

<b>Service Area:</b> Corporate Compliance	<b>YALE NEW HAVEN HEALTH SYSTEM</b>	
<b>POLICY &amp; PROCEDURES</b>		
<b>Title:</b> Conflicts of Interest		
<b>Date Approved:</b> 06/16/13, 02/18/14, 09/09/14, 09/08/15, 10/16/15, 12/01/2015, 9/20/16, 03/26/19		<b>Approved by:</b> System Compliance Committee
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<b>Supersedes:</b> Yale New Haven Health I.1 & I.A.11/Type 1: Business Conduct/Ethics YNH Network Corporation Business Conduct/Conflict of Interest Yale-New Haven Hospital NC:B-3: Business Conduct/Conflict of Interest Bridgeport Hospital B:6: Conflict of Interest Greenwich Hospital A-D 17: Conflict of Interest		

## PURPOSE

The purpose of this Policy is to ensure that business activities are conducted free from the influence, or the perception of the influence, of conflicts of interest (COI). This policy also establishes the standards for determining the existence of conflicts of interest, the requirements for disclosing conflicts and the process for reducing, managing or eliminating conflicts.

## APPLICABILITY

This policy applies to YNHHS, and each of its affiliated entities, its affiliated hospitals (Bridgeport Hospital, Greenwich Hospital, Yale New Haven Hospital, Lawrence + Memorial Hospital, Westerly Hospital, and any other hospital that affiliates with YNHHS), its affiliated providers (including but not limited to Northeast Medical Group and Visiting Nurse Association of Southeastern Connecticut), and each of their subsidiary entities.

## DEFINITIONS

1. **Conflicts of Interest (COI):** A potential Conflict of Interest arises as a result of situations or circumstances whenever an individual's interests, such as professional obligations or judgment owed to the YNHHS and its constituencies are compromised by, or could be perceived as being compromised by, his or her leadership roles, secondary commitments or financial interests.
2. **Covered Individual:** A Covered Individual refers to any of the following individuals:
  - a. **Employed Medical Staff Members** all employed licensed practitioners who have been appointed to YNHHS's Medical Staff through the usual credentialing process.

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- b. Key Executives are persons designated by the Chief Executive Officer of YNHHS or one of the System Entities, or his/her delegates, to have significant roles in the management or administration of the business of the Hospital.
  - c. Designated Departments/Committees/Individuals-  
The following specific departments:
    - Pharmacy
    - Office of Privacy & Corporate Compliance (OPCC)
    - Supply Chain/ Procurement
    - Legal & Risk Services Department (LRSD)
    - Center for Emergency Preparedness and Healthcare Solutions (CEPHS)
    - Center for Outcomes Research and Evaluation (CORE)
 Committees:
    - Pharmacy & Therapeutics (P&T)
    - Formulary Integration Committee (FIC)
    - ITS Purchasing Committees
    - Clinical Governance Committee
 Individuals:
    - Grant-funded employees
    - Directors and above
    - Medical Staff members with an Administrative role\* \**“Medical Staff Members” includes those who (i) serve as clinical department directors, medical directors, chiefs, associate chiefs and/or (ii) serve on a clinical evaluation, pharmacy and therapeutics, or selection committee in support of the Hospital’s supply chain management function.*
3. **Family:** Family refers to a Covered Individual’s spouse, partner or similar relationship, parents and grandparents, children and their spouses/ partners, siblings, close relatives, step and in-law relatives of all of the preceding categories and any other person that resides in the same household.
4. **Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the Covered Individual or his/her family member that reasonably appear to be related to his or her organizational responsibilities (including teaching, administration, research or clinical care):
  - a. When the value of any remuneration or equity interest received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$10,000 or when the Covered Individual or family member holds any equity interest (e.g., stock, stock option, or otherwise ownership interest). For purposes of this definition, remuneration includes salary, and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, etc.); or
  - b. When the value of any equity interest in the entity as of the date of disclosure exceeds \$10,000 or represents more than a 5% ownership interest in the entity; equity interest includes any stock, stock option, or other ownership interest, as

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determined through reference to public prices or other reasonable measures of fair market value.

