

HEMATOLOGY-ONCOLOGY ASSOCIATES OF CNY

DEPARTMENT: Compliance CONTRIBUTING DEPT: Research	POLICY DESCRIPTION: Compliance Conflict of Interest Policy
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The mission of Hematology Oncology Associates of Central New York (HOA) is to provide the highest level of quality care in a healing environment for the mind, body and spirit of patients dealing with cancer and blood disorders. HOA is committed in the prevention, diagnosis, treatment, and cure of cancer and associated diseases through programs of excellence in research, education, outreach, and cost-effective patient care. HOA recognizes that while HOA employees have an opportunity to improve and advance cancer care and research through outside activities and collaborations with industry, such relationships may give rise to conflicts of interest or commitment with their HOA responsibilities. HOA has adopted this Conflict of Interest and Commitment Policy (Policy) to identify, review, and manage situations that may give rise to conflicts. HOA will permit, disclose, and manage outside interests and relationships in the context of preserving and protecting HOA's commitment to its mission and community.

This Policy holds that a conflict of interest (COI) exists when an individual's personal financial interests could directly and significantly impact their HOA responsibilities and a conflict of commitment exists when an individual's outside activities interfere with or detract from their HOA responsibilities.

HOA's Compliance Officer in coordination with the CEO and under the oversight of HOA's Board, is responsible for the administration of this Policy.

This Policy applies to financial interests or relationships and/or outside activities, whether paid or unpaid, that create or reasonably appear to create a conflict of interest or commitment in the context of an individual's HOA responsibilities, which include the design, conduct, reporting, review, or oversight of research, clinical care, business or purchasing decisions, and/or mentoring or supervision of trainees and students.

This policy applies to Covered Persons and their Immediate Family Members. Please refer to Roles and Responsibilities section for definitions.

External Interests, Relationships, and Activities

While employees can have external financial interests and relationships and engage in outside activities related to their HOA responsibilities, those interests and activities should not influence the employee's professional judgement or bias or interfere with their HOA responsibilities in any way.

External Financial Interests and Relationships. External personal financial interests or relationships (Financial Interests) that an HOA employee has with external entities related to their Institutional Responsibilities may introduce or appear to introduce a conflict of interest. Covered Persons must disclose Financial Interests to HOA

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Outside Activities or Interests. Regardless of whether a Financial Interest exists, outside activities and relationships (e.g., consulting, speaking, advising), even if not compensated and/or not providing personal financial benefit, could present conflict concerns. Likewise, outside interests (e.g., intellectual property), even if not generating revenue, could also present conflict concerns. Therefore, Outside Activities and Interests related to a Covered Person's Institutional Responsibilities, even when not compensated or non-monetary, require disclosure to HOA.

Review and Approval. Covered Persons who engage in outside activities, regardless of whether they receive compensation, must ensure that their Chief and the Compliance Officer is aware of and approves of the activity. Chiefs should consider whether the time requirements or nature of the activity could compromise the Covered Person's ability to fulfill their Institutional Responsibilities before sharing with the Compliance Officer.

Additionally, any independent outside activities with for-profit entities that involve written agreements for services between the outside entity and the Covered Person must first be submitted to the appropriate Chief and then to the Compliance Officer for review.

Executive Officer Roles. Covered Persons should not hold executive officer roles (e.g., Chief Executive Officer [CEO], Chief Clinical Officer [CCO], or Chief Financial Officer [CFO]) in external for-profit companies that do business with HOA or are related to HOA's mission while concurrently holding their HOA position. Subject to review and approval by the Compliance Officer, executive positions that Covered Persons are permitted to hold include but are not limited to:

- Early-stage start-up companies that are formed by that Covered Person in their area of expertise (Compliance may impose limits on the tenure of such executive roles);
- For-profit entities formed by a Covered Person for the sole purpose of providing personal consulting services;
- For-profit entities whose business is completely unrelated to the Covered Person's Institutional Responsibilities or HOA's mission (e.g., legacy family business).

Board of Directors Positions. All requests for a Covered Person to serve on a for-profit board of directors must be reviewed and approved by the Compliance Officer in advance. HOA recognizes that service on a board of directors can be beneficial, and there may be circumstances in which such service should be allowed. However, board of directors service by Covered Persons for a for-profit entity must be compatible with the interests of HOA's mission. HOA Senior Executive Officers are prohibited from for-profit board of directors service

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Consulting, Speaking, and Advisory Engagements. Involvement in consulting, speaking, and advisory activities (including scientific advisory boards) related to a Covered Person's Institutional Responsibilities, whether compensated or non-compensated, is permitted providing the activity does not present unmanageable conflict of interest or conflict of commitment concerns or involve any of the prohibited activities detailed below. The nature of the services that a Covered Person may perform on behalf of an external entity as a consultant or adviser are the provision of advice and the exchange of ideas.

