Policy

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Title: Management of Industry Relations and Conflicts of Interest Policy: Corporate Integrity Program

Home Department: Corporate Integrity Program

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POLICY STATEMENT:

Cedars-Sinai Medical Center ("CSMC") and Cedars-Sinai Medical Care Foundation ("CSMCF"), dba Cedars-Sinai Health System (CSHS), believe that the fulfillment of the mission of a leader in health services, biomedical research, and the training of physicians and other healthcare professionals requires effective, transparent, and principled working relationships with pharmaceutical companies and medical device manufacturers (as further defined below, "Industry"), and entities providing goods or services to CSHS (as further defined below, "Vendors"). In furthering such relationships, CSHS is committed to working with its faculty, affiliated physicians, affiliated physician groups, as well as its executive and management staff, to ensure that potential conflicts of interest ("COIs") are identified, reviewed and appropriately managed. CSHS believes that potential COIs involving Industry or Vendor relations do not preclude partnerships that appropriately promote and support CSHS's mission. In turn, CSHS believes that beneficial relationships with Industry or Vendors do not preclude full transparency and effective management of potential COIs involving CSHS or its affiliated physicians and staff. In the interest of such transparency, this policy is always available on Cedars-Sinai's public website.

CSHS will not allow an employee, officer, or agent to participate in the selection, award, or administration of a contract supported by federal funds if a real or apparent conflict of interest would be involved.

PURPOSE:

This policy has a two-fold purpose:

1. To guide CSHS in the development and management of Industry and Vendor relations among its faculty, affiliated physicians, affiliated physician groups, as well as among its executive and management staff. In this regard, this policy is intended to be a master policy for guiding the oversight responsibilities of the Committee for the Management of Industry Relations and Conflicts of Interest, as well as for the work of any industry relations/conflict of interest programs which CSHS may from time to time create.
2. To ensure full compliance with the requirements of 42 CFR Part 50 Subpart F (Promoting Objectivity in Research), 45 CFR Part 94 (Responsible Prospective Contractors), and any other

conflict of interest laws and regulations to which CSHS is subject, as these may apply to government-funded research conducted at or through CSHS.

DEFINITIONS:

1. For purposes of this policy, the following terms are defined as follows:
    a. **Academic Activities** means, for purposes of this policy, activities of the type indicated by (but not limited to) the following:
        I. Serving as an officer, committee chair, program chair, or board member of a medical, scientific, or professional association;
        II. Serving as a peer reviewer, editor, or on the editorial board of a peer-reviewed professional journal or other similar publication or activity;
        III. Lecturing at a university, medical college, or other Institution of Higher Education; or medical society meeting;
        IV. Serving as a speaker, program chair, or moderator at a program or event that meets the following three (3) criteria: (1) The program meets the accreditation or certification requirements and standards of ACCME, AOA, AMA, AAFP, or ADA CERP; (2) The commercial sponsor, if any, does not select the speakers nor does it provide the program/event manager with a distinct, identifiable set of individuals to be considered as speakers; and (3) the commercial sponsor, if any, does not directly pay the speakers, program chairs, or moderators;
        V. Participation in health- or medicine-related governmentally convened bodies; to include but not limited to NIH study sections and FDA advisory committees.

    This definition is intended to identify those types of outside, professional activities that presumptively would not constitute a conflict of interest for Cedars-Sinai. It is, however, possible for conflicts of commitment to arise in relation to these and other outside activities. Cedars-Sinai may, from time to time, establish policies or other requirements regarding the management of conflicts of commitment. Cedars-Sinai may also, from time-to-time, require of some Covered Individuals an accounting of their Non-Cedars-Sinai Academic Activities.
    b. ***Cedars-Sinai Faculty (CS Faculty)*** means individuals who have entered into a Professional Services Agreement (PSA) and occupy a faculty job code with Cedars-Sinai (regardless of level of FTE); OR individuals with an appointment as Distinguish

Professor, Professor, Associate Professor, Assistant Professor, or Instructor within any one of the three tracks of Cedars-Sinai Professorial Series.

c. ***Cedars-Sinai Medical Care Foundation (CSMCF) Physicians*** means physician-employees of CSMCF and physician-employees of those medical groups that have entered into professional services agreements with CSMCF. CSMCF physicians are required to comply with various provisions of this policy as specified below.

d. ***Covered Individuals*** means those individuals who are obligated in part or in whole to comply with the provisions of this policy. Some policy provisions may apply only to some members of the CSHS community, while other provisions may apply to all individuals otherwise covered by this policy. For example, some provisions may apply to full-time faculty but not to physician members of CSMC Centers of Excellence, or to Medical Staff members in Medical Staff leadership positions or on Medical Staff committees; while other provisions may apply to all these (and other) members of the CSHS community. CSHS employees and staff members who are not Covered Individuals under the terms of this policy may still be subject to the requirements of conflict of interest policies developed, from time to time, by the Human Resources Department.

e. ***Disclosure of Significant Financial Interests*** means a Covered Individual's disclosure of SFIs (as defined below) to CSHS, in a manner and at a time as provided for by this policy.

f. ***Extramural Professional Activity*** means any activity that relates to the Covered Individual's Institutional Responsibilities (as defined below) that are performed for or on behalf of Industry or Vendors, or otherwise outside of CSHS oversight and administrative control, for which the Covered Individual receives direct or indirect remuneration of any kind. For purposes of this policy and except as otherwise expressly provided in this policy, Extramural Professional Activities performed for or on behalf of Industry or Vendors include, without limitation, providing information, direction, guidance, advice, deliberation, consultation, or other services for which the Covered Individual receives direct or indirect remuneration of any kind. Examples of Extramural Professional Activities include, but are not limited to, providing medical and/or scientific consulting services to a medical device manufacturer, providing scientific training to employees of a pharmaceutical company, providing training to customers or potential customers of a medical device manufacturer at the request of the medical device manufacturer,

and serving on the board of a health information technology company. (This definition is intended to be broad in scope and to be broadly interpreted.)

g. ***Financial Conflict of Interest ("FCOI")*** means an SFI that could directly and significantly affect the management decision-making process related to CSHS services, the delivery of healthcare services, the provision of professional training, or the design, conduct, or reporting of Research (as defined below).

h. ***FCOI Report*** means CSHS's report of a Financial Conflict of Interest to a PHS Awarding Component (as defined below) or other Federal agency.

i. ***Financial Interest*** **("FI")** means anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, stock or options in a company that has no current commercial market by which to gauge the value.

