Hennepin Healthcare Research Institute (HHRI)
Conflict of Interest (COI) Policy

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Purpose

The purpose of this policy is to enable and facilitate the research and education missions of the HHRI (institution) by assuring their objectivity and independence from competing financial interests. The stakeholders considered in this policy are the public, our patients and research subjects, the scientific community, the agencies who fund our activities, and our faculty, staff and trainees.

An equally compelling purpose is to maintain compliance with all applicable federal and state laws and regulations related to conflicts of interests and with the policies and requirements of the regulatory agencies which oversee our activities, including but not limited to the United States Public Health Service (USPHS) and Federal Drug Administration (FDA) (42CFR50 and 21CFR54.2).

Conflict of interest. The specific goal of this policy is to address financial conflicts of interest (FCOI). For this policy, financial conflict of interest refers to competing financial interests or incentives. Specifically, it is a situation in which a covered individual (see Definitions, page 12) has a relationship with an external entity that may create financial incentives that may compete with his/her academic or professional interests, obligations, or institutional responsibilities. A conflict of interest does not imply wrong-doing or improper relationships, but does require disclosure, evaluation and sometimes mitigation. In accordance with applicable federal regulation noted above, this policy is intended to protect the design, conduct and reporting of research conducted by HHRI (including work funded under PHS/NIH grants or cooperative agreements) from bias resulting from FCOIs of covered individuals.

Appearance of conflict of interest. Some situations fall outside the definition of COI but may raise questions in the mind of a reasonable observer which are best addressed in order to assure that the situation has been considered (see Appendix I, HCMC Code of Conduct for additional information). The COI committee reserves the right to include such issues of appearance in its deliberations and approaches to managing the financial relationships of investigators.

Policy

This policy is applicable to:

- all persons appointed, employed by or compensated by the HHRI;
- all persons engaged in the conduct of research activities under the auspices of the HHRI who are in a position to influence the design, conduct or reporting of research or other scholarly activity; This includes "Investigators" *as* defined by 42CFR50.603 which means the project director or principal Investigator of any PHS proposed or funded research and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- all persons who have direct influence over purchasing decisions or contracts made on behalf of HHRI;
- all holders of HHRI Research and Education accounts;
- all members of HHRI's Board of Directors, members of HHRI's Conflict of Interest Committee, and members of regulatory committees including the IRB, IACUC and the IBC;
- For purposes of reporting financial interests under this policy, covered individuals also include a spouse or domestic partner, and dependent children.

Covered individuals at HHRI must comply with HHRI's Policy on Conflict of Interest and all applicable federal and state laws related to conflict of interest and shall not engage in activities that compromise their professional judgment or compete with the fulfillment of their obligations to HHRI.

Relationships constituting a potential COI must be reported to the HHRI COI Committee **prior to their initiation**. Changes in existing relationships must also be reported before the changes take place. The purpose of this requirement is to avoid COI when possible, or to make all parties aware of the proposed relationship and any possible mitigation requirements.

Covered individuals may not participate in relationships with business entities that:

- result in payments to the covered individual which are intended to influence how the covered individual conducts institutional activities;

- constitute ghost writing (having one's name and institutional affiliation associated with a publication or other article where the covered individual has no substantial input into the publication or article). Authorship should be restricted to those individuals who meet the following criteria:
    - made a significant contribution to the conceptualization and/or design or conduct of the project;
    - participated in the analysis and interpretation of the data, or other substantial scholarly work;
    - participated in drafting, reviewing and/or revising the work; and
    - approved the final version of publication.

- involve the covered individual's endorsement of a product or service developed and/or sold by a particular business. This applies to both written and oral endorsements when the product or service relates to the covered individual's institution- related expertise and/or institutional activities, whether or not the individual uses his or her institutional title in making the endorsement;

- involve acceptance of gifts of any amount or value from industry doing business or seeking to do business with the HHRI. Examples include but are not limited to pens, pads, other promotional items, cash, food and drink, entertainment such as tickets to events, golf and other sports outings, medical or research equipment, devices or other products or services or discounts on same, use of company vehicles or vacation facilities, hotels, transportation and other travel expenses, stocks, equity, and other such financial offerings, group gifts, textbooks, biological samples, software, computer hardware and accessories, electronic devices such as cell phones, pagers, music and video players, PDA's consulting, financial and other services and office and research supplies. It is recognized that there are circumstances when individuals have no control over receipt of gifts and may inadvertently violate this policy, such as attendance at Industry Sponsored professional meetings where a mandatory lunch is provided and there is no practical alternative.

Covered individuals must report all external relationships annually. The definitions of significance provided throughout this policy provide the regulatory bases for disclosure, reporting, and management of financial conflicts of interest that HHRI must adhere to and enforce as a recipient of Public Health Service (PHS) funding. However, the institution's disclosure threshold is more restrictive since it doesn't have minimum thresholds for disclosure – all external financial interests must be disclosed. Annual reporting is intended to be inclusive of all financial relationships and not confined to relationships relevant to specific ongoing or proposed projects. In addition, when proposing or conducting a specific research project, investigators must identify any financial interests *related to that specific research project (via the Compliance Committee Standardized Reporting Form)* to ensure that no arrangement has been entered into whereby the value of an ownership interest will be affected by the outcome of the research. This includes any financial interests in the sponsor, product or service being tested, or in any direct competitor of the sponsor, product or service being tested. This reporting will be done via the Compliance Committee Standardized Reporting Form found in application materials for the IRB, IACUC, and IBC and in the Grant and Contract Application for External Support. New financial interests and substantial changes in a financial or business interest (see Definitions, page 12) must be reported within 30 days of acquisition or discovery. HHRI will take action to review reported interests, make a determination of whether the interest is related to PHS/NIH-funded research (i.e., the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research) and represents an FCOI (i.e., could directly and significantly affect the design, conduct or reporting of PHS/NIH-funded research), and report FCOIs to the National Institutes of Health (NIH) within 60 days of disclosure if the interest is related to an NIH supported project.

In order to make conflict information available to colleagues, collaborators, trainees and research subjects, certain information regarding the conflict situation shall be made available via a publicly accessible web site or written response to any requestor within five business days of a request. This shall include, at a minimum, the following: the Investigator’s name; the investigator’s title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

This information shall be made available prior to the expenditure of any federal funds and will be updated at least annually or within 60 days of disclosure of a newly identified financial conflict of interest. The information will remain available for at least three years from the date that the information was most recently updated.

Where a conflict of interest is identified, the covered individual may be required to follow an approved conflict mitigation plan that provides mechanisms to manage, reduce or eliminate the conflict.

When covered individuals participate in sponsored research involving sub-grantees, contractors or collaborators outside the institution, HHRI will take reasonable steps to ensure that these outside associates comply with appropriate conflict of interest reporting, disclosure, review and management plan requirements.

Appropriate disciplinary action may be taken by the HHRI against covered individuals who violate this policy.

Whenever a Financial Conflict of Interest 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 a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest 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 NIH supported research project to determine whether any NIH supported research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

HHRI will document the retrospective review which will include at least the following key elements:

- Sponsor type, name, and project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review.

If bias is found related to an NIH supported project, the HHRI will notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report will be submitted as a "Revised FCOI Report." The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the HHRI's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, HHRI will submit FCOI reports annually as prescribed by applicable regulation.

Other disciplinary actions, in addition to retraining and/or any legal penalty(ies), may include oral admonishment, written reprimand, or reassignment, demotion, suspension, or termination. Investigators may also be prohibited from further grant or contract proposal submission or participation in research activities. As outlined above, policy violations that involve Pubic Health Service (PHS) supported projects shall be reported to a responsible grantee official and shall specify the type of administrative action taken including requesting disclosure addendums to previously published papers if necessary. Policy violations that involve other sponsored funds shall be reported to the sponsor as directed by the terms and conditions of the award.

