## 2.2A Conflicts of Interest

# **POLICY**

# **Preamble**

The Hastings Center acknowledges that Employees, and their families and Dependents, have the right to acquire, retain and accumulate personal financial assets and to establish relationships with outside entities. However, each Employee also has the responsibility to manage his or her relationships and financial affairs in a manner that does not interfere with, or improperly influence the performance of, his or her duties and responsibilities as an Employee of the Hastings Center.

The Hastings Center will exercise oversight and care in eliminating or managing Conflicts of Interest that do or may arise because of an Employee's Outside Activities and Relationships relevant to his or her role as a Hastings Center employee or because of an Employee's Financial Interests in Hastings Center activities. The Hastings Center will also exercise oversight and care in eliminating or managing Conflicts of Interest that result from Investigators holding Significant Financial Interests related to externally funded projects. The Hastings Center will comply with all reporting responsibilities imposed by state or federal laws with respect to Financial Interests that have been disclosed while protecting the personal privacy of Employees, except where disclosure is required by applicable law or this policy. If a federal agency funder requires notification of the existence of a Financial Conflict of Interest, of the existence of a Financial Conflict of Interest that is being managed, or of the existence of a Financial Conflict of Interest that cannot or should not be managed that is associated with a project proposed to that agency by the Hastings Center or that is already awarded, the Hastings Center will comply with this reporting requirement, but will maintain the specific fiscal details of the subject Financial Conflict of Interest as confidential information to the extent allowed by laws or regulations.

# Disclosure

- 1. As part of fulfilling his or her responsibilities, and to assist the Hastings Center in avoiding or managing Conflicts of Interest, each Employee must disclose:
  - a. All Outside Activities and Relationships that are relevant to an Employee's role as a Hastings Center Employee, whether compensated or not and including but not limited to activities and relationships that result in outside income, royalties and equity holdings, and
  - b. Any known Financial Interests that he, she or a Dependent has in any of the following:
    - i. Any Hastings Center purchase or procurement of goods or services (whether or not pursuant to a formal contract) or in any investment or loan made by the Hastings Center.
    - ii. Any agreement relating to Hastings Center technology or other intellectual property that is or will be subject to negotiations between the Hastings Center and any third person or entity.
  - Such disclosures must be made annually and whenever a new Outside Activity or Relationship, or Financial Interest, arises.
- 2. All Investigators must disclose:
  - Any Significant Financial Interests he or she has in any project that is being proposed to an
    external funder (whether the investigator is or is not the proposed PI of that project, and
    whether the Hastings Center will be the primary institution or involved under a subcontract or
    other arrangement),

- b. Any Significant Financial Interests he or she has in an externally funded project to which it is being proposed that the Investigator be added, and
- c. Any Significant Financial Interest that the Investigator proposes to acquire during the course of an externally funded project.
- d. Such disclosures must be made when a project is proposed to a funder, and thereafter annually and whenever a new Outside Activity or Relationship, or Financial Interest, arises.
- 3. An Employee who fails to make disclosures required by this policy, or who otherwise violates any of the provisions in this policy, may be subject to discipline for misconduct and/or insubordination under Hastings Center policies, practices and procedures, up to and including dismissal.
- 4. An Employee or Investigator who disagrees with a decision regarding the existence of a Conflict of Interest, Significant Financial Conflict of Interest or the necessary elements of a conflict management plan may submit a written appeal in accordance with Section III of these Procedures.
- 5. Situations involving Outside Activities or Relationships, or Financial Interests also may involve issues addressed in other policies in the Hastings Center's Policies and Procedures Manual, such as policies about Conflicts of Commitment or Research Misconduct, among others. Employees must comply with these and all other applicable policies and regulations.

# Reason for this Policy

This policy confirms the Hastings Center's commitment to the basic values of openness, academic and scholarly integrity, integrity of business policy and procedure, independence, and safe and ethical research, as well as to its tradition and expectation that Employees will conduct their relationships with the Hastings Center with candor and integrity. To ensure the integrity of all institutional activities, including review and conduct of research (including research involving human subjects), and the associated fiscal, contractual and procurement transactions, regardless of the source of support, the Hastings Center has elected to apply the same Conflicts of Interest policy to all its activities.