j. ***Industry*** means pharmaceutical companies, medical device manufacturers, distributors of medical devices and implantables, biotech companies, health- or biomedical-related IT companies, and any other type of company involved in the creation, manufacturing, marketing, or distribution of products and services used in patient care, biomedical research, or the training of healthcare professionals.

k. ***Institution of Higher Education*** means an educational institution in any state that:
(1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 USCS § 1091(d)(3);
(2) is legally authorized within such state to provide a program of education beyond secondary education;
(3) provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the relevant department of the federal government;
(4) is a public or other nonprofit institution; and
(5) is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such agency or association that has been recognized by the relevant department of the federal government for the granting of pre-accreditation status, and the relevant

department of the federal government has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

l. ***Institutional Responsibilities*** means a Covered Individual's professional responsibilities on behalf of CSHS as those responsibilities may be defined by employment or personal services agreements, job descriptions, consulting contracts, or CSHS policies. These may include, for example: activities such as administration and management functions, research, research consultation, teaching, professional or clinical services, and service on CSHS committees such as the Institutional Review Board or the Data and Safety Monitoring Board.

m. ***Investigator*** means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for (as opposed to simply assisting with) the design, conduct, or reporting of Research, which may include, for example, collaborators or consultants.

n. ***Leadership Role*** means serving as a Board member or company officer, or their equivalent, in an Industry or Vendor company.

o. ***Management Plan*** means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the delivery of healthcare services, the provision of professional training, or the design, conduct, and reporting of Research will be free from bias and/or the appearance of a COI.

p. ***Medical-Legal Service*** means providing assistance to lawyers, law firms, insurance companies, administrative hearing officers, arbitrators or mediators, governmental agencies, judges, and/or plaintiffs or defendants regarding medical and/or healthcare issues, to include but not limited to: assisting with the preparation of a case for purposes of litigation, arbitration or mediation, and/or providing expert witness testimony in depositions, hearings, trials, arbitrations and/or mediations. Medical-Legal Service does not mean, and therefore this policy does not apply to, situations in which a Covered Individual is engaged in providing the above-described types of services on behalf of CSHS and/or in a case or dispute involving CSHS as a party-in-interest.

q. ***PD/PI*** means a Project Director or Principal Investigator of a Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator (as defined below) under this policy.

r. ***PHS*** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

s. ***PHS Awarding Component*** means the organizational unit of the PHS that funds any Research that is subject to this policy.

t. ***Research*** means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term "Research" is intended to encompass basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes, but is not limited to, any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract whether authorized under the Public Health Service Act (42 U.S.C. 201, et seq.) or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. For the purposes of this policy, "Research" also includes educational activities funded by the National Science Foundation (NSF).

u. ***Senior/Key Personnel*** means the PD/PI and any other person identified as senior/key personnel by CSHS in the grant application, progress report, or any other report submitted to the PHS by CSHS; or in any other sponsored Research application and/or agreement.

v. ***Significant Financial Interest*** **("SFI")** means:

   I. An ownership interest in a publicly-traded Industry or Vendor company provided the ownership interest is valued at $5,000 or more and the ownership interest was purchased at the specific direction of the Covered Individual, or his/her spouse, registered domestic partner, or dependent children;

   II. An ownership interest in a privately-held Industry or Vendor company regardless of the current value of the ownership interest provided the ownership interest is personally held by the Covered Individual or his/her spouse, registered domestic partner, or dependent children;

III. A Leadership Role in an Industry or Vendor company held by a Covered Individual or his/her spouse, registered domestic partner, or dependent children;

IV. Extramural Professional Activities performed for or on behalf of an Industry or Vendor company by a Covered Individual or his/her spouse, registered domestic partner, or dependent children provided the total payments, of all forms (e.g., income from intellectual property rights and interests, consulting fees, honoraria, travel, meals, etc.), totaled $5000 or more for the twelve-month period preceding the last required disclosure in the PASSPORT system as outlined in this policy;

V. Travel sponsored or reimbursed by an Industry or Vendor company, provided the estimated value of the sponsored or reimbursed travel was $5000 or more, to include travel involving a Covered Individual's spouse, registered domestic partner, or dependent children. When required, a disclosure of reimbursed or sponsored travel will include the following information: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; (iv) the duration of the trip; and (v) the name(s) of the Covered Individual's spouse, registered domestic partner and/or dependent children if they received reimbursed or sponsored travel;

VI. The term SFI does not include the following types of Financial Interests:

- Salary, royalties, or other remuneration paid by CSMC to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by CSHS, including payments of a share in royalties by CSMC related to the Covered Individual's assignment of intellectual property rights to CSMC pursuant to CSMC's *Patents & Inventions Policy: Technology Transfer*;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, 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 advisory committees or review panels for a Federal, state, or local government agency, 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.

w. ***Vendor(s)*** means any entity, or the employee or agent of any entity, which currently provides, or is in a position to provide, goods and/or services to CSHS. CSMC hospital-based physician groups, and their owners, members, and employees, are not considered Vendors for purposes of this policy. Physician groups affiliated with CSMCF, and their owners, members, and employees, are not considered Vendors for purposes of this policy. Members of the CSHS Medical Staff are also not considered Vendors for purposes of this policy.

2. The Committee for Management of Industry Relations and Conflicts of Interest has the authority to provide clarification or explanation of the terms defined above for purposes of applying the provisions of this policy.

POLICY ADMINISTRATION:

1. **Committee for Management of Industry Relations and Conflicts of Interest ("IR/COI Committee"):**
   a. The IR/COI Committee is responsible for the following:
      I. Reviewing, or causing to be reviewed, all disclosures of FIs and other interests required under the provisions of this policy;
      II. Determining, or causing to be determined, whether each SFI disclosed is related to Research, and if so, whether the SFI is an FCOI. An SFI is "related to" Research if the IR/COI Committee reasonably determines that the SFI could be affected by the Research or is in an entity whose financial interest could be affected by the Research or that the research could be affected by the SFI. An FCOI exists if the IR/COI Committee reasonably determines that the related SFI meets the definition of FCOI set forth in this policy;
      III. Developing, or causing to be developed, a Management Plan that specifies the actions that have been or will be taken to manage the FCOI, and ensuring

that responsible CSHS executive and management staffs have implemented the Management Plan. In instances where an FCOI affects PHS- or other Federally-funded human subject research, the CSMC Institutional Review Board (IRB) with responsibility for approving the research will retain authority to determine if the research is allowed to proceed under the terms of the Management Plan developed by the IR/COI Committee;

IV. Reporting to the CSHS President/CEO the IR/COI Committee's determinations under items 1.a.II and 1.a.III above, as well as any other matter regarding the Industry and Vendor relations and Extramural Professional Activities of Covered Individuals that the President/CEO directs or that the IR/COI Committee determines warrants reporting;

V. Reviewing and assessing all instances of Institutional Conflicts of Interest ("ICOI") in accordance with the Institutional Conflict of Interest Policy: Corporate Integrity Program;

VI. Providing CSHS's President and CEO with policy recommendations that the IR/COI Committee judges may enhance or refine processes and practices in the management of industry relations and conflicts of interest;

VII. Fulfilling any other duties or responsibilities assigned to it by CSHS's President and CEO.

b. The IR/COI Committee is CSHS's designated Institutional Official ("IO") for purposes of complying with the requirements of 42 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors). The IR/COI Committee is therefore also responsible for all reporting required under these requirements.

