

Ascension Wisconsin Research Integrity and Protection

Disclosure and Management of Financial Interests

Ascension Wisconsin encourages its researchers to participate in meaningful professional relationships with industrial and other private partners. These partnerships are established for mutually beneficial reasons and many times produce knowledge and technology that will help to meet societal needs. In addition research findings and ideas can often be used in development of products and applications that may directly benefit society, and which result in financial gain for the researcher and/or the institution.

In certain circumstances, relationships with outside interests can create, or appear to create, conflicts of interest. While having a conflict of interest does not imply wrongdoing or inappropriate activity, conflicts do require review and management to ensure that the conflict does not improperly influence, or appear to improperly influence, how research is proposed, conducted or reported. Transparency is the cornerstone of effective conflict oversight and management.

Financial interests must be managed in a way that ensures the objectivity of Ascension Wisconsin research, the safety of human subjects, and protects the reputations of researchers and Ascension Wisconsin itself. Many times, disclosure itself minimizes a perception of bias in the conduct of research. It is therefore critical that all conflicts be disclosed promptly and thoroughly, and in accordance with federal requirements and Ascension Wisconsin policy.

This guidance explains the process for identifying and disclosing conflicts and the methods by which they are managed by the institution.

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How does the process work and who does it apply to?

Ascension Wisconsin associates, staff and affiliates are responsible for disclosing financial relationships that might result in or have the appearance of a conflict, per institutional policy. Specific to research, Ascension Wisconsin Research Integrity and Protection Policy and Procedure: Financial Conflicts of Interest in Research, requires review of financial interests that meet the definition of “significant financial interests.” This policy is based on regulations implemented by the federal government in 1995 and revised in 2011 and applies to all covered individuals.

A **Covered Individual** is defined as:

Any Ascension Wisconsin associate or medical staff member who has the authority to make independent decisions related to the design, conduct, or reporting of a 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, or individuals who are likely to be authors on publications of research findings.

This policy specifies that all covered individuals must complete a Financial Disclosure form before beginning and funded research, at least annually and, within 30 days of discovering or acquiring any changes in the information provided or at the time of application, for PHS-funded research.

What do I need to know?

As a covered individual, you have a number of responsibilities regarding disclosure of financial interests.

- You should be aware of the relevant Ascension Wisconsin and federal policies regarding disclosure of financial interests. The Financial Conflicts of Interest in Research policy can be found in PolicyStat or on the Research Integrity and Protection website. Additional information can be obtained by contacting Jackie.Kirchen@ascension.org (Research) or Sarah.Kleaveland-Kupczak@ascension.org (System).
- You should know what is considered a Significant Financial Interest (SFI). A financial interest becomes significant if you or a covered family member have one or more of the following interests that reasonably appear to be related to your institutional (Ascension Wisconsin) responsibilities.

The following are examples of an SFI:

- Received income from a publicly-traded entity during the 12-months prior to disclosure that (in combination with the value of any equity interest in the entity) exceeds \$5,000.
- Hold ANY equity interest in a non-publicly traded entity, OR received more than \$5,000 income from a non-publicly traded entity during the 12-months prior to disclosure.
- Hold intellectual property rights and interests (such as patents, copyrights, royalty rights or licensing agreements).
- Were reimbursed for travel or had ANY of your travel costs sponsored by an entity.
- Received gifts from an entity that in aggregate, exceed \$250 in value during the 12-months prior to disclosure.
- Held a fiduciary position in a for-profit or nonprofit entity and received remuneration for expenses in the 12-months preceding disclosure.

SFI does NOT include:

- Any income, reimbursement, or sponsorship of travel by a government agency, higher education institution, academic teaching hospital, medical center, or research institute affiliated with a higher education institution.
- Income of travel paid by Ascension Wisconsin or covered by a sponsored award through Ascension Wisconsin.
- Income received from Ascension Wisconsin or intellectual property owned by Ascension Wisconsin.
- You must disclose financial interests related to your institutional responsibilities, which are professional activities that you undertake on behalf of Ascension Wisconsin. Institutional responsibilities include (but are not limited to) research, research consultation, teaching, professional practice, institutional committee membership, or service on panels such as the IRB.
- Some common examples of financial interests that do not need to be disclosed include: income from “passive” investments (e.g., retirement accounts, mutual funds, and large brokerage accounts), and salary, royalties, or other remuneration paid by Ascension Wisconsin.
- If the Conflict of Interest Official finds noncompliance (either failure to disclose as outlined in the policy, or failure to comply with the terms of the management plan) then you may be required to complete additional training; research funding can be withheld; and/or other appropriate enforcement mechanisms (including withholding wages or suspension/termination of employment) can be recommended to the proper Ascension Wisconsin administrator.
- The Conflict of Interest Official and IRB work together in evaluating disclosures to determine whether a SFI might adversely affect subjects and in the development and implementation of a conflict of interest management plan. The IRB has authority to add provisions to the management plan if deemed necessary for the protection of human subjects. The Conflict of Interest Institutional Official grants final approval for the management plan.

What do I need to do?

You need to complete a few simple steps in order to be compliant with Ascension Wisconsin policy and federal regulations.

- Covered individuals working on funded research projects must complete the Financial Disclosure form:
 - 1) before being involved in any funded research;
 - 2) annually not later than July 1;
 - 3) before applying for PHS research funding; and
 - 4) within 30 days of a new or updated Significant Financial Interest, when listed on PHS funded research.
- A new covered individual is required to submit a Financial Disclosure form prior to involvement in any research-related activities.
- When working on Public Health Service agency (e.g., NIH) funded research, disclosures are required within 30 days of new interests being acquired, or at the time of application for funding.
- Complete training at least every four years; COI training is included in the Ascension Wisconsin CITI training program.
- Provide information requested by the Ascension Wisconsin Conflict of Interest Official or IRB as they review your disclosure.
- If a Financial Conflict of Interest Management Plan is created, you may request changes to the plan. Once you have documented your agreement to the plan, any funding related to your SFIs will be released.
- If a management plan is in place, you are responsible for all of its terms, conditions and actions. You must respond to all requests for information and/or meetings regarding Ascension Wisconsin's responsibility to monitor compliance with the plan.
- Even if you have no financial interests that meet the definition of "significant financial interest", you still need to complete the required training and annual disclosure form.

How to submit a Financial Disclosure form?

The Significant Financial Interest (SFI) Disclosure Form must be completed and submitted to the Ascension Wisconsin Research Integrity and Protection Office, as described above.

The fCOI disclosures are completed online at: https://is.gd/AWRI_fCOI

An SFI Disclosure Form must be submitted by each Covered Individual.

Policies & Regulation

- Ascension Wisconsin Research Integrity and Protection Policy and Procedure: Financial Conflicts of Interest in Research (available in PolicyStat or on the RI&P website)
- Ascension Wisconsin Research Integrity and Protection SOP: Researcher Education
- NIH regulations (<https://grants.nih.gov/grants/policy/coi/index.htm>)

Other Conflict of Interest Training Modules

- NIH FCOI Tutorial (2011) (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>)