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Author Deb Block: HRPC PROGRAM MANAGER
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Institutional Review Board (IRB): Clinical Research Conflict of Interest (COI) Policy

PURPOSE:

To detail the criteria for research conflict of interest (COI) or the appearance of it to be a conflict of interest (COI) that threatens the integrity of the research process and to establish clear requirements for disclosure, management, resolution and reporting from Investigators, Co-investigators, Supporting Research Staff and IRB members. To inform how COI situations will be addressed and to discuss how the IRB will proceed with review when an investigator, research staff or IRB member has disclosed a significant financial interest, regarding their professional interest, proprietary interest, or potential self-gain that may occur as a result of federally funded research or private industry studies.

The opportunity for researchers to receive financial or other personal rewards from their endeavors is not intrinsically unacceptable, as long as it does not adversely affect the objectivity, integrity, or professional commitment of an investigation.

This policy and the requirement for disclosure helps assure the public's trust in the objectivity of research reviewed and approved by the Aspirus Wausau Hospital, Inc. Institutional Review Board (AWH - IRB).

AREAS AFFECTED/STAKEHOLDERS:

This policy is applicable to all participants of federally funded research or private industry studies

approved and monitored by the AWH-IRB and is not limited to groups registering patients. Participation includes having an active role in the development, conduct, and /or analysis of a research study and reporting of the study results.

DEFINITIONS:

Significant Financial Interest (SFI) (pertains to the investigator, their spouse and dependent children)

Anything of monetary value or potential monetary value including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options, or other ownership interests), reimbursed travel or sponsored travel related to institutional responsibilities, and intellectual property rights (e.g. patents, copyrights, licensing agreements, and royalties from such rights). The term does not include any of the following:

1. Equity interest in a publically traded entity that, when aggregated for an investigator and the investigator's immediate family, does not exceed \$5,000 in value in the twelve months preceding the disclosure as determined through reference to public prices or other reasonable measures of fair market value (Note: When the proposed project requires the use of human subjects and approval from the Institutional Review Board, these monetary thresholds do not apply. In such cases, the disclosure threshold is any amount above \$0.);
2. Salary, royalties, or other payments that, when aggregated for an investigator and the investigator's immediate family, are not expected to exceed \$5,000 during the next twelve-month period;
3. 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;
4. Salary or other remuneration received from Aspirus or its affiliates, including salary received from external sources through sponsored agreements administered by Aspirus;
5. Standard royalties received for published scholarly work or other professional writings;
6. Income from seminars, lectures, or teaching engagements and service on advisory or review panels for 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;
7. Income from services on advisory committees or review panels for governmental entities, public or non-profit entities;
8. Travel that is reimbursed or sponsored by 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 or reimbursed or sponsored by an entity where the combined monetary value is less than \$5,000 for all categories. (Note: this doesn't not need to be a legal affiliation);
9. Intellectual property rights assigned to Aspirus and agreements to share in royalties related to such rights.

Conflict of Interest (COI)

A conflict of interest is defined as a close personal or professional association with the submitting Investigator(s); direct participation in the research (e.g., protocol development, Principal or Sub-investigator); or any significant financial interest in the sponsoring company defined as (example, \$5,000 or 5% ownership) that could directly and significantly affect the design, conduct, or reporting of research.

Federal regulations provide that investigators must disclose potential conflicts of interest. Reviewers of these disclosures must determine if a significant financial interest could "directly and significantly affect the design, conduct, or reporting" of federally or privately funded activities.

Perceived Conflict of Interest (PCOI)

A significant Financial or Associational interest that could appear to directly or significantly affect the design, conduct or reporting of the Research.

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Members of the Immediate Family

Dependents

Spouse

All members of the household

Investigators

Includes all physicians or staff who are responsible for the overall design, conduct, and reporting of research data.

Research Personnel

Includes employees, at the level of research coordinators or assistants, who participate in the design, conduct and reporting of research.

IRB Members

Includes the IRB chairperson and all members who participate in the review and vote of research for the protection of human research subjects.

Researchers

Includes investigators and research personnel as defined in this policy.

Officials of Aspirus Wausau Hospital

Chief Operating Officer (COO)
Chairperson of the IRB
Chief Executive Officer (CEO)
Institutional Review Board (IRB) members

Professional Interest:

The researcher has played a substantial role in the prior development of a product or technology.

The researcher has a substantial on-going affiliation with an organization that has a role in the development or sale of a product or technology, including organizations holding patents to or licenses for the development or sale of research products. This would include instances in which the researcher serves as an officer, director, trustee, general partner, employee, or on a scientific advisory board or similar capacity for such organization, regardless of whether the researcher is currently being compensated for that position. Such organizations would also include those in which the researcher is negotiating for or has an arrangement concerning prospective employment or affiliation, or those from which the investigator receives or expects to receive compensation in the amount of \$5,000 or more annually for laboratory activities, honoraria, consultative services, or other activities. The significance of the conflict will depend, to some degree, on whether reimbursement for professional activities involves compensation limited to that normally required to support the scientific process, or is substantially larger, leading to actual or potential personal financial gain for the researcher or an immediate family member.