2. Industry Relations/Conflict of Interest Program ("IR/COI Program"):

a. Cedars-Sinai will, from time to time, establish and maintain an Industry Relations/Conflict of Interest Program ("IR/COI Program"). The President and CEO will assign responsibility for the IR/COI Program to one or more Cedars-Sinai executives as needed to ensure the proper functioning of the Program. The IR/COI Program and its staff will have all administrative responsibilities associated with the implementation of this policy, including, but not limited to, the following:

I. Administering the COI disclosure process for Covered Individuals;
II. Administering the process for pre-approval of Industry and Vendor relations and other Extramural Professional Activities for Covered Individuals;
III. Administering the process for pre-approval of Medico-Legal Services provided by Covered Individuals;
IV. Providing advice and counsel on policy standards and precedents to those with authority to approve Industry and Vendor relations, other Extramural Professional Activities, as well as Medico-Legal Services provided by Covered Individuals;
V. Providing staffing support, as well as advice and counsel, for the IR/COI Committee in the conduct of its responsibilities under this policy;
VI. Providing, or causing to be provided, all training required by applicable conflict of interest laws and regulations or that might otherwise be necessary for the implementation of this policy;
VII. Fulfilling any other responsibilities that may be assigned, from time to time, by the President and CEO in order to assist CSHS in the conduct and enhancement of its Industry and Vendor relations.

b. In carrying out its administrative responsibilities under this policy, the IR/COI Program and its staff will act in accordance with any policy decisions, interpretations of policy requirements, or FCOI determinations made by the IR/COI Committee.

POLICY IMPLEMENTATION MEASURES:

1. **Disclosures of Industry- or Vendor-Related FIs and/or Extramural Professional Activities:**
   a. **Covered Individuals:** The disclosure provisions of this policy apply to the following members of the CSHS community:
      - Executives (except for those whose annual disclosure requirement is set by the Board of Director's conflict of interest policy);
      - Department Chairs and Vice Chairs;
      - Directors of CSMC Institutes;
      - CS faculty;
      - Physicians with Participation Agreements in CSMC Centers of Excellence, or their equivalent;

- Members of CSHS Medical Staff serving in leadership positions, whether elected or appointed, to include members of Medical Staff committees;
- CSMCF physicians;
- Management staff at the Director level or equivalent;
- Investigators funded in part or whole by a PHS or other Federal agency research grant or contract;
- Investigators serving as PIs/PDs on human subject research conducted under CSHS IRB approval regardless of funding;
- Advance Practice Nurses serving in certain job classifications as determined by the Chief Nursing Officer (CNO);
- CSHS employees serving as buyers on behalf of CSHS;
- Independent contractors functioning in positions that might normally be filled by CSHS employees who are Covered Individuals as identified above;
- Other members of the CSHS community as may be directed to disclose by the President/CEO.

b. Covered Individuals will be required to complete a no-less-than annual disclosure of all FIs in and Extramural Professional Activities performed on behalf of, Industry or Vendors, as well as Medical-Legal Service. For some Covered Individuals, the annual disclosure process may take the form of a review and updating of previously pre-approved Extramural Activities, as well as publicly available information on the Covered Individual's FIs with Industry and Vendors. Industry- or Vendor-related FIs of a Covered Individual's spouse, domestic partner, or dependent child are attributable to the Covered Individual himself/herself and must be disclosed as such.
c. The IR/COI Committee will be responsible for approving the design, timing, and content of the annual disclosure process.
d. The IR/COI PROGRAM will have administrative responsibility for the conduct of annual disclosures by Covered Individuals.
e. The annual disclosure process will be designated "CSHS Annual Industry Relations Review" (Industry Relations Review) process.
f. Investigators will have additional disclosure requirements as provided below in "Special Provisions for Investigators Engaged in PHS- and Other Federally-Funded Research."

2. **Pre-Approval Requirement for Industry or Vendor Involvement:**
    a. **Covered Individuals:** The pre-approval for Industry or Vendor involvement provisions of this policy apply to the following members of the CSHS community:
        - Executives;
        - Department Chairs and Vice Chairs;
        - Directors of CSMC Institutes;
        - CS faculty;
        - CSMCF physicians;
        - Non-Faculty PIs and Co-PIs who are CSHS employees;
        - Management staff at the Director level or equivalent;
        - Independent contractors functioning in positions that might normally be filled by CSHS employees or staff who are Covered Individuals as identified above.

    b. Covered Individuals, as defined in 2.a. above, must receive prior approval, as provided below, for the following FIs and Extramural Professional Activities:
        I. The acquisition of any ownership interest in an privately-held Industry or Vendor company, or in any hospital or health system (other than those acquired through managed investment and/or retirement accounts);
        II. The assumption of any leadership role in an Industry or Vendor company, or in a hospital or health system, regardless of compensation; and
        III. Any Extramural Professional Activities provided to or on behalf of an Industry or Vendor company, or hospital or health system.

    c. Pre-approval is not required for engaging in Academic Activities as defined by this policy. Faculty may be offered a time-away allowance, of up to 20 days for full-time faculty, during which faculty may be engaged in Academic Activities away from CSHS. CSHS may, from time to time, establish other requirements for tracking a faculty member's time away from the Medical Center for Academic Activities and other outside Extramural Professional Activities; as well as other requirements for receiving reimbursement for expenses incurred during time-away associated with Academic Activities.

    d. See Section "Other Provisions" (below) for additional requirements regarding the pre-approval of Extramural Professional Activities.

