



## **CLINICAL POLICY**

### **INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST IN CLINICAL HEALTH CARE**

**A. EFFECTIVE DATE :**

May 18, 2021

**B. PURPOSE :**

Clinical Practitioners at UConn Health promote the clinical health care mission of the University. The participation of UConn Health clinical practitioners in activities of professional associations, industry collaborations, and other public and private entities can assist in the advancement of patient care, while also serving the academic interests of the University. In addition, such participation brings enhanced national and international status to UConn Health and the State of Connecticut. Over the past decade, the opportunity for UConn Health faculty and staff to engage in external professional activities and collaboration with industry has increased markedly, and is encouraged by the state and federal governments because of the resulting clinical health care benefits.

However, it is vital that Clinical Practitioners adhere to state and federal regulations dealing with avoiding and managing potential and existing conflicts of interest. In order for us to maintain public trust and support in carrying out our mission, UConn Health must demonstrate that it subjects itself to the highest standards of ethical behavior and is as transparent as possible regarding potential conflicts.

This Policy on Financial Conflicts of Interest in Clinical Health Care (“Policy”) promotes objectivity in clinical health care by establishing standards to reasonably ensure that the planning, support and delivery of clinical health care will not be biased by any conflicting financial interest of a Clinical Practitioner. This Policy applies to all aspects of clinical health care.

**C. POLICY :**

All Clinical Practitioners must in accordance with this Policy disclose any significant financial interest (including those of a spouse or dependent child) that relate to the Clinical Practitioner’s institutional responsibilities and, if applicable, comply with any financial conflict of interest management or mitigation plans.

**D. SCOPE :**

This policy applied to any person (regardless of title or position) who is responsible for the planning, support and delivery of clinical health care or educational activities. This includes key clinical administrators as defined by the Committee.

**E. DEFINITIONS :**

**Clinical health care** – the provision of medical, dental, nursing, or other health-related care to patients for their preventive care, or for the treatment of disease or injury.

**Clinical Practitioner** – any person (regardless of title or position) who is responsible for the planning, support and delivery of clinical health care or educational activities. This includes key clinical administrators as defined by the Committee.

**Entity** – any corporation, partnership, sole proprietorship, limited liability company, limited liability partnership, firm, franchise, association, organization, holding company, joint stock company, joint venture, receivership, business or real estate trust, or any other legal entity organized for profit, nonprofit, or charitable purposes.

**Equity Interest** – any interest in the profits or other ownership interest in any Entity, including common stock, preferred stock, other securities, partnership interests, membership interests, and any right to acquire any of the foregoing such as options, warrants, and convertible securities.

**Financial Conflict of Interest (FCOI)** – a significant financial interest that could directly and significantly affect the planning, support or delivery of clinical health care.

**Financial Interest** – any direct or indirect interest of monetary value, whether or not the value is readily ascertainable, including (as defined in this policy) but not limited to: Equity Interest; Income Interest; any interest in Intellectual Property; and Gifts of any kind.

**Immediate Family** – spouse and dependent children.

**Income Interest** – any salary, any other payment for services (e.g., consulting fees, honoraria or paid authorship), or dividends, interest, or other distributions.

**Institutional Responsibilities** – a Clinical Practitioner's professional responsibilities on behalf of UConn Health, which include clinical health care, teaching, service, consulting, professional practice, and membership or service on UConn Health, University, or external committees, boards or panels, including but not limited to those that influence or direct vendor selection or purchasing. (Policy on Faculty Professional Responsibilities).

**Intellectual Property** – all patents, copyrights, trade and service marks, trade and service names, and all applications for the same, and all trade secrets, and rights with respect to any of the foregoing, such as income-sharing rights or licensee interests.

**Manage** – taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the planning, support and delivery of clinical health care will be free from bias.

**Significant Financial Interest (SFI):**

A. A Financial Interest consisting of one or more of the following interests of the Clinical Practitioner (and those of the Clinical Practitioner's spouse or dependent children) that reasonably appears to be related to the Clinical Practitioner's Institutional Responsibilities.

1. With regard to any publicly traded entity, an SFI 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 or represents >5.0% ownership in a single entity.