Prohibited External Activities. Certain activities are prohibited by their nature and/or the terms and conditions that accompany such activities; they include the following:

- Participation in speakers' bureaus sponsored by pharmaceutical, biotechnology, medical device, or other for-profit entities is prohibited.
- Participation in speaking or educational activities where content is controlled by pharmaceutical, biotechnology, medical device, or other for-profit entities is prohibited (i.e., outside entities may not require specific content or materials or have any approval rights over content or materials).
- Endorsement of products or commercial ventures is prohibited. Employees approached to represent HOA on any activity that can be construed as an endorsement must gain approval by the Compliance Officer and CEO.
- Interactions with industry specifically prohibited in HOA's Policy for Interaction with Industry.

Conflict of Commitment

A conflict of commitment exists when an individual's Financial Interests or Outside Activities and Interests interfere with or detract from their Institutional Responsibilities

Commitment.

HOA employees' primary professional obligations are to HOA, and their primary professional commitments of time and intellectual energies are expected to be devoted to clinical care, research, education, and other activities supporting HOA's mission. While employees can engage in outside activities in the area of their HOA responsibilities, those activities should not impinge on the employee's ability to perform their professional duties and should not interfere with or detract from their HOA Responsibilities. Conflicts of commitment generally develop when an employee's outside activities impose excessive demands on their time and/or when an employee enters into a fiduciary relationship with an outside entity.

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Conflict of Interest Disclosure

Covered Persons are required to disclose, to HOA, Financial Interests and Outside Activities and Interests that relate to their Institutional Responsibilities. Covered Persons must disclose interests for themselves and any Immediate Family Members.

When to Disclose:

- Upon initial hire;
- Within 30 days of acquiring a new Significant Financial Interest;
- Within 30 days of newly becoming a Covered Person by virtue of position or role; and
- At least annually, even if attesting to no change from previous disclosures.

The formal annual disclosure process launches once each year and requires disclosure of Financial Interests and Outside Activities and Interests that exist at the time of disclosure and/or existed in the previous calendar year.

Compliance formally launches the annual disclosure process to all Covered Persons on an annual basis. Disclosure and Attestation Form will be distributed.

What to Disclose:

Financial Interests

Financial Interests include any of the following interests of a Covered Person or an Immediate Family Member related to the Covered Person's Institutional Responsibilities:

- Ownership/Equity Interests. Stock, stock options, and other ownership or equity interests in publicly traded and non-publicly traded entities, regardless of value. This excludes (i.e., do not disclose) ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the Covered Person does not control investment decisions.
- Compensation. Any remuneration for services, such consulting fees, advisory board compensation, honoraria, speaking fees, and paid authorship from for-profit and not-for-profit entities. This excludes (i.e., do not disclose) salary or other remuneration paid by/through HOA, or remuneration

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for seminars, lectures, or teaching engagements sponsored by, or from service on advisory committees or review panels for, U.S. federal, state, or local government agencies; U.S. institutions of higher education; U.S. academic teaching hospitals; U.S. medical centers; or U.S. research institutes affiliated with U.S. institutions of higher education.

- **Executive Officer Role.** A role at an outside entity that carries with it a fiduciary duty to the entity and/or holds with it the responsibility to make business decisions on behalf of the entity — such as Chief Executive Officer (CEO), Chief Scientific Officer (CSO), Chief Operating Officer (COO), or Chief Financial Officer (CFO) — and serving as a member on a board of directors. Disclosure of executive officer roles is required regardless of whether compensation is received.
- **Intellectual Property Rights and Interests (IP).** Intellectual property rights and interests relating to patents or copyrights upon receipt of income related to such rights and interests. Also included (and required to be disclosed) are intellectual property rights and interests relating to patents or copyrights — regardless of whether income has been received — in any case where the technology underlying the patent or copyright is the subject of a Covered Person’s research at HOA.
- **Sponsored/Reimbursed Travel.** Any direct reimbursements (if an entity reimbursed the Covered Person directly) or coverage of costs (if an entity handled the costs without paying or reimbursing the Covered Person) for travel-related expenses (e.g., transportation, lodging, out-of-pocket expenses) associated with outside activities (e.g., consulting, speaking). This excludes (i.e., do not disclose) travel paid for by/through HOA, or paid for by/through a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a U.S. research institute affiliated with a U.S. institution of higher education. Note: Disclosure of sponsored/reimbursed travel is required only for Covered Persons who are Investigators on research funded by the PHS (Public Health Service, which includes the National Institutes of Health, the National Cancer Institute, etc.)