Proprietary Interest

The researcher has a financial interest in the research product being evaluated because the researcher or an immediate family member has a material interest in the product or technology that may result in financial gain (e.g., where the investigator may receive royalties or other compensation following the commercial sale of the product or technology). Such royalties may be in the form of personal compensation to the researcher may be used in support of the researcher's research.

The researcher as financial interest in the research product being evaluated because the researcher or an immediate family member has an equity interest or option of \$5,000 or more in a commercial enterprise, which will benefit from the sale of the product or technology.

Miscellaneous

There may be other instances in which an investigator or an immediate family member has an affiliation or relationship, such that objective impartiality could be questioned. In such instances, the investigator should disclose the nature and extent of the affiliation or relationship.

Use of Human Subjects in Research

Human Subject means a living individual about whom an investigator conducting research obtains data through interventions or interaction with the individual or obtains data through identifiable private information. If a potential conflict of interest exists and human subjects are involved in the research, the investigator will need to obtain approval of the Aspirus Wausau Hospital Institutional Review Board for the Protection of Human Subjects.

POLICY:

- I. In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.
- II. The Institutional Review Board evaluates Financial Interests involving Research Investigators and any other personnel involved in the design, conduct, analysis, reporting or review of research.
- III. Authority and Organization
 - a. The federal government presently regulates conflicts of interest pertaining to government grants by requiring that recipients of federal funding maintain a written policy. This policy is consistent with those regulations. Formulating this policy to manage, reduce, or eliminate potential or real conflicts of interest (or conflicts of commitment) among management personnel or investigators and requires that the Officials of Aspirus delineate the value structure to which investigators and research personnel must adhere.
- IV. Management of Investigator, Research Staff & IRB Members COI
 - a. All investigators, Research Staff & IRB Members must disclose in a timely, full and complete manner conflicts of interest to the Institutional Review Board (IRB). The IRB is also aware there may be additional financial conflicts of interest that are not captured by FDA financial disclosure requirements. Therefore, the IRB will also require investigators to disclose other financial relationships with companies sponsoring research, such as consulting agreements.
 - b. In addition, all must update their disclosure within 30 days of discovering or acquiring a new Disclosure Interest. (Note: The updated disclosure may occur as an investigator becomes involved in a new research project in which he/she was not previously and no prior conflict existed)
 - c. Investigators and research personnel must also disclose equity positions of member of their immediate family which could create a conflict or the perception of a conflict of interest between their Aspirus research obligations and their outside interests.
 - d. Each potential conflict will be reviewed on an individual basis. If outside relationships and organizational commitments are identified, the IO and/or the officials of AWH will work to manage, resolve or eliminate conflicts. The IRB may require that conflicts be disclosed in the informed consent, that the investigator

recluses him/herself as the principal investigator, or from the entire study.

V. Disclosure and Documentation of Financial Interest and COI

- a. No regular or alternate member may participate in the initial or continuing review of any research project in which the member has a conflict of interest, except to provide information as requested.
- b. It is the responsibility of each voting member or alternate member of the IRB to disclose any COI in a study submitted to IRB and reclude him or herself from deliberations and voting.
- c. Institutional investigators or research staff whose job status or compensation is affected by research that is reviewed by IRB must excuse themselves from any meeting at which such a protocol is reviewed.
- d. Disclosure of potential conflict of interest on the part of the researcher is required as follows:
 1. Prior to developing a protocol or serving in a leadership role in the conduct and /or analysis involving the research product for which there is a possible conflict of interest, an investigator must disclose the possible conflict of interest to the IRB. Conflicts that develop during the conduct and /or analysis of the trial of the research product or during the dissemination of results must also be disclosed within 30 days.
 2. At the beginning of any presentation of clinical trial results, either through oral presentation or publication, an investigator should disclose, if applicable, private sources of funding provided specifically for conduct of the study or reporting of results.
 3. Failure to disclose any conflict of interest could result in the loss of privilege to participate in AWH IRB approved research or pharmaceutical studies.
 4. Undisclosed potential conflicts will be brought to the attention of the Institutional official of the IRB and AWH officials. On an ad-hoc basis, the IO of the Aspirus Wausau Hospital IRB convenes a committee to review possible conflicts of interest to determine whether there is a sufficient basis to apply the sanction. Sanctions may be applied for non-compliance with the requirements or provisions of this policy such as removal from a particular project, letter of reprimand; special monitoring of future work, probation from future IRB approved studies.
 5. The determination will be reported to the IO/ and/or COO, who with the approval of the IRB chairperson will apply the sanction. If the IO and officials of Aspirus Wausau Hospital, Inc. perceive he/she has a "conflict of interest" reviewing the disclosed information, he/she shall disqualify himself/herself and request that the review is done by the other officials of Aspirus Wausau Hospital, Inc.
 6. At the request of the Institutional Official/, it is the task of the Aspirus Inc./AWH legal counsel to investigate novel or difficult situations in order to provide the officials of Aspirus Inc./AWH with the best impartial and

informed advice. A record of all proceedings will be kept.