- a. 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 – see definition of Income Interest).
  - b. Equity Interest includes any stock, stock option, or other ownership interest (see definition), as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly traded entity, an SFI 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 Clinical Practitioner (or the Clinical Practitioner's spouse or dependent children) holds any Equity Interest;
  3. With regard to Intellectual Property (see definition), an SFI exists upon receipt of income exceeding \$5,000 related to such rights and interests and not reimbursed through the University; or
  4. A proprietary interest in the products, services, technologies, or instruments being prescribed or used in the Clinical Practitioner's clinical health care.
- B. With regard to any sponsored travel, Clinical Practitioners also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Clinical Practitioner and not reimbursed to the Clinical Practitioner so that the exact monetary value may not be readily available), related to their Institutional Responsibilities if the value of any reimbursed or sponsored travel when aggregated, exceeds \$5,000 from any single entity; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a) as an academic teaching hospital, a medical center, or a clinical health care institute that is affiliated with an Institution of higher education. Details of this disclosure must include the purpose and duration of the trip, the identity of the sponsor/organizer, the destination and the duration.
- C. The term Significant Financial Interest does not include the following types of financial interests:
1. Salary, royalties, or other remuneration paid by UConn Health to the Clinical Practitioner if the Clinical Practitioner is currently employed or otherwise appointed by UConn Health, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
  2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Clinical Practitioner does not directly control the investment decisions made in these vehicles;
  3. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a) as an academic teaching hospital, a medical center, or a clinical health care institute that is affiliated with an institution of higher education; or
  4. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a) as an academic teaching hospital, a medical center, or a clinical health care institute that is affiliated

with an institution of higher education.

**F. MATERIAL(S) NEEDED :**

None

**G. PROCEDURE :**

**TRAINING**

All Clinical Practitioners must provide, or be capable of providing upon request, annual certification that they have read this policy. The following circumstances will require a Clinical Practitioner to certify that s/he has read the policy: (in the timeframes noted in parentheses):

1. This policy changes such that Clinical Practitioner requirements are affected (within 60 days). In these cases, Clinical Practitioners need only certify their review of the changes.
2. A Clinical Practitioner is new to UConn Health (prior to engaging in clinical health care).
3. The Committee finds that a Clinical Practitioner is not in compliance with the Policy or a management plan, as applicable (within 10 days).

**DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

Each Clinical Practitioner must disclose his/her SFIs (including those of the Clinical Practitioner's Immediate Family) that reasonably appear to be related to the Clinical Practitioner's Institutional Responsibilities. In determining whether a financial interest has to be disclosed, the Clinical Practitioner shall consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure.

1. **Annual Disclosure:** Clinical Practitioners have a professional and ethical responsibility to disclose and/or update reported SFIs annually.
2. **Disclosure Upon Acquisition, Discovery or Change:** Clinical Practitioners have an on-going responsibility to disclose, within thirty (30) days, any newly acquired or discovered SFIs or any changes in previously disclosed SFIs.
3. **Prior to Engaging in Clinical Health Care:** Clinical Practitioners have a responsibility to disclose if they provide clinical health care and have SFI(s) in a business which manufactures or distributes pharmaceuticals, medical devices, or other health care products.

**REVIEW AND MANAGEMENT OF CLINICAL SIGNIFICANT FINANCIAL INTERESTS**

- A. The Executive Vice President for Health Affairs has delegated implementation of the disclosure, review, and management process to the Clinical Conflict of Interest Committee (the "Committee") and its designees. The Committee and its designees are the designated Institutional officials for purposes of soliciting and reviewing clinical SFIs, and managing clinical FCOIs at UConn Health.
- B. Clinical Conflict of Interest Committee
  1. The Executive Vice President for Health Affairs appoints Committee members. The Committee shall include at a minimum a chair, and eight additional members representing UConn Health, at least two of which must be members of faculty/staff bargaining units, such

- as AAUP. Additional members and ad hoc members may be appointed.
2. Committee members must declare any conflicts they have with business brought before the Committee. Those Committee members with conflicts do not participate in discussion except to provide information requested by the Committee and do not vote on any issue where they have a conflict.
  3. The Committee may utilize consultants, subscription services, and other aids as it finds necessary, and where funding is identified. Consultants must declare any conflicts and individuals may not serve as consultants on issues where they have a conflict. Consultants are non-voting.
  4. The Committee must have a quorum, defined as three voting members, present to conduct business. The Committee may convene with some or all members participating by telephone or videoconference. A simple majority of the members present is required for a motion to be approved.
  5. The Committee chair may establish a procedure for the review and management of disclosures by one or more designated individuals acting on behalf of the Committee. However, management plans shall be approved by a quorum of the Committee.
  6. The Committee shall meet regularly, and in no case less than two times annually.