Significant financial interests do not include:

- Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:
 - a. The financial interest does not exceed \$5000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - b. The financial interest does not represent more than a five percent ownership interest in any single entity;
- Salary, royalties, or other remuneration from HOACNY;
- Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are not expected to exceed \$5000 during the next 12 month period;

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- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or non-profit entities.

Outside Activities and Interests

Regardless of whether a Financial Interest exists, outside activities and relationships, even if not compensated and/or not providing personal financial benefit, could present conflict concerns and require disclosure. Outside Activities and Interests incorporate non-financial interests/relationships and include the following:

- Non-compensated provision of services for an outside entity (e.g., consulting, speaking, education, advisory board service, scientific advisory board service, and medico-legal work);
- Intellectual property rights and interests relating to patents or copyrights, regardless of whether income has been received, in any case where the technology underlying the patent or copyright is the subject of a Covered Person's research at HOA. This excludes (i.e., do not disclose) non-compensated services provided for/through HOA, or unpaid service performed for U.S. federal, state, or local government agencies; U.S. institutions of higher education; U.S. academic teaching hospitals; U.S. medical centers; or U.S. research institutes affiliated with U.S. institutions of higher education.

Where to Disclose: Disclosures are made by contacting the Compliance Officer.

Conflict Reviews

The Compliance Officer and the CEO have the authority to and are responsible for reviewing disclosed Financial Interests and Outside Activities and Interests to determine whether a conflict of interest or conflict of commitment exists in the context of the Covered Person's Institutional Responsibilities. If a disclosure involves research, the outcome of the review will be discussed with the Director of Research and the Director of Research Operations upon completion of review. This review shall be completed within sixty days of reporting per *42 CFR Part 50, Subpart F*

In reviewing disclosures, HOA considers the nature and extent of a Covered Person's Financial Interests and Outside Activities and Interests in relation to their responsibilities at HOA (e.g., clinical, research, education, training, business, purchasing), considering any actual or perceived bias in HOA decision-making that could arise from related interests. Examples of related interests that could present conflicts include but are not limited to the following when related to an outside entity with which a Covered Person has interests:

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- An entity is a vendor or potential vendor of HOA, and the Covered Person is in a position to influence business or purchasing.
- An entity sponsors, funds, or otherwise supports research at HOA in which the Covered Person is directly involved.
- An entity makes a product that is being evaluated in research at HOA in which the Covered Person is directly involved.
- An entity is licensing intellectual property with which the Covered Person has rights.
- Intellectual property relative to which the Covered Person has rights is being evaluated in research at HOA in which the Covered Person is directly involved.
- An entity makes a gift (e.g., unrestricted funds or loaning of equipment) to HOA under the control of or directly in support of the Covered Person's Institutional Responsibilities.
- An entity supports the Covered Person's participation in continuing education activities or professional conferences.
- A Covered Person has the authority to direct the efforts of staff, trainees, or others under their supervision at HOA and is conducting research involving a for-profit entity to which their efforts could be directed.
- Outside activities that interfere with or detract from a Covered Person's Institutional Responsibilities (e.g., insufficient attention to HOA responsibilities, such as HOA clinical care or research, mentoring of trainees, supervision of staff, administrative responsibilities).
- Excessive or unauthorized use of HOA time or resources for outside activities related to any entity.

HOA must identify and manage, reduce, or eliminate identified Conflicts of Interest or Conflicts of Commitment in the manner detailed in this Policy.

In the case of HOA Senior Executives, in addition to Compliance and CEO review, disclosures are also reviewed by the Board.

HOA will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final report or,

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where applicable, from other dates specified in [45 CFR 75.361](#) *Retention Requirements for Records*

Conflict Determinations and Conflict Management

Conflict Determinations

COI Determinations. The Compliance Officer and the CEO, have the authority and are responsible for reviewing disclosed Financial Interests and Outside Activities and Interests to determine whether a Conflict of Interest or Conflict of Commitment exists in the context of a Covered Person's Institutional Responsibilities (e.g., clinical, research, education, training, business, purchasing).

A Conflict of Interest exists when an individual's Financial Interests or Outside Activities and Interests could directly and significantly impact their Institutional Responsibilities, or an individual's Financial Interests or Outside Activities and Interests could be directly and significantly impacted by their Institutional Responsibilities.

If a Conflict of Interest determination is made, HOA must develop conflict of interest management strategies to manage, reduce, or eliminate the conflict. COI Management Plans are strategies designed to mitigate the potential for a Covered Person's related interests to impact or bias applicable Institutional Responsibilities.

Conflict of Commitment Determinations. A Conflict of Commitment exists when an individual's Financial Interests or Outside Activities and Interests interfere with or detract from their Institutional Responsibilities. Conflicts of commitments are handled in consultation with a Covered Person's immediate supervisor and department leadership, and generally result in reduction or elimination of one or more outside activities.

COI Determinations Related to Research. In the case of research, a Financial Conflict of Interest (FCOI) exists when an Investigator has Financial Interests, determined by HOA, that relate to and have the ability to directly or significantly impact or bias the design, conduct, or reporting of research, or create the perception thereof.

In the case of research-related conflicts of interest, HOA's determinations and management strategies must make primary the protection of objectivity in the design, conduct, and reporting of HOA research and the safety and welfare of human research subjects.

Human Subjects Research. When an Investigator has an FCOI related to human subject research, HOA's primary objective must be to ensure that the FCOI does not impinge on the rights and welfare of human subject research participants in the related research.

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An FCOI determination for any human subject research must be managed, reduced, or eliminated. Management strategies must be sufficient and appropriate to adequately protect the rights and welfare of human subject research participants in the related research.

Additionally, a Covered Person will not be permitted to serve as Principal Investigator (PI) or Co-Principal Investigator (co-PI) on an interventional human subject research protocol if the Covered Person has any of the following financial interests in any one entity sponsoring or supporting the research or otherwise related to the research as noted, absent compelling circumstances, which will be determined by the COIC, or its designee(s):

- Compensation for services exceeding \$25,000 in the prior 12-month period (e.g., consulting, advisory board, speaking, honoraria);
- Equity interests (e.g., stock, stock options) in a publicly traded entity exceeding \$25,000 in value;
- Any equity interests (e.g., stock options or warrants) in a non-publicly traded entity (e.g., start-up company);
- Any intellectual property interests to which the Covered Person has rights (e.g., inventor) when the intellectual property is being tested, evaluated, or further developed in the research;
- Holding an Executive Officer role.

The Compliance Officer and CEO may consider compelling circumstances that may allow a Covered Person to serve as a PI or Co-PI in the related interventional human subjects research in cases where the above-noted interests exist. The following factors will be considered when determining whether compelling circumstances exist:

- Specialized or unique experience and/or expertise of the conflicted Covered Person related to the research;
- Risk level to the human subjects, including whether the specialized experience and expertise of the conflicted Covered Person is such that the safety and welfare of the human subjects are best served if that individual participates in the research, despite the conflict;
- Research structure and study design, including aspects that could serve as potential controls (e.g., multisite, blinded, external data safety monitoring board);
- Correlation between the related interests and the aims of the research;
- Specific role and responsibilities of the conflicted Covered Person in the research.

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If compelling circumstances are demonstrated and a conflicted Covered Person is permitted to remain engaged in interventional human subject research as PI or co-PI under a Management Plan, the Compliance Officer may define limits on any external compensation that may be received during the course of a research study where applicable, and/or impose other limits or actions related to financial interests during the course of the research.

In any case that a conflicted Covered Person is permitted to be involved in any human subject research, in any role, the research will be conducted under robust management strategies to protect the rights and welfare of human research subjects as well as the objectivity and integrity of the research.

Conflict Management

COI Management Plans. If the Compliance Officer and CEO determines that a COI or FCOI exists that can be managed, a Management Plan will be developed and implemented.

Management Plans are strategies implemented by HOA to mitigate Conflicts of Interest and Financial Conflicts of Interest by setting parameters around the related interests or activities and the Covered Person's impacted Institutional Responsibilities. Management Plans must be implemented prior to the initiation of the activity for which the conflict exists, and Covered Persons subject to a Management Plan must acknowledge and agree in writing to the terms of the Management Plan.

Any or all of the following may be included as terms in a Management Plan; this is a non-exhaustive list and alternative or additional terms may be included at the recommendation of the Compliance Officer and CEO, to address a specific COI or FCOI:

- Disclosure of the related interest(s) to the following, as applicable
 - o Staff under a Covered Person's supervision or mentorship;
 - o Research project team members and collaborators;
 - o Patients.
- Disclosure of the related interest(s) in presentations, publications, manuscripts, and press releases;
- Recusal or limitation in role, such as
 - o Recusal from business or purchasing decisions;

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o Prohibition or limit on involvement in (or independent involvement) in research data collection or analysis, human research subject recruitment, enrollment and/or consent activities, performing certain research interventions or procedures, and/or involvement in adverse event evaluation and reporting;

o Prohibition on serving as the Principal Investigator or Co-Principal Investigator;

o Prohibition or limitations on serving as the treating physician on related single-patient-use treatment plans.

- Oversight of activity (e.g., research) by a neutral internal or external third party (e.g., an independent individual or oversight committee);
- Specific limitations on new or additional Financial Interests or activities with the related entity (e.g., prohibition or limit in external compensation from a related entity during the course of related research).

Oversight Committee. Senior Leaders will determine whether the risk of bias in research data resulting from FCOIs should be mitigated by periodic reviews by subcommittees established by Senior Leadership, composed of representative management and staff.

Appeals. If a Covered Person disagrees with a decision regarding a conflict determination, the individual may appeal the determination to Compliance. All appeals must be made in writing within 15 calendar days of the individual's receipt of the conflict determination.

External and Public Disclosures

External Disclosures. Regardless of the disclosure requirements outlined in this Policy or additional disclosure strategies instituted by HOA in Management Plans, each Covered Person is responsible for being transparent with respect to their Financial Interests and Outside Activities and Interests in all matters, internal and external to HOA, related to their Institutional Responsibilities. This includes but is not limited to ensuring to disclose completely and accurately in accordance with the disclosure requirements of journals, conference or meeting conveyers, professional associations, government agencies, and continuing medical education providers. If there is any doubt as to whether or not a Covered Person's Financial Interests and/or Outside Activities and Interests should be disclosed in a particular instance because of a relevance standard, Covered Persons should err on the side of disclosure.

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Conflict of Interest Training

All Covered Persons are required to sign off on a conflict of interest statement and review the Conflict of Interest Policy yearly.

As per regulations (42 CFR 604(b)), all individuals responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement, are required to undergo initial FCOI training and are required to be trained at least every 4 years. Training can be accomplished by reviewing **Public Health Law: 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity of Research, 42 CFR Part 50, Subpart F**, and by completing the online tutorial made available by the **NIH office of Extramural Research** at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> .

Monitoring and Auditing

Compliance will routinely monitor and audit compliance with the conditions of this Policy and other COI-related policies. Compliance will conduct regular and scheduled audits using both risk-based and random approaches in its efforts to:

- Verify the accuracy of disclosures of Covered Persons' Financial Interests and Outside Activities and Interests to HOA in compliance with this Policy;
- Assess Covered Persons' compliance with Management Plans, including the review of relevant documentation (e.g., publications, presentations, research consent forms, notifications to laboratory members and research staff and collaborators), and interviews with persons subject to the Management Plan and representative colleagues, research staff, and/or lab team members);
- Verify the completeness and accuracy of Covered Persons' disclosures in publications and presentations.

Compliance will utilize external and/or publicly available information to compare a Covered Person's disclosures to HOA in the interest of verifying the completeness and accuracy of disclosures.

Compliance will work with Covered Persons and the HOA community in its monitoring and compliance activities in an effort to educate and support in a proactive manner.

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Roles and Responsibilities

A. Covered Persons. Covered Persons (as defined in this Policy) are those individuals subject to the training, disclosure, and other requirements outlined in this Policy, and are required to comply with all applicable requirements outlined in the Policy.

B. Compliance. Compliance is responsible for the administration and oversight of HOA’s COI program, including the intake and review of individual, institutional, and research-related disclosures; the management of identified conflicts; and the maintenance of COI-related training and policies. Compliance supports senior leaders and compliance subcommittees,. Compliance is responsible for supporting and providing guidance to Covered Persons in COI-related matters.

C. Compliance is charged with:

- Identifying, managing, and minimizing actual and potential conflicts of interest and commitment;
 - Proposing guidelines and recommendations to improve COI policy and procedures and decision-making about relationships with industry;
 - Promoting the understanding of HOA’s conflict policies within the HOA community.
- Subcommittees will provide independent oversight of specific HOA activities in accordance with certain Management Plans instituted in accordance with this Policy.

Compliance and Enforcement Covered Persons who fail to comply with this Policy — including failure to disclose or submission of an erroneous, misleading, or incomplete disclosure as required by this Policy, or failure to comply with a Management Plan, may be subject to disciplinary action, up to and including termination of employment.

Reporting compliance concerns by using the traditional avenues of raising compliance questions or concerns. This includes reporting to Compliance and/or to HOA’s confidential and anonymous compliance hotline.