In addition to supporting these basic values, this policy is also designed to:

- 1. Satisfy federal regulations requiring the Hastings Center to establish and implement policies concerning Significant Financial Interests held by:
  - a) Personnel engaged in research funded by certain federal agencies (e.g., Public Health Services (Title 42 CFR Part 50, Subpart F and 45 CFR Part 94) and the National Science Foundation (Award and Administration Guide)), and
  - b) Certain personnel involved in research involving human subjects funded by the Department of Health and Human Services.

Such policies allow the Hastings Center to maintain eligibility for federal funding from the Public Health Service and the National Science Foundation and, in the case of research involving human subjects, funding from any federal agency that is a signatory to the Common Rule (Title 45 CFR 46) when researchers have Significant Financial Interests in research involving human subjects.

2. Protect researchers and other Employees from misplaced charges of Conflicts of Interest by providing mechanisms for disclosure and prior objective review and approval of Outside Activities and Relationships, Financial Interests, and Significant Financial Interests.

## Individuals affected by this policy

This policy affects all Hastings Center Employees and any individual who meets the definition of an Investigator.

# Who should know about this policy

Members of the Hastings Center's Board of Directors

**Hastings Center President** 

Hastings Center CFO/COO

All other Hastings Center Employees

Hastings Center consultants and subcontractors on externally funded projects

# **Exclusions**

There are no exclusions from this policy.

# Website address for this policy

http://www.thehastingscenter.org/policy/coi

# **Contacts**

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# **Definitions**

# **Board of Directors**

The Board of Directors of The Hastings Center.

### **Conflicts Committee**

The Hastings Center's Conflicts Committee will be appointed by the President and include the following membership:

- The COI Officer (ex officio)
- The President
- 1 Hastings Employee (appointed by the President)
- 1 member of the Board of Directors (appointed by the Chair of the Board of Directors)

Conflicts Committee members will be appointed to a maximum of three-year terms.

### **COI Officer**

The Conflict of Interest Officer, who will be the COO or his or her designee.

### **Dependents**

An Employee's spouse and unemancipated child(ren), including stepchildren and adoptees, under the age of 18.

# **Director of Development**

Director of Development at the Hastings Center

# **Employee**

Each employee of the Hastings Center, wherever located and whether full-time or part-time.

#### **EOARFIS**

An Employee Outside Activities, Relationships and Financial Interests Statement

# **Equity Interest**

Any ownership interest in a company or business, including, but not limited to, stocks, stock options or warrants, membership or partnership interests or rights, and similar interests.

## **Conflicts of Interest**

Situations where an Employee's Outside Activities or Relationships or an Employee's Financial Interest compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence the Hastings Center's business, research or decisions in ways that could lead directly or indirectly to financial or other gain for the Employee or the Employee's Dependents or could give an improper advantage to others to the detriment of the Hastings Center.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator's Financial Interest (including Significant Financial Interest) compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if such Significant Financial Interest could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data and development of findings and recommendations, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods. These conflicts also pose a risk to the trustworthiness of the research.

Conflicts of Interest also include the use of Hastings Center facilities, personnel, equipment, IT Resources, confidential information or other resources for purposes that could lead directly or indirectly to financial gain for the Employee and/or his or her Dependents.

### **Financial Interest**

Any interest that will, could or is intended to lead to a profit or an ascertainable increase in the income or net worth of an Employee and/or a Dependent. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including, but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

#### **ISFIS**

An Investigator Significant Financial Interest Statement.

### **Institutional Responsibilities**

An Employee or Investigator's professional responsibilities on behalf of the Hastings Center, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service.

## **Intellectual Property Rights**

Any interest in intellectual property, including, but not limited to, patents, copyrights, licenses, royalties from such rights, agreements to share royalties and similar interests.

## **Investigator**

A project director, a principal investigator of a research project and any other person, regardless of title

or position, who has responsibility for the design, conduct or reporting of research or project results at or involving the Hastings Center, including Employees, subgrantees, contractors, subcontractors, collaborators and consultants. In general, any individual specifically named in a proposal and any individual whose resume or curriculum vitae is appended to a proposal is an Investigator for the purposes of this policy.

# **Outside Activities and Relationships**

An Employee's activities and relationships that are relevant to his or her role as a Hastings Center Employee, including but not limited to activities and relationships that result in outside professional income, royalties and equity holdings. Outside Activities and Relationships may be compensated or uncompensated, and may involve the Employee or his or her spouse or dependent children.

### President

The President of the Hastings Center.

# **Significant Financial Interest**

A Financial Interest held by an Investigator and/or an Investigator's Dependent that reasonably appears to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds \$5,000;
- Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000;
- Any Equity Interest in a non-publicly traded company or business, regardless of value; and
- Any Intellectual Property Rights, regardless of value, in relation to which the Investigator has received any income.
- Any reimbursed or sponsored travel unless that travel was reimbursed or sponsored by a
  Federal, state, or local government agency, or institution of higher education, an academic
  teaching hospital, a medical center, or a research institute that is affiliated with an institution of
  higher education.

Significant Financial Interest does not include:

- An Employee's salary or royalties received from the Hastings Center,
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local
  government agency or an institution of higher education, an academic teaching hospital, a
  medical center, or a research institute that is affiliated with an institution of higher education, or
- Income from service on panels for a federal, state or local government agency or institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

## **Spouse**

An Employee's husband or wife.

# Responsibilities

# **COI Officer**

Design and implement disclosure, review and Conflict of Interest management procedures to satisfy Hastings Center policy as well as federal and other funder requirements and regulations to ensure objectivity in research and research regulatory compliance.

Receive disclosures of Employee Outside Activities or Relationships and Employee Financial Interests in Hastings Center procurement or contractual transactions, or any Hastings Center investment, loan, or any agreement relating to Hastings Center technology or other intellectual property. Receive disclosures of Investigator's Significant Financial Interests.

Review these disclosures to identify real or potential Conflicts of Interest arising from these Outside Activities or Relationships, Financial Interests, or Significant Financial Interests. Transfer these disclosures to the Conflicts Committee for further review.

Work with the Conflicts Committee to develop appropriate conflict management and mitigation plans for Conflicts of Interest arising from disclosed Outside Activities or Relationships, or Financial Interests, or Significant Financial Interests. Where plans call for elimination of the activity, relationship or interest, oversee this elimination.

Satisfy all federal regulatory requirements relevant to the subject matter of this policy and applicable to Hastings Center including, but not limited to, requirements related to (i) reporting, (ii) record keeping, (iii) causing required clauses to be included in agreements with subgrantees, subrecipients, contractors, subcontractors and collaborators in federally funded research projects, (iv) making any required public disclosures of Significant Financial Interests and (v) training Investigators.

Report annually to the Conflicts Committee on the status of formal plans implemented to manage or reduce any Employee or Investigator Conflicts of Interest, and on compliance with applicable state requirements, federal regulations and Hastings Center policies.

Serve as an ex officio member of the Conflicts Committee.

# **Conflicts Committee**

Review disclosures of Employee Outside Activities or Relationships and Employee Financial Interests in which the COI Officer has identified real or potential Conflicts of Interest. Review all disclosures of Investigator's Significant Financial Interests where a Significant Financial Interest is disclosed. In all these cases, determine whether a Conflict of Interest or a Financial Conflict of Interest exists.

Develop appropriate conflict management and mitigation plans for Conflicts of Interest or Financial Conflict of Interest arising from disclosed Outside Activities or Relationships, or Financial Interests, or Significant Financial Interests. Plans may call for elimination of the activity, relationship, or interest.

Review and comment on Hastings Center procedures (including design of statements and disclosure forms for gathering information) proposed by the COI Officer for the disclosure of Outside Activities or Relationships or Financial Interests by Employees and for disclosure of Significant Financial Interests by Investigators.

Advise the COI Officer as requested.

Receive and evaluate appeals from Employees and Investigators regarding management of real or potential Conflicts of Interest arising from disclosed Outside Activities or Relationships, Financial Interests, and Significant Financial Interests.

### **Employee**

Disclose, as required by this policy, any and all Outside Activities or Relationships, and Financial Interests that he, she or a Dependent has in Hastings Center activities or transactions. Such disclosures must be made annually, or if new, as far in advance as possible of the beginning of the Outside Activity or Relationship, or of the contract, purchase, procurement, investment or loan to be made by or to the Hastings Center, or in any agreements relating to Hastings Center technology or other intellectual property.

Comply with the requirements of any management or mitigation plan approved by the Conflicts Committee.

# Investigator

Disclose, as required by this policy, any and all Significant Financial Interests that he, she or a Dependent has and update such disclosures within thirty days when necessary to maintain accuracy due to changed circumstances.

Comply with the requirements of any management or mitigation plan approved by the Conflicts Committee.

### **President**

Appoint the Conflicts Committee.

# **PROCEDURES**

- I. Disclosures of Outside Activities and Relationships Relevant to Employee's Hastings Center Role, and Financial Interests in Hastings Center Purchases or Procurement of Goods or Services, Contracts, Investments and/or Loans to be Made by or to the Hastings Center, or Agreements Relating to Hastings Center Technology or Other Intellectual Property.
  - A. Prior to the beginning of each fiscal year, the COI Officer will remind all Employees of the obligation to disclose:
    - Any and all Outside Activities and Relationships currently held by the Employee and/or their dependents that are relevant to the Employee's role as a Hastings Center Employee, including but not limited to activities and relationships that result in outside professional income, royalties and equity holdings. Activities and relationships may be compensated or uncompensated.
    - Any and all Financial Interests currently held by the Employee and/or their Dependents in Hastings Center purchases or procurement of goods or services, contracts, investments and/or loans, or agreements relating to Hastings Center technology or other intellectual property.
  - B. The reminder notice will also:
    - 1. Describe the necessity of updating disclosures or submitting new disclosures during the year if new or altered Outside Activities and Relationships or Financial Interests develop or are pending.
    - Remind Employees that a disclosure related to Outside Activities and Relationships relevant to the Employee's role as a Hastings Center Employee, or of Financial Interests in any Hastings Center purchase or procurement of goods

or services, or in any investment or loan made by the Hastings Center, or in any agreements relating to Hastings Center technology or other intellectual property, must be made as far in advance of the beginning of the activity or relationship or the purchase, procurement, investment, loan or agreement as possible to provide sufficient time for the COI Officer to review the disclosure and for possible review by the Conflicts Committee.

- C. The COI Officer will develop a process whereby each new Employee completes a disclosure statement disclosing his or her existing and known Outside Activities and Relationships and Financial Interests in accordance with this policy or certifies that he or she has no known Outside Activities or Relationships, or Financial Interests to disclose at that time.
- D. Employees who, or whose Dependents, have a known Outside Activity or Relationship relevant to the Employee's role at the Hastings Center or a known Financial Interest in any Hastings Center purchase or procurement of goods or services, or in any investment, loan or agreements relating to Hastings Center technology or other intellectual property must disclose the Outside Activity or Relationship or the Financial Interest on the Employee Outside Activities, Relationships, and Financial Interests Statement (EOARFIS) in advance of beginning the activity or acquiring the relationship or, in the case of Financial Interests, in advance of the purchase, procurement or agreement. Completed EOARFISs are to be submitted to the COI Officer.
- E. The COI Officer will review each EOARFIS to first determine if the disclosure is necessary under this policy. Disclosures found to be unnecessary will be returned to the Employee. If necessary, the disclosure will be reviewed by the COI Officer for completeness and clarity. When judged to be complete, the COI Officer will determine if the disclosure is new or a renewal of a previous disclosure.
- F. New disclosures will be reviewed by the COI Officer to determine whether there is an actual or potential Conflict of Interest. Each identified actual or potential Conflict of Interest will be forwarded to the Conflicts Committee for their review and to determine whether it can and should be managed by the Hastings Center.
  - 1. If the Conflicts Committee determines that the Conflict of Interest is unmanageable or inappropriate to manage, steps will be taken to eliminate the Conflict of Interest, which may include asking the Employee to eliminate the Outside Activity or Relationship, or blocking execution of the Hastings Center's transaction that is the subject of the Financial Interest, or changing the Employee's role and/or responsibilities. If, after the Conflict of Interest has been eliminated, it is still possible and desirable to complete the Hastings Center transaction, the COI Officer will notify the President.
  - 2. If the Conflicts Committee determines that the Conflict of Interest is manageable, a written conflict management plan will be developed with the input of the Employee. Once a management plan has been established and accepted, the Conflicts Committee will forward all necessary documentation to the COI Officer, who will notify the Employee, the President and the Chair of the Board of Directors.

- G. Renewal disclosures will be reviewed by the COI Officer to determine if elements of the disclosure or associated Hastings Center transaction have changed such that the original disposition of the disclosure should be reconsidered.
  - 1. If a significant change is identified, the disclosed Outside Activity or Relationship, or the Financial Interest, will be re-reviewed as a new disclosure under Section I.E of these Procedures.
- H. The COI Officer will keep written records of all disclosures and decisions relating to

# II. Disclosures of Investigator Significant Financial Interest in an Externally Funded Project

- A. Before an Investigator agrees to participate in a project that is being proposal to an external funder (whether the investigator is the PI or not of that project, and whether the Hastings Center would be the primary institution or involved under a subcontract or other arrangement), the Investigator must complete an Investigator Significant Financial Interest Statement (ISFIS) reporting whether he or she and/or his or her Dependent(s) has a Significant Financial Interest relating to that proposed project, and submit the ISFIS to the COI Officer.
- B. Before an Investigator can be added to an ongoing externally funded project (whether the investigator will be the PI or not of that project, and whether the Hastings Center is the primary institution or involved under a subcontract or other arrangement), the proposed new Investigator must complete a ISFIS reporting whether he or she and/or his or her Dependent(s) has a Significant Financial Interest relating to that project, and submit the ISFIS to the COI Officer.
- C. If an Investigator who is already participating in a project that is externally funded (whether the investigator is the PI or not of that project, and whether the Hastings Center would be the primary institution or involved under a subcontract or other arrangement) plans to acquire a new Significant Financial Interest relating to that project, that Investigator must complete a ISFIS reporting this planned new Significant Financial Interest, and submit the ISFIS to the COI Officer.
- D. Upon receipt of ISFISs from Investigators, the COI Officer will review each ISFIS for completeness. An incomplete ISFIS will be returned to the Investigator who submitted it and the deficiency noted. If the ISFIS is complete, the COI Officer will do one of the following:
  - 1. If the Investigator indicated they do not have a Significant Financial Interest, the proposal or project record will be updated to indicate that an ISFIS disclosing no Significant Financial Interests has been submitted by the Investigator.
  - If the Investigator indicated they do have a Significant Financial Interest, the
    proposal or project record will be updated to indicate that an ISFIS has been
    submitted disclosing a Significant Financial Interest and the ISFIS will be
    forwarded to the Conflicts Committee.
- E. When the Conflicts Committee receives an ISFIS indicating the existence of a Significant Financial Interest related to a proposed or ongoing externally funded project, the Conflicts Committee will determine whether the disclosed Significant Financial Interest will create a Financial Conflict of Interest if the proposed project is initiated or if the

Investigator is added to the project, or if the Investigator acquires the new Significant Financial Interest. If no Financial Conflict of Interest is identified, the proposal or project record will be updated to reflect the disclosure and the basis for the Conflicts Committee's determination of no Financial Conflict of Interest. The ISFIS and disclosure form will be stored in a secure location. If a Financial Conflict of Interest is identified, it will be considered to determine whether it can and should be managed by the Hastings Center.

- If the Financial Conflict of Interest is judged to be unmanageable or inappropriate to manage, steps will be taken to eliminate the Financial Conflict of Interest, which may include withdrawing the project proposal that is the subject of the Financial Interest, removing the Investigator from the project, changing the Investigator's role and/or responsibilities in the proposed project, having the Investigator eliminate the Significant Financial Interest. If, after the Financial Conflict of Interest has been eliminated, it is still possible and desirable to conduct the project or proposed project, the COI Officer will update the proposal or project record to document the actions taken to eliminate the Financial Conflict of Interest, and file the ISFIS and disclosure and all other relevant documentation in a secure location.
- 2. If the Financial Conflict of Interest is judged to be manageable, a written conflict management plan will be developed by the Conflict of Interest Committee with the Investigator. The management plan may include, but is not limited to, public disclosure of financial conflicts of interest, disclosure directly to any human subjects participating in the research, appointment of an independent monitor, modification of the research plan, change of personnel or responsibilities, reduction of the financial interest. Once a management plan has been established and accepted, the COI Officer will update the proposal or project record to reflect the disclosure, the Conflicts Committee's decision, and the details of the management plan, and file the ISFIS and disclosure and all other relevant documentation in a secure location. When the project is initiated, the management plan will be implemented.
- F. Disclosures updating previous disclosures will be reviewed by the COI Officer to determine if elements of the disclosure or the determination of a Financial Conflict of Interest have changed such that the original disclosure should be reconsidered.
  - If there is no significant change, the COI Officer will record the disclosure in the COI Officer's database, document the conclusion that nothing has changed and any previous actions taken, and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated. When the project is initiated, any necessary management plans previously developed will be implemented.
  - 2. If a significant change is identified, the disclosure will be re-reviewed as a new disclosure under these Section II.D of these Procedures.
- G. Proposed or ongoing projects funded by external funders that require management plans for recognized Financial Conflicts of Interest will be implemented and the COI Officer will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the project.

- H. For proposed or ongoing projects funded by external funders that require management plans for recognized Financial Conflicts of Interest, the COI Officer will execute whatever notifications of the funder and/or public disclosure are required based on the funder's terms and conditions for award.
- I. Annually, the COI Officer will provide a written notice to all Investigators who have filed ISFISs, whether they initially indicated a Significant Financial Interest or not, of the need to update their ISFIS.
- J. If the COI Officer learns that an Investigator's Significant Financial Interest was not disclosed in a timely way or, for whatever reason, was not previously disclosed or reviewed, the COI Officer shall, within thirty days, forward documentation relating to the Significant Financial Interest to the Conflicts Committee. The Conflicts Committee will, within thirty days:
  - 1. Determine whether the Significant Financial Interest will or does create a Financial Conflict of Interest; and
  - 2. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
  - 3. In addition, 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 Conflicts Committee to constitute a Financial Conflict of Interest, or failure by the Hastings Center 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 COI Officer shall, within 120 days of the Conflicts Committee's determination of noncompliance, complete a retrospective review of the Investigator's activities and the externally-funded research project to determine whether any research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The COI Officer will document the retrospective review in accordance with federal regulations and report to the Conflicts Committee.
  - 4. If bias is found, the COI Officer will notify the funder promptly and submit a mitigation report to the funder. 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 Hastings Center's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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).
- K. Prior to expenditure of any funds under an externally funded project, the Hastings Center shall ensure public accessibility of information concerning any Significant Financial Interest disclosed to the Hastings Center by an Investigator who is the principal investigator or is otherwise senior or key personnel for the project if the Conflicts Committee has determined that the Significant Financial Interest creates or will create a Financial Conflict of Interest. The information made publicly available shall include the Investigator's name, title and role in 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 Significant Financial 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.
- L. Prior to the expenditure of any funds under an externally funded project, the COI Officer shall provide to the external funder a report of any Investigator's Significant Financial Interest if the Conflicts Committee has determined that the Significant Financial Interest creates or will create a Financial Conflict of Interest and describe the management plan for that Conflict of Interest. In cases in which the Conflicts Committee identifies a Financial Conflict of Interest and requires elimination of it prior to the expenditure of the external funds and such elimination has taken place, the COI Officer shall not make a report to the external funder. If a Financial Conflict of Interest is identified after funds have been expended, the COI Officer will report to the funder within sixty days of first disclosure of the Significant Financial Interest. Annual reports will be made to the funder regarding this previously undisclosed Financial Conflict of Interest thereafter for the duration of the project.

# III. Appeals

Employees or Investigators who disagree with a decision regarding the existence of a Financial Conflict of Interest or the necessary elements of a conflict management plan may submit a written appeal to the COI Officer. The COI Officer will submit the appeal to the Conflicts Committee for review. The decision of the Conflicts Committee on the matter will be final for all purposes.

# **Related Forms**

- Employee Outside Activities, Relationships and Financial Interests Statement
- Investigator Significant Financial Interests Statement

Policy reviewed and updated August 23, 2012