3. **Pre-Approval Requirement for Medical-Legal Services:**
    a. **Covered Individuals:** The pre-approval requirement for Medical-Legal Services applies to the following members of the CSHS community:
        - Executives;
        - Department Chairs and Vice Chairs;
        - Directors of CSHS Institutes;
        - Management staff at the Director level or equivalent;
        - CS faculty;
        - CSMCF physicians;
        - Independent contractors functioning in positions that might normally be filled by CSHS employees who are Covered Individuals as identified above.
    b. Covered Individuals, as defined in 3.a. above, must also receive prior, written approval as provided below for all Medical-Legal Service. For example, a faculty member or CSMCF physician must receive prior, written approval to provide services to an attorney or law firm in preparation for the initiation or conduct of litigation. The following examples of Medical-Legal Service do not require pre-approval, but do require disclosure:
        I. Physician is subpoenaed as the treating physician to testify, even if not the plaintiff or defendant;
        II. Physician is the treating physician for a worker's comp case and must testify;
        III. Physician is deposed as the treating physician;
        IV. Physician is asked to provide a written opinion but has not yet agreed to take the case.
    c. Medical-Legal Service will not be subject to the special reporting requirements of Investigators as described below.
    d. See Section "Other Provisions" (below) for additional requirements regarding the pre-approval of Extramural Professional Activities.

4. **Recusal Requirements for Covered Individuals with Industry or Vendor Relations:**

a. **Covered Individuals:** The recusal provisions of this policy apply to the following members of the CSHS community:
    - Full- and part-time CSHS employees, both exempt and non-exempt;
    - CS faculty;
    - CSMCF physicians;
    - Non-employed physicians functioning, under contract, as CSHS medical directors, program directors, and CSHS Institute directors;
    - Members of CSHS Medical Staff functioning in a Medical Staff leadership position, to include members of Medical Staff committees;
    - Members of CSMC hospital-based physician groups functioning in their CSMC role, provided compliance with this policy is included as a provision of the hospital-based physician group's contract with CSMC;
    - Physicians with participation agreements in CSMC Centers of Excellence, or their equivalent, provided compliance with this policy is included as a provision of the physician's participation agreement with CSMC;
    - Independent contractors functioning in positions that might normally be filled by CSHS employees;
    - Healthcare professionals-in-training, to include medical students, residents, (ACGME and non-ACGME) fellows, PhD candidates, post-doctoral fellows, nursing students, and allied health students;

b. Any Covered Individual, as defined in 4.a. above, with an FI in an Industry or Vendor company, whether or not that FI must be otherwise disclosed to CSHS under the terms of this policy, must recuse himself or herself from any purchasing or other business decision affecting the Industry or Vendor company with whom the Covered Individual has an FI.
    I. The Covered Individual must disclose the FI to the other members of the committee, work group, or process which will make the purchasing or other business decision prior to any decision being made;
    II. The Covered Individual with the FI in the affected Industry entity or Vendor may participate in discussions regarding a product or service to be purchased provided that the FI has already been disclosed;

III. The Covered Individual with the FI may not be present when a purchasing or other business decision is made.

c. The IR/COI Committee has authority to grant exceptions to this recusal requirement.

5. Gifts, Gratuities, and Offers of Entertainment from Industry and Other Vendors:

a. **Covered Individuals**: The gift provisions of this policy apply to the following members of the CSHS community:
- Full- and part-time CSHS employees, both exempt and non-exempt;
- CS Faculty;
- CSMCF physicians;
- Non-employed physicians functioning, under contract, as CSHS medical directors, program directors, and CSHS Institute directors;
- Members of CSHS Medical Staff functioning in a Medical Staff leadership position, to include members of Medical Staff committees;
- Members of CSMC hospital-based physician groups functioning in their CSMC role, provided compliance with this policy is included as a provision of the hospital-based physician group's contract with CSMC;
- Physicians with participation agreements in CSMC Centers of Excellence, or their equivalent, provided compliance with this policy is included as a provision of the physician's participation agreement with CSMC;
- Independent contractors functioning in positions that might normally be filled by CSHS employees;
- Healthcare professionals-in-training, to include medical students, residents, (ACGME and non-ACGME) fellows, PhD candidates, post-doctoral fellows, nursing students, and allied health students.

b. CSHS wishes to establish and maintain, to the extent reasonably possible, an environment free of Industry-provided or Vendor-provided gifts, offers of entertainment, and other gratuities. This goal of gift-free environment pertains to:

I. Personal gifts, regardless of value;

II. Free meals, whether provided on or off campus, regardless of value;

III. Offers of entertainment (e.g., tickets to sporting events, concerts, etc.), regardless of value;

IV. Compensation, or any other forms of gratuity, offered for listening to a sales talk by an Industry or Vendor representative;
V. Compensation, or any other forms of gratuity, offered for prescribing medications;
VI. Compensation or any other forms of gratuity, including reimbursement for travel-related costs, for attending a professional conference or Industry-sponsored or Vendor-sponsored event, where the Covered Individual is not speaking or otherwise actively participating or representing CSHS at the event;
VII. Any other items or services offered as a gratuity by Industry or Vendor representatives.

c. CSHS's establishment of a gift-free environment does not apply to holiday gifts from Vendors or Industry representatives provided (1) the gift is consumable (e.g., food, candy, non-alcoholic beverages, etc.); (2) the gift is $200 or less in value; (3) the gift is intended for the benefit of an entire department, office, or unit; and (4) the manager of the department, office, or unit has expressly authorized the acceptance of the gift.
d. CSHS's establishment of a gift-free environment also does not apply to personal gift giving between a Covered Individual and a Vendor or Industry representative with whom the Covered Individual has a family relationship or with whom the Covered Individual has a personal relationship that pre-dates any vendor relationship.
e. Gifts, entertainment, and other gratuities offered by patients, their families, members of CSHS's Medical Staff, and CSHS benefactors are permitted subject to any other policies that CSHS may, from time to time, establish.
f. CSHS intends to create this gift-free environment through the voluntary cooperation and "self-policing" of Covered Individuals.

6. Commercial Support for Training and Educational Programs:

a. **ACCME Programs:**

I. Vendor and Industry support for all CME programs at CSHS must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support (Standards to Ensure the Independence of CME Activities); as these standards may from time to time be revised or amended;

II. All other Cedars-Sinai education or training programs for which Vendor or Industry support is provided must also meet all requirements in the ACCME Standards for Commercial Support, even if the education or training program is not CME approved.

b. **ACGME and Other Training Programs:**

I. Vendor or Industry support for healthcare professionals in training at CSHS includes, but is not limited to:

1. Educational material, including textbooks and reference books;
2. Reimbursement for travel, or travel directly provided;
3. Salary support;
4. Support for research activities; and
5. Honoraria.