- c. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income greater than \$10,000 related to such rights and interests.
  - d. A financial interest does not include any; income, salary or remuneration in cash or in kind, benefits, gifts, honoraria, travel expense, goods or services received in the aggregate during a calendar year that does not exceed Stark Law non-monetary compensation rate for the current year. Financial interest does include aggregate investments whether in the form of debt, stock or other equity ownership, options or warrants to purchase stock, securities or similar with a value exceeding \$10,000 or representing a five (5%) percent or greater interest in any entity, enterprise or trust; royalties on any patent or other intellectual property interests with a value exceeding \$10,000, unless paid by YNHHS Financial Interest (excludes mutual funds or other equity funds in which the day-to-day control of investments is held by a person not subject to the YNHHS COI policy).
5. **Outside Affiliate** (*entity you are affiliated with*): refers to any person, corporation, partnership, or other organization with respect to which the Covered Individual or any member of his/her Family (1) is a director, trustee, officer, employee, member, or partner; or (2) has a significant financial or other interest.
  6. **Physician Owned Distributorships**: Physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).
  7. **Primary Commitment**: The time, energy and loyalty that Covered Individuals are required to dedicate to the YNHHS.
  8. **Secondary Commitment**: Activities that are not part of the Primary Commitment, which include but are not limited to employment, consulting or participation in outside businesses or organizations. The time, energy and loyalty Covered Individuals dedicate to outside Leadership Roles and other compensated or non-compensated extramural activities. Secondary Commitments do not include personal activities conducted on holidays, vacations and weekends.
  9. **Conflict of Commitment**: exists when a secondary commitment requires a commitment that could interfere with an employee's obligation to YNHHS.
  10. **Vendor**: Any individual, business, partnership, corporation or other entity that sells or conveys goods/services to the YNHHS, or for the purchase/sale of goods/ services to, for, by YNHHS.

## POLICY

YNHHS is committed to conducting its affairs in accordance with the highest ethical and legal standards. In order to maintain these standards, it is the policy of YNHHS that potential,

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perceived and actual conflicts of interest are to be avoided or minimized when possible. A Conflict of Interest does not necessarily imply wrongdoing, as a Conflict of Interest depends upon the circumstances. Disclosure provides the opportunity for checks and balances and for appropriate decision making in order to protect both YNHHS and its Covered Individuals.

It is a mandatory component of annual performance reviews for YNHHS Covered Individuals to complete the COI process on an annual basis. New employees or Committee members, who are identified as Covered Individuals, must complete their COI disclosure form prior to hire and current Covered Individuals must update their COI disclosure form within 30 days of a change that result in an SFI and/ or affiliation.

It is YNHHS policy that we will not conduct business with physician owned distributorships.

### PROCEDURE

#### **I. YNHHS COI PROCEDURE**

A. The Office of Privacy and Corporate Compliance (OPCC) has oversight for the YNHHS COI process and is responsible for surveying YNHHS's Covered Individuals on an annual basis through an electronic conflict of interest software.

#### **B. Medical Staff Members & New (Non-Formulary) Product Requests:**

- i. Employed Medical Staff Members are obligated to complete the YNHHS Conflicts of Interest Disclosure Statement on an annual basis.
- ii. Prior to hire, a medical staff member is required to complete a Conflicts of Interest Disclosure Statement.
- iii. All Medical Staff Members are required to disclose Conflicts of Interest when requesting the purchase by YNHHS or any YNHHS affiliated hospital of any new product, drug or capital equipment for use in any department.
- iv. Medical Staff Members who are looking to submit a new product request or any party who has a formal role in reviewing or authorizing new product requests must contact Supply Chain for guidance.
- v. Any Medical Staff Member or secondary approval authority who discloses a SFI in the parent company of a new product may not independently submit a request for the purchase of a new product from that company, may not trial/ use such products absent formal committee review and approval for addition to formulary or participate in the review and approval process.
- vi. Each committee responsible for reviewing new product requests must develop processes to ensure that the above mentioned request process is followed and any conflict of interest disclosure is mitigated, managed, or eliminated.

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### C. **Supplier Evaluation and Selection Process:**

- i. Physician Subject Matter Experts (SMEs) and project facilitators must complete a COI disclosure survey prior to participation in any project. Any SME or facilitator who does not complete a COI disclosure may not participate in project meetings, calls and related discussions.
- ii. COI disclosures will be shared with the YNHHS COI Committee for review and recommended action as necessary. For transparency purposes, general information on disclosures (such as discloser name, company name, and whether a SFI exists) will be provided to the Supplier Evaluation and Selection Committee and other appropriate parties.
- iii. Each committee responsible for evaluating and selecting suppliers must develop processes to ensure that their committee is operating in compliance with these requirements and any conflict of interest disclosure is mitigated, managed, or eliminated.

- D. The OPCC is responsible for providing the System Compliance Committee and System Audit Committee with an annual report on the YNHHS COI process, survey results and Management Plans.