7. The IO and/or officials of Aspirus are required to keep COI disclosures for at least three years in a secure place.
8. Under federal regulations, Aspirus Wausau Hospital must provide initial and ongoing FCOI reports to the Public Health Service (PHS) awarding component for all investigators on PHS-funded research projects:
 - a. Prior to the expenditure of funds;
 - b. During the period of award (within 60 days of identifying new FCOI); and
 - c. Annually, due at the same time as when the grantee submits the annual progress report, including a multi-year progress report, or at the time of extension
9. The FCOI report must include the following
 - a. Grant number
 - b. PD/PI or contact PD/PI
 - c. Name of Investigator with the FCOI
 - d. Name of the entity with which the investigator has an FCOI
 - e. Nature of FCOI
 - f. Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,99; amount between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or a statement that a value can't be readily determined;
 - g. A description of how the financial interest relates to PHS-funded research and the basis for the AWH determination that the financial interest conflicts with such research.
 - h. Key elements of the investigator's management plan, which include:
 - i. Role & principle duties of the conflicted investigator in the research project;
 - ii. Conditions of the management plan
 - iii. How the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the investigator's agreement to the management plan; and
 - v. How the management plan will be monitored to ensure investigator compliance
 - vi. Other information as needed.

VI. Education and Training in COI

- a. Investigators, research staff and IRB members are required to participate in

education and training activities related to financial conflict of interest issues including those required by their specific institution if not an Aspirus employee.

- b. Prior to engaging in any funded research, Investigators, Research Staff, and IRB members must complete the training program with regarding disclosures, and the Public Health Service (PHS), and Financial Conflict of Interest (FCOI) regulations. Training will be repeated every 4 years and within 30 days if newly engaging in any research activities.
- c. The officials of Aspirus will develop awareness of the Conflict of Interest Policy in several ways:
 1. Publication of the policy in the Aspirus electronic Policy and Procedure system and distribution to all researchers.
 2. Incorporation of an explanation of the policy in a letter to accompany the request for annual updated Conflict of Interest Statement
- d. This policy will be made available to the public on the Aspirus website per 42CFR Part50

VII. Public Accessibility: Under the federal regulations, Aspirus must make certain information concerning FCOIs held by PHS-funded investigators publically accessible prior to expenditure of funds. To satisfy this requirement, AWH IRB IO will provide a written response to any requestor within five working days of a request or may post on a publicly accessible website FCOIs held by PHS-funded investigators.

- a. The following information will be provided:
 - i. Investigator's name
 - ii. Investigator's title and role on the PHS research project
 - iii. Name of the entity in which the SFI is held; nature of SFI and
 - iv. Approximate dollar value

VIII. At the request of the individual subject to this policy, the IRB as a whole will evaluate the recommendations made by the chairperson of the IRB and IO to determine whether additional or different action is necessary to prevent, manage, reduce or eliminate conflicts of interest.

IX. Refer to Corporate Ethics Policy – Conflict of Interest and for information related to members of the Board of Directors, refer to Conflict of Interest – Board of Directors

REFERENCES:

- 45 CFR 50 Subpart F and 42 CFR 94
- HHS Final Rule on Conflicts of Interest
- Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigator's
- 21 CFR 46.103, 107
- 21 CFR 56.107
- 21 CFR 54 (as reference)
- FDA Information Sheets, FAQs, Section II, question 12

Attachments

- [A: Research Investigator/Key Personnel's Conflict of Interest Statement](#)
- [B: Conflict of Interest Statement](#)
- [C: Public Health Service \(PHS\) Agencies](#)

Approval Signatures

Step Description	Approver	Date
Approver- Board	Kayla Moser: SENIOR EXECUTIVE ASSISTANT	11/2022
Approver - IRB	Deb Block: HRPC PROGRAM MANAGER	06/2021

Applicability

Aspirus Divine Savior Hospital, Aspirus Eagle River Hospital, Aspirus Iron River Hospital, Aspirus Ironwood Hospital, Aspirus Keweenaw Hospital, Aspirus Langlade Hospital, Aspirus Medford Hospital, Aspirus Medical Group Inc., Aspirus Merrill Hospital, Aspirus Rhinelander Hospital, Aspirus Stanley Hospital, Aspirus Stevens Point Hospital, Aspirus Tomahawk Hospital, Aspirus Wausau Hospital, Aspirus Wisconsin Rapids Hospital, Howard Young Medical Center