II. Such support is permitted only if:

1. The support promotes or furthers the specific educational goals of the training program;
2. Except for educational materials such as textbooks, the support is provided to the training program, and the training program is at liberty to control and direct the support to its trainees in whatever manner the program deems appropriate;
3. Textbooks and other educational materials may be accepted directly by trainees;
4. In the case of salary support, the support is pre-approved by the program director.

III. Training programs must report quarterly to their Chairs and Vice Presidents any Vendor or Industry support provided to their trainees in the previous quarter.

SPECIAL PROVISIONS FOR INVESTIGATORS ENGAGED IN PHS- AND OTHER FEDERALLY-FUNDED RESEARCH:[1]

[1] The provisions in this section regarding PHS-funded Research also apply to Research funded by (1) any philanthropic organization that requires compliance with PHS FCOI regulations, including 425 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors), and (2) the California Institute for Regenerative Medicine (CIRM).

1. **Covered Individuals:** For purposes of these Special Provisions for Investigators Engaged in PHS- and Other Federally-Funded Research, "Covered Individuals" are Investigators, as defined by this policy.

2. **Conflict of Interest Management in PFS- and Other Federally-Funded Research:**
   - **a. Special Disclosure Requirements:** Each Investigator who is planning to participate or who is currently participating in PHS- or other Federally-funded Research is responsible to ensure that the IR/COI Committee, as CSHS's "designated official," has the latest information on the Investigator's Industry- or Vendor-related FIs (and those of his/her spouse, registered domestic partner, and/or dependent children) as well as the Investigator's Extramural Professional Activities (excluding Medical-Legal Services) on the following four (4) occasions:
     - I. Prior to the time the Investigator submits an application or proposal for PHS- or other Federally-funded Research;
     - II. Prior to the investigator's expenditure or use of any newly awarded PHS- or other Federal-funding;
     - III. During the annual Industry Relations Review conducted under the auspices of the IR/COI Committee; and
     - IV. Within 30 days of the Investigator discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; unless the SFI was pre-approved as provided in 2.b above.
       1. In particular, Investigators will be required to provide the following information on any industry- and/or Vendor-related sponsored or reimbursed travel within 30 days of the conclusion of travel:
          a. The purpose of the trip;
          b. The identity of the sponsor/organizer;
          c. The destination;
          d. The duration of the trip; and
          e. The name(s) of the Covered Individual's spouse, registered domestic partner and/or dependent children if they received reimbursed or sponsored travel.

b. **Determinations of Financial Conflicts of Interest (FCOI) of PHS- and Other Federally-Funded Investigators:** Prior to CSHS's expenditure of any funds under a PHS- or other Federally-funded Research project (or prior to the application submission, if required by the Federal funding agency) and upon any disclosure by an Investigator as required by this policy, the IR/COI Committee shall:
    I. Review an Investigator's Industry- or Vendor-related FIs and Extramural Professional Activities;
    II. Determine whether any disclosed FI or Extramural Professional Activity qualifies as an SFI;
    III. Determine whether any SFI, determined to exist, relates to PHS- or other Federally-funded Research; and
    IV. Determine whether any related SFI constitutes an FCOI that requires a Management Plan, a report to the PHS Awarding Component or other Federal agency, and a public disclosure upon request.

c. **Management of FCOI for PHS- and Other Federally-Funded Investigators:** If an FCOI is determined to exist, the IR/COI Committee will take such actions as necessary to manage the FCOI. Management of an identified FCOI must include development and implementation of a Management Plan that specifies the actions that have been or will be taken to manage such FCOI, and might include, if necessary, a retrospective review and a mitigation report, as further described below. In instances where an FCOI affects PHS- or other Federally-funded human subject Research, the CSHS Institutional Review Board (IRB) with responsibility for approving the research will retain authority to determine if the research is allowed to proceed under the terms of the Management Plan developed by the IR/COI Committee. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:
    I. Public disclosure of the FCOI (e.g., when presenting or publishing the Research results);
    II. For Research involving human subjects, disclosure of the FCOI directly to participants in the informed consent document or other communication to the potential study participant;
    III. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the Research against bias

resulting from the FCOI;

IV. Modification of the Research plan;

V. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

VI. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

VII. Severance of relationships that create financial conflicts.

d. Review and Management of Disclosures of NEW FCOIs: Whenever, in the course of an ongoing PHS- or other Federally-funded Research project, an Investigator who is new to participating in the Research project discloses an Industry- or Vendor-Related FI or Extramural Professional Activity, or an existing Investigator discloses sufficient information about a new Industry- or Vendor-Related FI or Extramural Professional Activity, the IR/COI Committee shall, within 60 days:

I. Review the Industry- or Vendor-Related FI or Extramural Professional Activity and determine whether it constitutes an SFI;

II. Determine whether the SFI is related to PHS- or other Federally-funded Research;

III. Determine whether an FCOI exists; and, if so,

IV. Implement, on at least an interim basis, a Management Plan that specifies the actions that have been or will be taken to manage such FCOI. Depending on the nature of the SFI, the IR/COI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS- or other Federally-funded Research between the date of disclosure and the completion of the IR/COI Committee's review.

e. Review and Management of Existing FCOIs Not Previously Disclosed: Whenever the IR/COI Committee identifies an Industry- or Vendor-Related FI or Extramural Professional Activity that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by CSHS during an ongoing PHS- or other Federally-funded Research project (e.g., was not timely reviewed or reported by a sub-recipient), the IR/COI Committee shall, within 60 days after receiving sufficient information about the existing FCOI in question:

I. Review the Industry- or Vendor-Related FI or Extramural Professional Activity

and determine whether it constitutes an SFI;

II. Determine whether it is related to PHS- or other Federally-funded Research;

III. Determine whether an FCOI exists; and, if so,

IV. Implement, on at least an interim basis, a Management Plan that specifies the actions that have been or will be taken to manage such FCOI going forward.

f. Retrospective Reviews: Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an Industry- or Vendor-Related FI as well as Extramural Professional Activity that is determined by the IR/COI Committee to constitute an SFI and FCOI, failure by the IR/COI Committee to review or manage a disclosed SFI and FCOI, or failure by the Investigator to comply with a Management Plan, then the IR/COI Committee shall, within 120 days of a determination of noncompliance, cause to be completed, by appropriate parties (e.g., the CSHS Scientific Integrity Committee, the Legal Affairs Department and/or the Corporate Integrity Program, as the case may be), a retrospective review of the Investigator's activities and the PHS- or other Federally-funded Research project to determine whether any PHS- or other Federally-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. The IR/COI Committee must document the retrospective review, and such documentation will include, but not necessarily be limited to, all of the following key elements:

I. Project number;

II. Project title;

III. PD/PI or contact PD/PI if a multiple PD/PI model is used;

IV. Name of the Investigator with the FCOI;

V. Name of the entity with which the Investigator has an FCOI;

VI. Reason(s) for the retrospective review;

VII. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

VIII. Findings of the review; and

IX. Conclusions of the review.

g. Actions Following Retrospective Review; Mitigation Reports: Based on the results of the retrospective review described above, the IR/COI Committee shall, if appropriate,

update, or cause to be updated, any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

I. If bias is found in a PHS-funded Research project, the IR/COI Committee will notify, or caused to be notified, the PHS Awarding Component promptly and submit, or caused to be submitted, a mitigation report to the PHS Awarding Component. If bias is found in other Federally-funded Research projects, the notification and report requirements of the pertinent funding agency, if any, are followed.

II. For PHS-funded Research, the mitigation report must include, at a minimum, the key elements documented in the retrospective review (listed above), a description of the impact of the bias on the Research, and the IR/COI Committee's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research; 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);

III. Thereafter, for PHS-funded Research, the IR/COI Committee will submit, or cause to be submitted, FCOI reports annually, as specified elsewhere in this policy;

IV. Depending on the nature of the FCOI, the IR/COI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS- or other Federally-funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the IR/COI Committee's retrospective review.

h. Monitoring Compliance with Management Plan: Whenever the IR/COI Committee directs that a Management Plan be implemented under this policy, the IR/COI Committee will monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the PHS- or other Federally-funded Research project.

i. Enforcement: CSMC has established adequate enforcement mechanisms, including providing for employee sanctions or other administrative actions, to ensure Investigator compliance with this policy, as appropriate. When needed sanctions or other administrative actions will be applied in accordance Human

Resources policies to include *Performance Management: Corrective Actions – Non-Bargaining Unit Policy: Human Resources/Organizational Development (available in PPM)* and/or Medical Staff policies to include *Medical Staff Rules and Regulations* (also available in PPM). The IR/COI Committee will monitor whether such enforcement mechanisms are in place and available to CSMC management when dealing with non-compliance of this policy. The IR/COI Committee will report to the President and CEO any deficiencies it finds in monitoring these enforcement mechanisms.

j. Reporting FCOI to PHS Awarding Component and Other Federal Agencies: Prior to CSHS's expenditure of any funds under a PHS- or other Federally-funded Research project (or prior to the application submission, if required by the Federal funding agency), the IR/COI Committee shall provide, or cause to be provided, to the PHS Awarding Component or other Federal agency, as appropriate, an FCOI report regarding any Investigator's SFI found by the IR/COI Committee to be a reportable FCOI and ensure that CSHS management has implemented a Management Plan in accordance with the provisions of this policy.

I. In cases in which the IR/COI Committee identifies an FCOI which is eliminated prior to the expenditure of PHS-awarded funds, the IR/COI Committee shall <u>not</u> submit an FCOI report to the PHS Awarding Component;

II. For any SFI that the IR/COI Committee identifies as a reportable FCOI subsequent to any initial FCOI report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the Research project), the IR/COI Committee shall provide to the PHS Awarding Component, within 60 days of the disclosure, an FCOI report regarding the newly disclosed reportable FCOI and ensure that CSHS management has implemented a Management Plan in accordance with the provisions of this policy. For other Federally-funded research, a Management Plan is also implemented, and the notification and report requirements of the pertinent funding agency, if any, are followed;

III. Pursuant to item 2(f) above, where such FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the IR/COI Committee or managed by CSHS

management (e.g., was not timely reviewed or reported by a sub-recipient), the IR/COI Committee will also cause to be completed a retrospective review to determine whether any PHS- or other Federally-funded Research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such Research;

IV. Additionally, pursuant to item 2(g) above, if bias is found in a PHS-funded Research project, the IR/COI Committee will notify, or cause to be notified, the PHS Awarding Component promptly and submit, or cause to be submitted, a mitigation report to the PHS Awarding Component. If bias is found in other Federally-funded Research projects, the notification and report requirements of the pertinent funding agency, if any, are followed;

V. Any FCOI report required under items (i) or (ii) above shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of CSHS's Management Plan. Elements of the FCOI report submitted to the PHS Awarding Component shall include, but are not necessarily limited to, the following:

- Project/Contract number;
- 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 an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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;
- A description of how the financial interest relates to the PHS-funded Research and the basis for the IR/COI Committee's determination that the financial interest conflicts with such Research; and
- A description of the key elements of CSHS's Management Plan, including:

(a) role and principal duties of the conflicted Investigator in the Research project; (b) conditions of the Management Plan; (c) how the Management Plan is designed to safeguard objectivity in the Research project; (d) confirmation of the Investigator's agreement to the Management Plan; (e) how the Management Plan will be monitored to ensure Investigator compliance; and (f) other information as needed;

VI. For any FCOI previously reported by CSHS with regard to an ongoing PHS-funded Research project, CSHS will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. CSHS will provide annual FCOI reports to the PHS Awarding Component for the duration of the Research project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

k. Public Disclosure of FCOI of PHS-Funded Investigators: Prior to CSHS's expenditure of any funds under a PHS-funded Research project, CSHS will ensure public accessibility, via written response to any requestor within 5 business days of receipt of a request, of information concerning any SFI that the IR/COI Committee determines to be a reportable FCOI in PHS-funded Research that is still held by Senior/Key Personnel of such Research.