## II. **REQUIRED DISCLOSURES**

- A. Covered Individuals must complete an electronic COI form at least once a year, or within 30 days of any new financial interest. Covered Individuals are strongly encouraged to disclose at any time a matter that may raise a potential conflict of interest and seek guidance or review.
- B. Individuals are required to log into the electronic conflict of interest software and update their disclosures to reflect new interests, activities, and relationships as required by this policy or otherwise at the discretion of the COI Committee.
- C. **Ownership & Work Relationships:** A direct or indirect financial interest of \$10,000 or more, including ownership of stock, stock options, equity, debt, other securities or other forms of ownership interest, salary or other remuneration received as an employee, consultant, or officer in any business or health care enterprise that produces services or products which compete with those of YNHHS.
- D. **Employment of Relatives and Partner Relationships:** Covered Individuals shall disclose any situation in which their relationship with a family member results in a potential, perceived or actual conflict of interest. A conflict of interest may be the result of a direct reporting relationship (e.g. supervisory relationship) or an indirect reporting relationship (e.g. if one employee holds a position which may influence the status or compensation of a family member).
- E. **Use of YNHHS resources** for personal gain or the gain of another person. Employees may not use their position at YNHHS as the impetus to start a manufacturing, service or consulting business that depends on YNHHS confidential information and/or specific operations knowledge obtained on the job at YNHHS or

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which utilizes YNHHS resources/facilities.

- F. **Service as an Officer or Employee of a Competing Healthcare Institution:** Covered Individuals shall not accept any position as an officer or employee of, or paid consultant to, any healthcare system or institution that is in substantial competition with YNHHS without the approval from COI Committee.
- G. **Gifts and Entertainment:** No Covered Individual shall accept gifts or entertainment from persons or entities that conduct business with YNHHS if the gifts or entertainment is for the purpose or perceived to influence business transactions. Gifts of cash or cash equivalents are never permissible. Any acceptance of gifts or entertainment must be in accordance with the YNHHS Gifts and Gratuities Policy, and the YNHHS Interactions with Vendors Policy. Question as to whether a particular gift or entertainment would be appropriate may be directed to the VP of the Office of Privacy & Corporate Compliance.
- H. **Confidential and Inside Information:** All Covered Individuals shall refrain from transmitting any knowledge, consideration, decision, or any other information that might be prejudicial to the interests of YNHHS to any person other than in connection with the Covered Individual's discharge of his/her responsibilities on behalf of YNHHS. The governing principle is that no material confidential information pertaining to YNHHS or its patients may be used for a Covered Individual's own or his/her family's benefit nor shall a Covered Individual disclose such information to others for his/her/their personal use.
- I. **Use of YNHHS Assets:** YNHHS credit purchasing power shall not be used to purchase goods and/or services for personal benefit or non-YNHHS activities. YNHHS facilities may be used only for YNHHS related purposes, which may include community benefit activities, and educational functions.
- J. **Conflict of Commitment:** Covered Individuals employed by YNHHS are expected to devote their primary professional loyalty, time, and energy to, as applicable, teaching, research, patient care, and service on behalf of or to YNHHS. Outside activities must be arranged so as not to interfere with the primacy of these commitments, and require notification to the appropriate manager and disclosed on the COI Disclosure form.
- K. **Paid Honoraria and Consultancy:** Covered Individuals who are employees of the YNHHS are expected to obtain the prior approval of their manager in advance of receiving paid honoraria or consultancy and must disclose any such arrangements on the Annual Conflicts Disclosure form. Accepting paid honoraria must be in accordance with the Interactions with Vendors policy. When considering requests for approval of paid honoraria and consultancy for employed Covered Individuals, managers shall consider the risk of interference with the primacy of an employee's commitments to YNHHS any potential for conflicts of interest, as well as any potential conflict with YNHHS's Mission or Code of Conduct.

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- L. **Disclosure of Individual Interest Prior to Approval of Transaction:** A Covered Individual must promptly disclose his/her interest in, or connection with, a proposed transaction or other matter being presented for consideration or approval to YNHHS if the transaction or matter is of the type that would require disclosure on the Annual Disclosure survey. The Covered Individual's disclosure and non-participation shall be recorded.
- M. **Influence upon the negotiation of contracts** between YNHHS and other organizations with which the Covered Individual and/ or their family member has a significant relationship (e.g. employment, consulting, Board member) or will receive favorable treatment as a result of such influence.