All financial conflict of interest records shall be maintained for at least three years from the date a final expenditure report is submitted for the project or from other dates as specified in the award document or contract.

This includes all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (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, as follows:

- Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361, as applicable, which includes the following exceptions:
    -If any litigation, claim, or audit is started before the expiration of the 3-year period, the records will be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.
    -When HHRI is notified in writing by an HHS awarding agency, cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period.
    -When records are transferred to or maintained by the HHS awarding agency or a pass-through entity, the 3-year retention requirement is not applicable.

Training

All persons engaged in research under the auspices of the HHRI are required to complete training in COI prior to engaging in any research that involves human or animal research subjects and at least every four years thereafter (or in the case of NIH supported research by the issue date of the Notice of Award or within thirty days of being new to the institution). In addition to the required COI training noted above, any covered person determined to be non-compliant with the institutional COI Policy or determinations of the COI Committee will be required to repeat COI training immediately (no later than 30 days from notice of non-compliance). Additional information about institutional requirements and instructions for completing COI training can be found in the HHRI Sponsored Programs Administration Guidance and Procedures manual and the HHRI's Human Research Protections Program Investigator 501 Manual.

Reporting and Evaluating a Covered Individual's Relationships with External Entities

On an annual basis, all covered individuals must report all current external relationships and/or interests, those that occurred in the previous year, and those that can reasonably be expected in the next 12 months.

For example, the covered individual must report:

- financial and / or business relationships and interests and those of immediate family members which relate to or compete with the covered individual's institutional responsibilities including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, whether publicly traded or not, stock options, or other ownership interests);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights); and
- other arrangements under which financial benefits have been received (e.g., gifts, loans or services).
- Reimbursed or sponsored travel

Reporting will consist of listing the entity with which the relationship exists, or is anticipated in the next 12 months, and the dollar amount. **There is no minimum dollar threshold for reporting; all covered financial relationships and/or interests must be reported**.

The dollar amount may be reported as a range:

$0 to $4,999
$5,000 – $9,999
$10,000 – $19,999
$20,000 – $99,999 by increments of $20k
$100,000 – $250,000 by increments of $50,000
> $250,000

If needed to adequately evaluate or manage a conflict, the Conflict of Interest Committee may ask for more detailed information, including information going back as far as three years.

Other relationships and/or interests that fall outside of the specific reporting guidelines described herein, such as those of a non-business or non-financial nature (e.g., close friend, immediate or extended family member – see Definitions, page 12), that may appear to create a conflict of interest or that might influence the way a covered individual allocates institutional resources, must also be reported and may require consideration by the COI Committee.

The COI Committee reserves the right to make further inquiries into the nature of the covered individual's report should additional information be required.

The following financial interests are exempt from these reporting requirements:

- Salary, royalties or other remuneration from the covered individual's institution;
- Income from activities sponsored by U.S. governmental agencies or entities;
- Income for serving as special reviewer or on a review panel for U.S. governmental agencies or entities, or a United States Institution of higher education, a United States academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.
- Travel expenses paid by an entity located within the U.S. as part of a research project (i.e. if reimbursement is received from a foreign institution of higher education for work on a research project at the foreign institution, those payments are not exempt from the HHRI's reporting requirements);
- Equity interest in mutual funds, pension or other institutional investment funds whose investment practices are beyond the control of the individual.

For the avoidance of doubt, covered individuals must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country).

Covered individuals who are temporarily on a leave of absence, sabbatical or reduced appointment must also report these external relationships. The COI Committee will take into consideration the covered individual's status when reviewing reported information.

The Conflict of Interest Committee

The HHRI will maintain a Conflict of Interest Committee to deal with issues concerning this policy. This committee shall be chaired by the Hennepin Healthcare Chief Compliance Officer, and shall have the following principle functions:

- to assist in the implementation of this policy;

- to review disclosures of conflict of interest;
- to develop and approve any plans to manage, reduce or eliminate conflicts;
- to recommend to the HHRI Executive Committee any disciplinary action to be taken under this policy; disciplinary actions to be approved by the HHRI Board of Directors;
- upon the request of affected personnel, to review a decision by an administration official that a disclosed situation constitutes an actual conflict of interest;
- to periodically review this policy, including the set financial thresholds.