I. In order to receive information on a Senior/Key Personnel's reportable FCOI in PHS-funded Research, a requestor must submit his/her request in writing to the following:

Manager, IR/COI Program
Corporate Integrity Program
Cedars-Sinai Health System
8700 Beverly Blvd.
Los Angeles, CA 90048

II. The request for information must specify the PHS-funded research project for which the information is requested. CSHS will not honor requests for information that are not sent to the above listed party and address and/or that do not specify the PHS-funded research project. Email requests for information or

postings to CSHS's internet website will not be honored;

III. For requests that meet the above requirements, the IR/COI Committee shall make available, via a written response, the following information regarding the Senior/Key Personnel's reportable FCOI:
   1. Senior/Key Personnel's name;
   2. Senior/Key Personnel's title and role with respect to the Research;
   3. Name of the entity in which the SFI is held;
   4. Nature of the SFI; and
   5. Approximate dollar value of the SFI, stated in the following dollar ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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;

IV. The IR/COI Committee will note in each written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the IR/COI Committee's identification of any new FCOI. Information concerning the SFI of an individual Investigator subject to this item (k) will remain available for responses to written requests for at least 3 years from the date that the information was most recently updated.

l. Records Maintenance and Records Access: CSHS's IR/COI PROGRAM will maintain records relating to all Investigator disclosures of financial interests and CSHS's review of, and response to, such disclosures (whether or not a disclosure resulted in CSHS's determination of an FCOI) and all actions under this policy or retrospective review, if applicable, for the longest of the following:

I. At least 3 years:
   1. From the date the final expenditures report is submitted to the PHS or other Federal agency;
   2. From, where applicable, the starting dates specified in 45 CFR 74.53(b) and/or 45 CFR 92.42(b);
   3. From the date of final payment; or

4. Where applicable, for the time periods specified in 48 CFR Part 4, Subpart 4.7.

II. Until resolution of any Federal agency action involving those records.

m. Certifications Related to Research Funding Applications and Contract Proposals: In each of its applications for Research funding and contract proposals to which 42 CFR Part 50 Subpart F or 45 CFR Part 94 applies, CSHS, through its Vice President for Research or his/her designee, will certify that it:

I. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all Research projects for which funding is sought or received from the PHS;

II. Will promote and enforce Investigator compliance with the requirements of 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, including those pertaining to disclosure of SFIs;

III. Will manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable;

IV. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and CSHS's review of, and response to, such disclosure, whether or not the disclosure resulted in CSHS's determination of an FCOI; and

V. Will fully comply with the requirements of 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable.

3. **Training:** The IR/COI Committee will inform each Investigator of CSHS's policy on FCOIs as set forth herein, the Investigator's responsibilities regarding disclosure of SFIs, and of the federal regulations underlying this policy. CSHS will require each Investigator to complete training regarding these elements prior to engaging in research related to any PHS-funded grant or contract and at least every 4 years, and immediately when any of the following circumstances apply:
   a. If CSHS revises this policy in any manner that affects the requirements of Investigators;
   b. If an Investigator is new to CSHS; or

c. If CSHS finds that an Investigator is not in compliance with this policy or a Management Plan developed under this policy.

4. **Sub-recipient Contract Requirements:** If CSHS carries out PHS-funded Research through a sub-recipient (e.g., subcontractors or consortium members), CSHS, as the awardee institution, will take reasonable steps to ensure that any sub-recipient Investigator complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, by:
   a. Incorporating as part of a written agreement with the sub-recipient terms that establish whether this policy or the sub-recipient's own FCOI policy will apply to the sub-recipient's Investigators.
      I. If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to CSHS's policy for disclosing SFIs that are directly related to the sub-recipient's work for CSHS;
      II. Additionally, if the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the agreement referenced above shall specify time period(s) for the sub-recipient to report all identified FCOIs to the IR/COI Committee. Such time period(s) shall be sufficient to enable the IR/COI Committee to provide timely FCOI reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable**;**
      III. Alternatively, if the sub-recipient's Investigators must comply with CSHS's policy, the agreement referenced above shall specify the manner and timing in which the sub-recipient's investigators are to disclose SFIs to the IR/COI Committee. Such time period(s) shall be sufficient to enable the IR/COI Committee to comply timely with its review, management, and reporting obligations under 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable.
   b. Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all sub-recipient Investigators consistent with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. However, in instances where the sub-recipient is required

by the sub-recipient agreement to comply with CSHS's policy, this reporting requirement will be carried out by and through the IR/COI Committee.

5. **CSHS Cooperation with PHS Awarding Component and HHS Regarding Remedies**:
    a. If the IR/COI Committee determines that the failure of an Investigator to comply with this policy or an FCOI Management Plan biased the design, conduct, or reporting of the PHS-funded Research, the IR/COI Committee will promptly notify, or cause to be notified, the PHS Awarding Component of the corrective action taken or to be taken by CSHS. If the PHS Awarding Component refers the matter back to CSHS for further action with directions on how to maintain appropriate objectivity in the PHS-funded Research project, CSHS will cooperate with such directions;
    b. CSHS acknowledges that the PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the IR/COI Committee's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the IR/COI Committee's determination of a reportable FCOI.
        I. CSHS will, as requested by the PHS Awarding Component and/or HHS, submit or permit on site review of all records pertinent to compliance with 42 CFR Part 50 Subpart F and 45 CFR Part 94, with the understanding that, to the extent permitted by law, the PHS Awarding Component and/or HHS will maintain the confidentiality of all records of financial interests;
        II. CSHS acknowledges that, the PHS Awarding Component may decide, based on its review, that a particular FCOI will bias the objectivity of the PHS-funded Research to such an extent that further corrective action is needed or that CSHS has not managed the FCOI in accordance with 42 CFR Part 50 Subpart F or 45 CFR Part 94, and that the PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding, or the issuance of a Stop Work Order by the Contracting Officer, or other enforcement action, such as under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.
    c. In any case in which the HHS determines that a PHS-funded Research project 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 reportable FCOI that was not managed or reported by CSHS as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, CSHS will require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

OTHER PROVISIONS:

1. **Provisions Regarding the Pre-approval of Industry- and/or Vendor-related FIs and Extramural Professional Activities:**
    a. Requests for pre-approval of the acquisition of any ownership interest in a Industry or Vendor company, or in any hospital or health system; or the assumption of any leadership role in an Industry or Vendor company, or in a hospital or health system, regardless of compensation; or the provision of any service or set of services (Extramural Professional Activities) to or on behalf of an Industry or Vendor company, or hospital or health system; as well as for any Medical-Legal Consulting must be submitted using forms or web-based tools as may be developed from time to time under the direction the IR/COI Committee. The IR/COI Committee will also be responsible for determining the type of information necessary to provide for pre-approval;
    b. The failure of the requestor to provide any information that may be requested by the IR/COI Committee or the CSHS official with authority to approve the request may result in a denial of the request for approval;
    c. Information provided in a request for approval will be judged in its totality in determining whether an Industry- or Vendor-Related FI or Extramural Professional Activity, or Medical-Legal Service, is approved or disapproved;
    d. Industry- or Vendor-related FIs and Extramural Professional Activities, as well as Medical-Legal Service, must be pre-approved, in writing, by the following individuals:

COVERED INDIVIDUALS	APPROVING AUTHORITY
CS Faculty	Faculty Member's Primary Chair (Primary chair may consult with SVP Academic Affairs/Dean of Medical Faculty, Institute Directors and/or others for purposes of approval)