C. Review and Management Process

1. The Committee or its designee shall identify and review all SFIs to determine if they are related to the Clinical Practitioner's institutional responsibilities and, if so, whether they constitute a FCOI.
  - a. The Committee shall aspire to review all disclosed SFIs promptly, and all other SFIs in a prompt manner after they have been identified by the Committee.
  - b. The Committee will establish a mechanism whereby a Clinical Practitioner may obtain an advisory opinion from the Committee or its designee, prior to incurring a SFI or engaging in sponsored travel that may later be considered a SFI. The Committee, or its designee, will endeavor to provide such guidance to Clinical Practitioners in a timely manner, so as to prevent conflicts before they even occur.
2. The Committee or its designee is authorized to request any other information that it deems necessary to assist it in its determinations, including consultation or opinion from individuals outside the Committee.
3. The Committee may involve the Clinical Practitioner and/or his/her Department Head to assist in the determination of whether an SFI is related to institutional responsibilities and/or constitutes an FCOI.
4. For review of disclosures of reimbursed or sponsored travel, the Committee may determine if further information is needed, including determination or disclosure of monetary value.
5. If the Committee or its designee determines that an FCOI exists for a clinical practitioner or a member of his or her immediate family, it will then determine what conditions or restrictions, if any, should be imposed by UConn Health to manage, mitigate, or eliminate

such conflicts. Conditions may include, but are not limited to:

- a. Public disclosure of FCOIs, or disclosure of FCOIs to specific patients, which may include a notification of that financial interest to all patients for whom the clinical practitioner prescribes a branded product of that business.
  - b. Monitoring of the clinical health care by independent reviewers;
  - c. Modification of the clinical health care;
  - d. Disqualification from participation in all or a portion of the activities that could be affected by the FCOI;
  - e. Divestiture or reduction of the SFI;
  - f. Severance of relationships that create actual or potential conflicts.
6. The Committee or its designee will adequately document its determinations, recommendations, FCOI management plans and retrospective reviews.

#### NOTIFICATION AND REPORTING

- A. If an FCOI is identified, the Committee or its designee is responsible for:
  1. Development of a management plan to eliminate or appropriately mitigate the FCOI;
  2. Notification of the Clinical Practitioner of the management plan designed by the Committee for his/her FCOI;
  3. Ongoing monitoring of the Clinical Practitioner's compliance with the management plan.
- B. Reasonable efforts will be made to maintain the privacy of information gathered in the Committee's deliberations, within the limits imposed by applicable laws and regulations.

#### MAINTENANCE OF RECORDS

- A. All records related to the implementation of this policy (e.g., *Individual Financial Disclosures*, minutes of the meetings of the *Committee*, notifications to clinical practitioners, actions taken to resolve or mitigate FCOIs, etc.) will be maintained securely by the Committee, or its designee, in compliance with state records retention requirements.
- B. FCOI records shall be subject to periodic review for compliance with this policy by the Executive Vice President for Health Affairs, his designee, or by any agency per applicable regulations.

#### PUBLIC ACCESSIBILITY

A copy of this Policy will be made available via UConn Health web site.

#### MONITORING COMPLIANCE AND MITIGATION

- A. The Committee or its designee will monitor for compliance with the Policy. The Committee will establish the procedures to be used for monitoring compliance.
- B. If an SFI is not disclosed within the time frame specified in the Policy the individual will be notified of the failure to disclose and the failure to disclose will be elevated to increasing levels of management for resolution. The Committee will establish procedures for elevation of failures to disclose.

- C. Failure to comply with a management plan or requirements of this Policy other than failure of timely disclosure will be referred to the Committee for further action. The Committee will determine whether noncompliance with the Policy has occurred and if so what corrective actions are required to mitigate the noncompliance. The Committee will provide the corrective actions to the appropriate organizational individuals and entities as identified by the Committee to address the corrective actions. As part of its assessment the Committee may conduct a retrospective review to determine whether noncompliance with this Policy actually or could appear to have biased the planning, support or delivery of clinical health care.
- D. Violations of this policy may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Conduct Code, and other relevant University policies.
- E. University personnel must also comply with applicable provisions of the Connecticut State Code of Ethics, Connecticut General Statutes, Sec. 1-79 through 1-89, which stipulates what types of activities are allowable for state employees who may have financial interests in companies, which do business with the State of Connecticut (<http://www.ethics.state.ct.us/>).