This Committee shall be comprised of the following organizational officers: the HHRI President, Vice President, Secretary/Treasurer, and Vice President of Operations/COO of the Institute, Hennepin Healthcare's Chief of Clinical Operations, the Chair (or Vice Chair) of the Institutional Review Board (IRB), the Chair of the Institutional Animal Care and Use Committee (IACUC) and a community member to be appointed by the President of the Institute. Should the Committee require additional expertise, including legal counsel, ad hoc members may be asked to participate as voting or non-voting members.

Under certain circumstances, the Chair of the Conflict of Interest Committee may determine that an executive-level review of a conflict of interest disclosure involving at least two members of the full Conflict of Interest Committee (i.e. the Chair and/or the Vice President of Operations/COO or another member) is appropriate. This executive review may be used when one or more of the following criteria are met: the financial disclosure is < $5,000; the disclosure involves an anticipated conflict; the proposed project involves minimal risk to humans; the proposed project requires minimal involvement of the conflicted person; the disclosed conflict involves minimal risk to study integrity (study design, generation of data, analysis of data, or presentation of results). Details of such conflicts and any necessary mitigation addressed via executive-level review will be documented, and a summary of any actions taken made available to the full Conflict of Interest Committee.

Determining Whether a Conflict of Interest Requires Management or Elimination

The COI Committee's criteria for evaluating disclosures will include but not be limited to 1) risks to research subjects; 2) risks to the scientific integrity of study design, data collection, analysis and reporting; and 3) expected benefits of activity. An FCOI exists when the Institution reasonably determines that a covered individual's significant financial interest is related to a project (i.e., the significant financial interest could be affected by the research or is the significant financial interest in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the research.

Whenever a covered individual's activities, relationships, or interests are under review by the COI Committee, the covered individual will have an opportunity to provide information to the committee either in person or by submission of a written statement and/or the provision of other written information.

Managing Conflict of Interest

When the COI Committee determines that a conflict of interest exists, the committee will evaluate the conflict situation considering factors including: the nature of the activity; the nature of the financial interest; and the potential for the conflict to influence the activity in question.

Where research is involved, the committee will evaluate the risk the research poses to research subjects and the degree to which the outcome of the research may be affected by any financial interest.

The committee will determine whether the conflict situation 1) can be effectively managed through development and implementation of a conflict mitigation plan; 2) can be managed by changing the covered individual's terms of participation in an institutional activity; or 3) needs to be eliminated. Possible recommendations include approval of the activity as proposed if it is concluded that the potential for conflict is so remote or inconsequential that there is minimal probability for biasing the objectivity of the activity. Other possible recommendations are to require periodic peer review of the activity (oversight) by individuals independent of the employee, outside monitors for the activity, divestiture of the financial or business interest, modification of the plan of work, or assignment of different employees without a financial or business interest to control the activity, or limiting the individual's role and responsibilities in the project. To the extent possible and reasonable under the circumstances, and in light of the importance of the activity, the review committees and responsible administrators will work with employees to develop means for the activity to take place while protecting the integrity and the reputation of the employees and the HHRI.

Examples of conditions or restrictions that might be imposed to manage a covered individual's Financial Conflict of Interest include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc;
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

In any case in which there has been a determination that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by federal regulation, the Institution shall require the covered individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

If the COI Committee determines that a conflict mitigation plan can effectively manage the conflict situation, the committee will work with the covered individual to develop a conflict mitigation plan that will:

- describe the circumstances that give rise to the conflict of interest under institutional policy;
- set forth specific mandatory mitigation mechanisms;
- set forth a plan for monitoring and follow-up;
- address any disclosures required;

- require a written confirmation of consent from the covered individual to all requirements of the management plan;
- comply with the requirements of any applicable sponsor regulations.

When personnel participate in sponsored research involving sub-grantees, contractors or collaborators outside the HHRI, reasonable steps will be taken to ensure that investigators working for these outside entities comply with appropriate conflict of interest disclosure, review, and management requirements. These steps may include requiring the investigators to comply with HHRI's policy or obtaining written assurances from the outside entity that it complies with applicable federal regulations or sponsor policies on conflict of interest.

The outcome of the COI Committee deliberations and any mitigation plan(s) will be shared with the covered individual's supervisor/department head.

Public Disclosure of FCOIs

Covered individuals must disclose their conflicts of interest when submitting research reports, reviews, opinion pieces, and letters to the editor or other types of communications for publication. Such disclosures must be made to the audience for educational presentations, and to the responsible reporter or editor for news articles, interviews or press releases. Journal articles and research reports may follow individual journal or funding agency reporting formats.

Disclosure to other research personnel working on a study may also be required by the COI Committee as a part of additional public disclosure requirements for conflict mitigation.

Institutional Conflict of Interest

Institutions such as the HHRI may have financial conflicts of interest independent of those of specific individuals. Examples include funds accruing to the institution rather than to an individual or specific lab or department, investments, interests derived from licensing, technology transfer or patents, or support of institutional educational conferences. Institutional COI raises issues similar to those raised by individual COI, and should be subject to the same scrutiny, disclosure and management procedures.

Educational activities – When an educational activity is conducted by HHRI as the sole organizer, these activities may not be supported by funds from vendors doing business with HHRI. When educational activities are co-sponsored by HHRI and other institutions (e.g. Hennepin Health System) which do not have a similar prohibition, the criteria of the Accreditation Council for Continuing Medical Education (ACCME) for COI in continuing medical education must be adhered to by all organizations involved (see APPENDIX II).

Gifts – The HHRI may not accept gifts or contributions from vendors with which it conducts business or when the donor has an interest in the research being supported, such as the purchasing of common equipment, on an institutional level. This policy would not apply to vendors providing goods or services to individual faculty or staff or laboratories (in which HHRI as an institution does not influence the choice of vendor other than by guaranteeing competitive bidding when required) but would apply to vendors in the case that the HHRI makes purchasing decisions as an institution, e.g., common equipment, biohazard disposal services.

An Institutional Conflict Committee consisting of the HHRI Conflict of Interest Committee plus a non-HHS/HHRI employed HHRI Board member will review all institutional conflicts of interest. The HHRI COO will report all institutional financial conflicts of any amount to the committee for review.

Definitions

Business	Any corporation, partnership, sole proprietorship, firm, franchise, association or organization, holding company, joint stock company, receivership, business or real estate trust or any non-governmental legal entity organized for profit, non- profit, or charitable purposes.
Business Interest	Holding any executive position in a business or membership on a governing board of directors of a business whether or not such activities are compensated. The term "governing board of directors" refers to the board of a business including boards or trustees, scientific advisory boards, medical advisory boards, and boards of professional societies.
Covered Individual	1. all persons appointed, employed by or compensated by the HHRI; 2. all persons engaged in the conduct of research activities under the auspices of the HHRI who are in a position to influence the design, conduct or reporting of research or other scholarly activity; 3. all persons who have direct influence over purchasing decisions or contracts made on behalf of HHRI; 4. all holders of HHRI Research and Education accounts; 5. all members of HHRI's Board of Directors, members of HHRI's Conflict of Interest Committee, and members of regulatory committees including the IRB, IACUC and the IBC; and 6. for purposes of reporting financial interests under this policy, covered individuals also include a spouse or domestic partner, dependent children, and any other family member whom the covered individual knows may personally benefit from actions taken by the covered individual.
Financial Conflict of Interest	Refers to competing interests or incentives that could reasonably appear to affect or be affected by the research being conducted at HHRI. Specifically, it is a situation in which a Covered Individual has external financial incentives that may compete with his/her academic or professional interests, obligations, or institutional responsibilities.
Immediate Family Member	The covered individual's spouse or domestic partner and dependent children.
Institutional Responsibilities	Research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Data Safety and Monitoring Boards
Significant Financial Interest	A financial interest consisting of one or more of the following interests of the covered individual (and those of the covered individual's spouse and dependent children) that reasonably appears to be related to the Covered individual's institutional responsibilities: (i) With regard to any publicly traded entity, a *significant financial interest* exists

	if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Covered individual (or the Covered individual's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. (iv) Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Covered individual and not reimbursed to the Covered individual so that the exact monetary value may not be readily available), related to their institutional responsibilities.

Selected Bibliography

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APPENDIX I

HCMC Code of Conduct (also available online at: https://mcd-ucm-contrb.hcmc.co.hennepin.mn.us/cs/groups/public/documents/webcontent/hcmc_p_016371.pdf

Values and Beliefs
We believe every person has dignity and worth; therefore we treat our patients, their families and each other with integrity, compassion, courtesy, and respect.

We believe affordable health care should be available to everyone; therefore we work efficiently, minimize waste, and take personal responsibility for the stewardship of our health care resources.

We believe we are at our best when we work as a team, therefore we work in collaboration to provide safe, effective, timely and equitable care, always keeping the patient's needs our highest priority.

We believe our future will be secured by investing in the potential of our staff, therefore we support learning that leads to personal growth, opportunities for advancement, and improvement in our organization.

Mission
We are committed to provide the best possible care to every patient we serve today; to search for new ways to improve the care we will provide tomorrow; to educate health care providers for the future; and to ensure access to healthcare for all.

Vision
We are committed to being the best place to receive care; the best place to give care; and the best place to work and learn.

Purpose of our Code of Conduct
This Code of Conduct sets forth general expectations that apply to all who are employed by, or interact with, Hennepin County Medical Center. We all model this behavior and use it to help resolve conflict and guide our decisions. It does not describe specific policies or practices that may be included in the Employee Handbook and approved policies, but instead sets guiding principles for conduct.

Integrity
We demonstrate ethics and trustworthiness by communicating openly and honestly. We establish trusting relationships by demonstrating consistency over time, meeting deadlines and following through on commitments. We don't misrepresent information or ourselves. When interacting with each other and with our patients, we are transparent and admit our mistakes. We take responsibility for meeting job requirements and performance expectations including following policies and procedures. We accept responsibility for our actions and contribute to a positive work environment.

Respect

We always treat each other and our patients respectfully. We do not tolerate bullying, intimidation or hurtful gossip. Recognizing that teamwork and collaboration flourish in the presence of trusting relationships, we cultivate a culture in which respectful behavior is the foundation.

Diversity
We are inclusive. We are respectful in our interactions with others by setting aside personal biases. We understand the impact of our behavior on others. We take responsibility for adapting our actions to accommodate the diverse backgrounds of others. We honor each other and ourselves by appreciating our differences including beliefs that may conflict with our own.

Business Ethics
We model integrity in our business dealings and by complying with regulatory requirements. We base our medical and business decisions on the best interests of our patients. We comply with laws because it is the right thing to do. We avoid any appearance of impropriety and do not tolerate deceit or intimidation in our business relationships. We do not accept kickbacks, bribes or anything of value for referrals or other business arrangements. We do not try to get an unfair advantage by making unlawful deals with competitors or business partners.

Illegal Behavior
We do not tolerate illegal activity. Criminal conduct such as illegal drug use, stealing or violence will be met with swift and decisive action. We do not tolerate sexual harassment or harassment based on race, color, creed, religion, age, gender, national origin, sexual orientation, disability, marital status, public assistance status or any other protected class status.

Conflicts of interest
We hold the trust of our community, patients and employees, to use our positions to further the mission of Hennepin County Medical Center. To maintain that trust, we do not participate in making or influencing decisions when our personal circumstances may cloud our judgment. We disclose any situation in which financial or other personal considerations may compromise or appear to compromise our judgment, delivery of patient care or ability to do our job. This may extend to relationships we or our family members have with vendors or others with whom we do business. We never try to use our relationship with Hennepin County Medical Center for our personal gain. We do not accept gifts from vendors or others we do business with because the acceptance of gifts may influence our judgment. We guard our public and charitable status by following laws and policy related to political activity and gifts.

Confidentiality
We recognize the importance of protecting patient confidentiality and honor that legal and ethical obligation with intense zeal. Our information privacy and security efforts are supported by everyone. We are also loyal to Hennepin County Medical Center and protect its employee and business information while complying with data privacy laws.

Record keeping
Documentation of patient care and business matters is part of our job. We recognize record keeping as a critical role and keep accurate and timely records for patient care and business activity. Our business records are kept in accordance with prevailing business standards including financial reports that are audited annually. Our bills and invoices for services provided are supported by proper documentation. We establish internal controls and audits to verify the accuracy of information. We release records when appropriate and in accordance with policy and law.

Patient and Employee Safety
We place the highest priority on the safety and well-being of our patients and employees. Everyone is engaged in and responsible for patient safety efforts. As models of high standards for health and safety, we act in accordance with our own policies and the law to ensure a safe campus and patient experience. Our campus is clean and smoking is not allowed in any area. We do not tolerate anyone consuming alcohol, using unauthorized controlled substances or illegal drugs or acting in a violent manner while on our campus. Everyone at Hennepin County Medical Center knows their role in the event of a disaster or emergency.

Reporting Concerns
Everyone is required to report possible violations of this Code of Conduct or any illegal or unethical conduct. We do not tolerate retaliation and expect all reports to be made in good faith. All reports are taken seriously and investigated as appropriate. We encourage reporting to managers/supervisors but recognize some may prefer to report anonymously. HCMC maintains a Compliance Hotline 1-877-874-8416 and Compliance Reporting Website where employees may anonymously report compliance issues at any time. The Compliance Reporting Website can be accessed at: hcmc.alertline.com. You may also contact the following to report concerns:
Minnesota Attorney Generals' Office Phone: 651-296-3353 or 1-800-657-3787
Website: www.ag.state.mn.us
United States Office of Inspector General
Phone: 1-800-447-8477
Email: HHSTips@oig.hhs.gov

APPENDIX II

The ACCME Standards for Commercial Support SM
Standards to Ensure Independence in Continuing Medical Education (CME) Activities

STANDARD 1. Independence
1.1 A CME provider must ensure that the following decisions were made free of the control of a Commercial Interest. (See www.accme.org for a definition of a 'Commercial Interest' and some exemptions.)
(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.
1.2 A Commercial Interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2. Resolution of Personal Conflicts of Interest
2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any Commercial Interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to the learners.

STANDARD 3. Appropriate Use of Commercial Support
3.1 The provider must take all decisions regarding the disposition and disbursement of commercial support.
3.2 A provider cannot be required by a Commercial Interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a Commercial Interest as conditions of contributing funds or services.
3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.
Written agreement documenting terms of support
3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.
3.5 The written agreement must specify the Commercial Interest that is the source of commercial support.
3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.
Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.
3.8 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.
3.9 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.
3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bone fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- ***For print****: advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face <u>and</u> are not paid for by the commercial supporters of the CME activity.*
- ***For computer based****: advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content.*
- ***For audio and video recording****: advertisements and promotional materials will not be included within the CME. There will be no "commercial breaks."*
- ***For live, face-to-face CME****: advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.*

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.
4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules

and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a Commercial Interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a Commercial Interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If one CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the Commercial Interest(s);
- The nature of the relationship the person has with each Commercial Interest.

6.2 For an individual with no relevant financial relationship(s), the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.

6.4 ‘Disclosure’ must never indluce the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.