Vice Chairs	Department Chair
Chairs and Institute Directors	SVP Academic Affairs/Dean of Medical Faculty
Non-Faculty PIs and Co-PI	Department Chair or Institute Director over area of research
CSMCF Physicians	CEO of CSMCF, or designee
Exempt Employees	Supervising Vice President
Independent Contractors	Supervising Vice President
Vice Presidents	Immediate Supervisor
Senior Vice Presidents	President and CEO
President and CEO	Chair, Board of Directors

e. Using forms or web-based tools as may be developed from time to time under the direction of the IR/COI Committee, the approving authority will approve or disapprove the Industry- or Vendor-Related FI or Extramural Professional Activity, or Medical-Legal Service, in a timely fashion relative to the facts of the request. Disapprovals must be made with specificity of the reasons or factors that justify the disapproval;

f. An approving authority, listed above, may approve "retrospectively" an Industry- or Vendor-Related FI or Extramural Professional Activity, or Medical-Legal Service, already held or performed by a Covered Individual, provided:
   I. The reason(s) why the interest or activity was not pre-approved provides a reasonable basis on which to excuse the failure of the individual to secure pre-approval of the interest or activity;
   II. CSHS has suffered no detrimental effect by the existence of the interest or activity; and
   III. The interest or activity would have been pre-approved;

g. In the case of an Industry- or Vendor-Related FI or Extramural Professional Activity, or Medical-Legal Service, existing prior to employment and expected to continue during employment, the hiring authority for the prospective Covered Individual must approve

in writing the interest or activity immediately following the acceptance by the candidate of a formal employment or contract offer. This policy should be provided to the new recruit as part of the recruitment process, and the approval or disapproval of Industry- or Vendor-Related FIs or Extramural Professional Activities, or Medical-Legal Service, shall be communicated to the IR/COI Committee and memorialized in the individual's contract with CSHS;

h. Except where CSHS may itself be a party to an agreement under which a Covered Individual is providing Extramural Professional Activities, approved Extramural Professional Activities may not be performed using CSHS equipment, supplies, facilities or personnel. The Activities must be conducted on the employee's own time either after or before his or her working hours or using vacation or holiday accruals (PTO). While performing approved Activities, Covered Individuals will be expected to comply with the requirements of CSHS policy on Time and Effort Reporting, if applicable, as well as applicable CSHS policies on approval of PTO;

i. An individual, who engages in approved Extramural Professional Activities, or Medical-Legal Service, does so independently of CSHS, unless a senior vice president expressly authorizes in writing the individual to act on behalf of CSHS. Unless such approval is provided in writing, the individual is not authorized to represent that he or she is acting on behalf of or as an agent of CSHS. CSHS does not provide any insurance coverage for Extramural Professional Activities or Medical-Legal Service, and CSHS's approval of any activities does not confer any insurance coverage, defense or indemnity obligations on CSHS with respect to such activities;

j. An individual may appeal a disapproval of a proposed Industry- or Vendor-Related FI or Extramural Professional Activity, or Medical-Legal Service, to the next level of authority for the individual. The appeal must be in writing, and must specify in detail the fact-specific reasons why the disapproval should be reconsidered. The institutional official to whom the appeal is submitted will have a reasonable period of time to consider and respond to the appeal. The decision by this official regarding the appeal will be final;

k. Marketing activities or participation in ghostwriting arrangements will not, under any circumstances, be approved for Covered Individuals.

    1. For purposes of this policy, active participation in an Industry- or Vendor-sponsored speaking engagement may be approved under the terms of this

policy, provided all of the following conditions are met:

- The participant/speaker and not the Industry- or Vendor-sponsor determines the content of the presentation;
- The participant/speaker is expected and intends to provide a fair and balanced assessment of any products or services discussed and to promote objective scientific and educational activities and discourse;
- The participant/speaker is not required by the Industry- or Vendor-sponsor to accept advice or services concerning speakers, content, etc. as a condition of the sponsor's compensation or contribution of funds or services; except, the participant/speaker may comply with Industry- or Vendor-sponsor directions or requirements for complying with FDA, or other federal, prohibitions on off-label marketing and other similar fraud and abuse considerations;
- The participant/speaker makes clear that the content of any presentation reflects the individual's own clinical and/or scientific views and not necessarily the views of CSHS;
- The use of CSHS's name in non-CSHS events is limited to the identification of the individual by his or her title and affiliation.

For purposes of this policy, ghost-writing includes, but is not limited to, any publication which identifies the individual as an author but which was researched and written, in whole or in part, by an Industry or Vendor representative, or by the agent of an Industry or Vendor representative. This does not include instances where the individual contributes substantially to the research and/or study being reported;

l. Timely notification of the approval or disapproval of Industry- or Vendor-Related FIs as well as Extramural Professional Activities, as well as Medical-Legal Service, will be made to the IR/COI Committee, in a manner and form determined by the IR/COI Committee.

2. **Professional Travel**:
   a. Reimbursement for travel or the direct provision of travel by an Industry or Vendor company or representative (Sponsored Travel) is permitted provided:
      1. The travel is in association with an approved Extramural Professional Activity;
      2. The travel is a planned, integral part of a sponsored Research project

conducted at CSHS or under the auspices of CSHS's IRB; or

3. The travel is in association with a program that conforms to ACCME guidelines (or for foreign travel, the foreign equivalent) in which the individual is a presenter, program chair, or other program official. Reimbursement for travel to an ACCME-approved program must conform to ACCME guidelines on travel support.

b. Reimbursement for travel or the direct provision of travel by an Industry or Vendor company or representative must be disclosed in the annual Industry Relations Review process, or as otherwise required under this policy.

3. Policy Compliance:

a. This policy applies to the individuals who fall within the categories identified earlier in this policy as Covered Individuals;
b. The IR/COI Committee has responsibility for the overall monitoring of compliance with this policy, to include providing guidance on its implementation and explanations of its terms and conditions. Questions and inquiries regarding the application of this policy to particular circumstances should be directed to the Chair, IR/COI Committee;
c. All CSHS executives, chairs, managers, and supervisors have responsibility for ensuring that the provisions of this policy are well-understood by their staff members, and for enforcing its provisions in their respective areas of responsibility. The Human Resources Department will provide appropriate guidance on any possible disciplinary action, occasioned by a violation of this policy, against an employee or faculty member, taking into account such factors as the seriousness of the violation, whether the individual has been subject to prior corrective action for a similar violation, and the individual's employment history with CSHS.

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