### III. **REVIEW AND MANAGEMENT OF DISCLOSURES**

- A. All disclosures will be first reviewed by the Covered Individual's manager. After manager's review and response, OPCC will review all disclosures prior to presenting them to the COI Committee.
  - i. The COI Committee may ask that the Covered Individual provide additional information or discuss the matter with the COI Committee in person. If additional information is requested, OPCC will reach out to the Covered Individual via electronic conflict of interest software.
  - ii. The COI Committee will examine disclosed conflicts to assess the degree of risk, and the Covered Individual's ability to manage, reduce or eliminate any identified conflicts.
  - iii. The OPCC will review physician disclosures in conjunction with available CMS Open Payments transactions.
  - iv. In the event a Covered Individual disagrees with the COI Committee's decision related to the primary methods of managing, reducing or eliminating the conflict, the Covered Individual may request a meeting with the YNHHS VP Corporate Compliance and the YNHHS SVP Human Resources to review the COI Committee's decision. The YNHHS VP Corporate Compliance and the YNHHS SVP Human Resources decisions are final.
  - v. Disclosures reviewed by the COI Committee that are determined to require either management or elimination of Conflicts of Commitment or Interest will be compiled and the conflict management actions taken in response will be reported to the YNHHS System Compliance Committee.
  - vi. The OPCC will retain documents in electronic conflict of interest software related to the COI Disclosure Statement submitted by Covered Individuals in accordance with the YNHHS Document Retention and Disposition Policy.
  - vii. Yale University COI Committee is responsible for sending YNHHS Compliance Department any YNHHS Medical Staff Member disclosure that has a SFI.

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Depending on the SFI, YNHHS COI Committee will determine if a Management Plan is needed.

- B. The primary methods of managing, reducing or eliminating conflicts shall include:
  - i. Modifying the YNHHS employment responsibilities of the conflicted member(s);
  - ii. Removing, reducing or altering the Leadership Role, Secondary Commitment or Financial Interest (e.g., partial or full divestiture or sequestration of one or more Financial Interests, reduction of time spent in furtherance of one or more Leadership Roles or Secondary Commitment).
  - iii. An agreed upon action plan (formal Management Plan) to minimize/ manage the risk and ensure that all appropriate parties are informed will be managed in electronic conflict of interest software.
  - iv. Recusal from all decision making processes that are pertinent to the identified conflict.
  - v. Full disclosure of identified conflicts to the decision making body (e.g. P&T Committee)
  - vi. Read and attest to YNHHS Confidentiality Policy and Form.
- C. If it is determined that a disclosure requires a Management Plan, the Management Plan will be provided to the Covered Individual and their supervisor/ DN CMO for review and signature.
  - i. Signed Management Plans must be completed within 10 business days
- D. Management Plans for Covered Individuals who are also members of the Pharmacy & Therapeutics (P&T), Formulary Integration Committee (FIC), ITS Purchasing Committees, Clinical Governance Committee (CGC), and any other committee with purchasing and decision making power, will be shared with the Chairperson of the respective committee, in addition to the relevant supervisor/ DN CMO.
- E. COI investigations and signed Management Plans will be stored in the electronic conflict of interest software.

## **IV. ENFORCEMENT AND SANCTIONS**

- A. The YNHHS COI Committee has the authority to require appropriate management and oversight of disclosures in accordance with this policy. Management may include the reduction or elimination of any interest, participation in an activity or relief of relevant duties until compliance is achieved.
- B. The OPCC will monitor compliance with management and oversight requirements in such manner as deemed appropriate and may investigate and take corrective action as necessary.
- C. Any Covered Individual who violates any provision of this policy, or any conditions



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imposed pursuant to this policy, may face sanctions up to and including suspension or termination of employment, removal from a Board, loss of the privilege of conducting research at or in connection with YNHHS, loss of Medical Staff privileges, loss of administrative appointments, cessation of business with a vendor, written warning to employment/ credentialing file and other appropriate actions.

- D. Covered Individuals are required to ensure compliance with this policy. Failure to complete the annual COI disclosure survey within the allotted timeframe may result in forfeiture of a merit increase in connection with the individual's performance review.
- E. All Covered Individuals whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy.

### V. **AUDIT**

- A. The OPCC may perform audits as needed.
- B. The YNHHS COI policy is subject to review and evaluation at least annually by the YNHHS COI Committee, with changes as appropriate.

### VI. **QUESTIONS**

- A. Any questions about this policy or the completion of Annual Disclosure Statements may be directed to the Office of Privacy & Corporate Compliance at 203-688-8416 or [conflictofinterest@ynhh.org](mailto:conflictofinterest@ynhh.org).