Financial Interests Related to Institutional Responsibilities.
 - a. Individuals who must complete a Financial Disclosure include:
 - All Covered Individuals listed on a funded research project
 - All Covered Individuals listed on a project where they have a financial interest, regardless of funding
 - b. Individuals must complete the Financial Disclosure form:
 - before being involved in any funded research
 - annually not later than July 1;
 - before applying for PHS research funding; and
 - within 30 days of a new or updated Significant Financial Interest, when listed on PHS funded research.
3. All new or current Covered Individuals must submit required COI research disclosure, and the review and management process below must be complete, prior to involvement in any research-related activities.
4. All conflicts of interest in association with the human subjects research project under review must also be disclosed to the IRB as follows:
 - with the initial IRB submission application;
 - at the time of continuing review of the project on the Continuing Report Form; and
 - Within 10 days of becoming aware of any previously undisclosed significant financial interest, Investigators must submit an amendment, with appropriate changes.

B. Review Significant Financial Interests and Management of Financial Conflict

1. The Institution's Conflict of Interest Official and FCOI-R Committee work together in considering whether a Covered Individual has a financial conflict in regard to human research and in the development and implementation of a plan to manage the conflict of interest.
2. The process for review and management of financial disclosures is as follows:
 - a. Covered Individuals complete a Financial Disclosure Form.
 - b. Research Integrity and Protection (RI&P) staff review each Financial Disclosure Form, consulting with individuals and departments involved as necessary.
 - c. If a Significant Financial Interest (SFI) is disclosed, RI&P Staff will obtain

information necessary to assess whether or not the SFI may be related to research and if related, whether or not the SFI may be a Financial Conflict of Interest (FCOI).

- d. A SFI may be considered a FCOI related to research if the SFI:
 - could directly and significantly affect the design, conduct or reporting of the research.
 - could be affected by the research or is in an entity whose financial interest appears to be affected by the research.
3. If RI&P staff assessment identifies there may be a FCOI, staff collaborates with the Conflict of Interest Official and other appropriate individuals to further assess and determine if a management plan is necessary.
4. If a financial or management conflict of interest exists that would reasonably appear to compromise objectivity of the research, a management plan will be proposed for ensuring research objectivity. Possible strategies include, but are not limited to:
 - Public disclosure of the FCOI when presenting or publishing the research
 - Disclosure of FCOI directly to potential research subject
 - Monitoring of research by independent reviewer
 - Modification of the research plan
 - Change of personnel or personnel responsibilities, or restriction of personnel from participation in all or a portion of the research
 - Reduction or elimination of the financial interest
 - Severance of relationships that create financial conflicts
5. The IRB will review the proposed management plan and has authority to:
 - add provisions to the management plan if deemed necessary for the protection of human subjects;
 - table the research project pending review and approval of the Conflict of Interest Institutional Official;
 - decide whether the financial interest and management plan, are adequate to allow the human research to be approved.
6. The Conflict of Interest Institutional Official grants final approval for the management plan.
7. Each person conducting research under a management plan is responsible for fully and promptly complying with the plan. The management plan will specify who is responsible for monitoring ongoing compliance with the plan.

C. Review of conflicts of interest disclosed after IRB approval of research

When an existing Covered Individual discloses a new SFI the review process described above will be initiated within 60 days. If a FCOI exists, a management plan will be implemented. If necessary, additional interim measures may be implemented to manage the SFI between the date of disclosure and completion of the review.

D. Additional Considerations for Research that is PHS Supported

1. Report Financial Conflicts of Interest to PHS-Sponsoring Agency. Prior to Ascension Wisconsin expenditure of any PHS funds, a FCOI report will be sent to the relevant sponsoring agency. Any subsequent FCOI identified for an ongoing study will be reported to the relevant sponsoring agency within 60 days. Annual FCOI reports will be sent to update the sponsoring agency on the status of a previously reported FCOI and any changes to the management plan. FCOI reports will include information required by federal regulations (42 CFR 50.605(b)(3) & 94 CFR 94.5(b)(3)).
2. Public Accessibility. This policy is publically accessible on the Ascension Wisconsin Research Conflict of Interest web site. Information regarding current FCOIs related to PHS-funded research will also be publicly accessible. The Ascension Wisconsin Research Conflict of Interest website will include instructions for requesting such information. A written response will be provided to the requestor within five business days. (42 CFR 50.605(a)(5)).
3. FCOI Not Identified or Managed in a Timely Manner. Whenever a FCOI 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 Institution to constitute an FCOI; failure by the Institution to review or manage such an FCOI; or failure by the Investigator to comply with a FCOI management plan, the Institution shall, within 120 days of the Institution's 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. (42 CFR 50.605 (a)(3)).
4. Additional Information. Additional information regarding requirements for FCOI in PHS funded research can be found in 42 CFR Part 50, Subpart F - Promoting Objectivity in Research.

E. Records

1. All Financial Disclosure Forms, records of review and action under this policy, and management plans will be retained for the longer of at least three years after:
 - The date of creation;
 - The date of termination or completion of a research award contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or
 - The date of final resolution for any investigation, audit, or similar action involving the records.
 - This information is confidential and available only to pertinent Ascension Wisconsin personnel.

F. Enforcement

Failure of Covered Individuals or the institution to comply with this policy will be referred to the Conflict of Interest Official for review. The Conflict of Interest Official may consult with

the Research Institutional Official, Research Integrity and Protection Director/IRB Administrator, IRB and the department head/chair, or other appropriate committees or leaders.

References

Federal regulations require assurance there are no conflicts of interest in research projects that could affect human subject participation and protection.

- FDA: [21 CFR 54.1](#); [21 CFR 54.2](#); [21 CFR 54.4](#); [21 CFR 312.64\(d\)](#); [21 CFR 812.110\(d\)](#)
- HHS: [42 CFR 50, Subpart F](#); [45 CFR 94](#)

Ascension Wisconsin Policies (*available in PolicyStat*): Physician Transactions; Gifts to Physicians, Non-monetary Compensation and Incidental Medical Staff Benefits, AW

IRB SOP (*available in Mentor eIRB*): Ancillary Review Requirements

Attachments

No Attachments

Approval Signatures

Approver	Date
Douglas Reding: Chief Medical Officer, AW	1/30/2019
Jackie Blundon: Dir-Human Research Protect Prgm	1/29/2019

Applicability

Affinity Health System, Affinity Medical Group, Ascension All Saints Hospital, Ascension Calumet Hospital, Ascension Columbia St. Mary's Hospital Milwaukee, Ascension Columbia St. Mary's Hospital Ozaukee, Ascension Eagle River Hospital, Ascension Good Samaritan Hospital, Ascension Medical Group WI, Ascension NE Wisconsin-Mercy Campus, Ascension NE Wisconsin–St. Elizabeth Campus, Ascension Our Lady of Victory Hospital, Ascension SE Wisconsin Hospital-Franklin Campus, Ascension SE Wisconsin Hsptl–Elmbrk/St Jsph Cmpus, Ascension Sacred Heart Rehabilitation Hospital, Ascension Sacred Heart-St. Mary's Hospitals, Ascension St. Francis Hospital, Ascension St. Michael's Hospital, Ascension Wisconsin, Howard Young Medical Center, Midwest Orthopedic Specialty Hospital, Ministry Health Care, Ministry Medical Group, Ministry Spirit Medical Transportation, Wheaton Franciscan Healthcare-Southeast Wisconsin, Wheaton Franciscan Medical Group