#### APPEALS

In situations where a Clinical Practitioner disputes the decision of the Committee, the Clinical Practitioner may request to present the case to the Committee in person and have the Committee reconsider its determinations/recommendations. If the Clinical Practitioner disputes the reconsideration of the Committee, the Clinical Practitioner may appeal in writing to the Executive Vice President for Health Affairs, or his designee. The Executive Vice President for Health Affairs, or his designee, may agree with the Committee's findings and/or recommendations, or may amend such findings and/or recommendations. The Executive Vice President for Health Affairs, or his designee, shall promptly notify the Clinical Practitioner and the Committee in writing of the conclusions of his/her review, including the actions that must be taken by the Clinical Practitioner to comply with this Policy. Upon receipt of the Executive Vice President for Health Affairs' or his designee's written decision, the Clinical Practitioner must promptly comply with the actions specified in that report. The Executive Vice President for Health Affairs' or his designee's decision shall be final.

#### IMPLEMENTATION AND ENFORCEMENT

- A. The Vice President of Human Resources, in consultation with the Dean of the appropriate School, if any, and the Clinical Practitioner(s) Department Head, Chairperson, or Director will review all noncompliance with this policy, including:
  1. Failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);
  2. Failure to remedy conflicts; and
  3. Failure to comply with a prescribed management plan.

B. Sanctions and penalties for those who disregard this policy, or refuse to comply with its terms, will be determined by the Vice President of Human Resources, in consultation with the Executive Vice President for Health Affairs, and the Dean of the appropriate School, if any, with advice from the Clinical Practitioner's Department Head, Chairperson, or Director.

**AUDIT PROCEDURES**

In order to ensure that all declarations are being made and financial conflicts managed, UConn Health will implement a relevant audit program through the University's Office of Audit, Compliance and Ethics.

**STATE OF CONNECTICUT ETHICS FOR PUBLIC OFFICIALS**

Connecticut General Statutes, Sec. 1-79 through 1-89, stipulates what types of activities are allowable for state employees who may have financial interests in companies which do business with the State of Connecticut <http://www.ct.gov/ethics/site/default.asp>. There are state regulations that deal with clinical health care activities. If Clinical Practitioners are engaged in clinical health care and receive any investment opportunities or payment directly from a company, the Clinical Practitioner needs to make sure that he/she is in compliance with the *State Code of Ethics*.

**H. ATTACHMENTS :**

None

**I. REFERENCES :**

None

**J. SEARCH WORDS :**

Conflict  
Conflict of Interest  
Clinical Conflict of Interest  
Clinical Practitioner

**K. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS :**

On file

**M. COMMITTEE APPROVALS :**

None

**N. FINAL APPROVAL:**

- |  |                   |
|--|-------------------|
| 1. <u>Andrew Agwunobi, MD (Signed)</u>                             | <u>06/02/2021</u> |
| Andrew Agwunobi, MD, MBA   | Date              |
| <b>UConn Health Chief Executive Officer</b>                        |                   |
| 2. <u>Anne Horbatuck (Signed)</u>                                  | <u>06/02/2021</u> |
| Anne D. Horbatuck, RN, BSN, MBA                                    | Date              |
| <b>Clinical Policy Committee Co-Chair</b>                          |                   |
| 3. <u>Scott Allen, MD (Signed)</u>                                 | <u>06/01/2021</u> |
| Scott Allen, MD  | Date              |
| <b>Clinical Policy Committee Co-Chair</b>                          |                   |
| 4. <u>Caryl Ryan (Signed)</u>                                      | <u>05/28/2021</u> |
| Caryl Ryan, MS, BSN, RN  | Date              |
| <b>VP Quality and Patient Services &amp; Chief Nursing Officer</b> |                   |

**O. REVISION HISTORY:**

Date Issued: May 9, 2017

Date Revised: April 6, 2020, May 12, 2021

Date Reviewed: