

SPONSORED ACTIVITY FINANCIAL DISCLOSURE POLICY

POLICY STATEMENT

This Sponsored Activity Financial Disclosure policy is designed to require appropriate training in, and management of, actual or potential financial conflicts of interest in externally sponsored activities, and is intended to fulfil the requirements of federal grantee institutions and contractors as set forth in 42 C.F.R Part 50, Subpart F, and 45 CFR Part 94, respectively.

SCOPE

This policy applies to all personnel, regardless of title or position, responsible for the design, conduct, negotiating, contracting, or reporting of externally sponsored activities (each an "Investigator").

An "externally sponsored activity" means PHS-Funded research, federally funded research, and public or privately funded research or services under the auspices of Chapman University. "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).

This policy also applies to employees in positions of administrative leadership or direction of recognized University research centers or institutes, where a regular job requirement is to make institutional decisions regarding externally sponsored activities on behalf of the University ("Directors").

POLICY

A. Disclosure of Significant Financial Interests.

- 1) Investigators and Directors are required to disclose all "Significant Financial Interests" (as defined below) of the Investigator/Director and/or the Investigator/Director's spouse (registered domestic partner) and dependent children. The University's Conflicts Officer (CO) or Financial Conflicts of Interest Committee will review disclosures of Significant Financial Interests and determine whether any constitute a "Financial Conflict of Interest" (FCOI). An FCOI is a Significant Financial Interest that could directly and significantly affect the design, conduct, negotiation, contracting or reporting of an externally sponsored activity.
- 2) Given the complexity of financial and non-financial relationships, Significant Financial Interest disclosures will be evaluated on a case-by-case basis to determine whether the disclosure constitutes an FCOI, and if so, to determine an appropriate action.
- 3) Significant Financial Interests may not require FCOI Committee review, and may be handled administratively, if the conflict does not directly and significantly affect the design, conduct, negotiating, contracting or reporting of an externally sponsored activity, does not involve students or human research subjects, or does not involve payment for personal services in excess of \$5,000 in a 12-month period. However, the Vice President of Research, or his/her designee, reserves the right to require FCOI Committee review.

B. Significant Financial Interest.

- <u>Definition</u>. A "Significant Financial" Interest means one or more of the following interests, if it reasonably appears to be related to the Investigator/Director's institutional responsibilities, including research, teaching or service to the University:
 - a. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator/Director (or Investigator/Director's spouse or dependent children) owns any equity interest, regardless of dollar value.
 - c. With regard to intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income related to such rights and interest. This does not include any royalty income received by the Investigator/Director from Chapman University for intellectual property rights assigned to Chapman by the Investigator/Director pursuant to Chapman's Inventions and Patents policy.
 - d. Any occurrence of reimbursed or sponsored travel related to your institutional responsibilities must also be disclosed, including instruction, research or service to Chapman University, with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research center affiliated with an institution of higher education. Travel that is reimbursed by Chapman University from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as a Significant Financial Interest. The Investigator/Director must disclosure the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration within 30 days of travel. Additional information, including the estimated cost of travel, may be requested by the CO and must be furnished upon request.
 - e. <u>Payment for services</u>. Any and all salaries and other payments for services (e.g. consulting fees, honoraria, study design, management position, independent contractor, service on advisory committees or review panels of for-profit entities, board membership of for-profit entities, seminars, lectures or teaching engagements for for-profit entities), when totaled together exceed \$5,000 during the previous twelve months or are expected to exceed \$5,000 over the next twelve months.
- Exclusions. The term "Significant Financial Interest" does not include: a) salary, royalties, or other remuneration from Chapman University; b) income from investment vehicles such

as mutual funds or retirement accounts, as long as the Investigator/Director does not directly control the investment decisions made in these vehicles; c) income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; d) income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

C. <u>Timing of Required Disclosures</u>

- Investigator/Directors must provide all required financial disclosures through the submission of a completed FCOI Disclosure Form:
 - a. On an annual basis, as specified by the Office of Research;
 - At any point when the investigator and/or research personnel establish a new outside relationship or change an existing relationship that creates a potential conflict under this policy.
- 2. In addition, Investigator/Directors must <u>update</u> those financial disclosures:
 - a. At the time of sponsored activity proposal submission;
 - b. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest;
 - c. When engaging in activities requiring disclosure.
- D. <u>Review of Financial Disclosures</u>. The following process shall apply to financial disclosures submitted by Investigator/Directors.
 - 1. <u>Determination of Financial Conflicts of Interest.</u> The CO or FCOI Committee will review each disclosed Significant Financial Interest to determine whether it could directly and significantly affect the design, conduct, negotiating, contracting or reporting of an externally sponsored activity. If an FCOI exists, then the FCOI Committee, or the CO in consultation with the FCOI Committee, will determine what conditions or restrictions, if any, should be imposed by the University to manage, reduce, or eliminate such conflict of interest.
 - 2. Management of Financial Conflicts of Interest.
 - a. If the CO or FCOI Committee determines that a Significant Financial Interest constitutes an FCOI, then the FCOI Committee will review the research, the financial interests in question, and the areas of conflict, and recommend a strategy to the CO for the management of the Financial Conflict of Interest with a combination of elements it deems most conducive to the continued objective pursuit of research.
 - b. The CO will consult with the Investigator/Director on the strategy recommended by the FCOI Committee and will present a management plan to the

Investigator/Director implementing the strategy.

- c. The management plan may include conditions or restrictions to manage, reduce, or eliminate Financial Conflicts of Interest, including but are not limited to: (i) monitoring of research by independent reviewers; (ii) modification of the research plan; (iii) disqualification from participation in the portion of the externally sponsored activity that would be affected by Significant Financial Interests; (iv) divestiture of Significant Financial Interests; (v) severance of relationships that create conflicts; or (vi) public disclosure of Financial Conflicts of Interest.
- d. The Investigator/Director must agree to the management plan before the research can proceed. If the CO and the Investigator/Director cannot agree upon a management plan, then the relevant regulatory bodies and funding agencies will be notified.
- e. The management plan is subject to final approval by the Vice President for Research. All management plans require monitoring by the CO, beginning six (6) months after the fully approved management plan is completed, and on a recurring schedule every six (6) months until such time as it is determined by the FCOI Committee, or the CO in consultation with the FCOI Committee, that the identified FCOI no longer exists.

3. Reporting of Financial Conflicts of Interest.

- a. Sponsoring agency. Significant Financial Interest that are determined by the CO/FCOI Committee to be Financial Conflicts of Interest'will be reported to PHS sponsoring agencies in accordance with their requirements within 60 days of the original disclosure.
- b. Public request. As required by PHS regulations, information on the nature of such Conflicts of Interest will be made available to members of the public by the CO in response to inquiries specifying the investigator name and the research project in question within 5 business days of receipt of such requests.
- E. <u>Enforcement</u>. The University will use appropriate mechanisms for enforcement of this policy, which shall provide for sanctions where appropriate. Disciplinary proceedings initiated in connection with this policy shall be conducted in accordance with the Chapman University Faculty Handbook, the Chapman University Staff Handbook or the Student Code of Conduct, as appropriate. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.
- F. <u>Records</u>. The University will maintain records of all financial interest disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three (3) years beyond the termination or completion of the grant or contract to which they relate, or until the resolution of any governmental action or litigation involving those records, whichever is longer.

G. Training.

1. Investigators on NIH/PHS-funded projects. Each Investigator (including senior/key

- personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS) affiliated agencies must complete training on the Investigator's responsibilities regarding conflicts of interest and disclosure of Significant Financial Interests via CITI.
- New or previously unfunded Investigators. New and/or previously unfunded Investigators
 who notify the Office of Research and Sponsored Projects Administration of their intent to
 submit a research proposal to NIH or another PHS-affiliated agency will be required to
 complete training (and make the disclosures described above) prior to submission of their
 proposal.
- Investigators/Directors on non-NIH/PHS projects, or research programs. For Investigators/Directors sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators/Directors initiating research sponsored by a private, for-profit entity, the activities are optional but strongly recommended.
- 4. Repeat training. Renewal training of active NIH/PHS-funded Investigators will be repeated every four years, and (i) on any occasion when Chapman University the training requirements, and (ii) when the University determines that the Investigator is found to be noncompliant with this policy or any management plan related to an identified FCOI.
- H. <u>University's Disclosure Statement.</u> The University's Disclosure Statement must be completed by all senior personnel who are submitting proposals to a federal sponsor. The certification page of a proposal cannot be signed until forms for all Investigator/Directors are submitted to the CO. By signing this form the applicant certifies that he/she has read this and a) does not have potential Financial Conflicts of Interest ("I certify that I have read the Financial Disclosure policy which is effective for all federal proposals submitted through the University. I certify to the best of my knowledge that neither I nor my spouse, or dependents hold any significant financial interest that would reasonably appear to be related to my research, teaching and service responsibilities to Chapman University") or b) does have potential conflicts ("I have the following relationships, affiliations, activities, or interests (financial or otherwise) which constitute potential conflicts under the Chapman University Conflict of Interest Policy"). In either case, the applicant also declares that he/she will notify the CO of any change or discovery requiring modification of the above statement.
- i. <u>Subrecipients.</u> The University is responsible for ensuring all subrecipients' compliance with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the University shall enter a written agreement with each subrecipient that shall specify whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of FCOIs by subrecipients to Chapman University to enable the timely review and reporting of such FCOIs in compliance with funding agency requirements.

For additional information regarding the identification, disclosure and reporting of financial conflicts of interest on federal PHS grants and contracts, please see National Institutes of Health's guidelines at https://grants.nih.gov/grants/policy/coi/index.htm and frequently asked questions at https://grants.nih.gov/grants/policy/coi/coi/faqs.htm#3152.

OFFICE RESPONSIBLE FOR POLICY

Name of Office: Office of Research

Contact information for questions about this policy: Michael Briggs, Director of Research Integrity

WEBSITE ADDRESS FOR THIS POLICY

https://www.chapman.edu/research/policies-and-guidance/index.aspx

WHO APPROVED THIS POLICY

Senior Staff member submitting the policy: Tom Piechota, VP for Research

Date approved:

President

PUBLICATION DATES

Effective: July 2, 2019

RELATED MATERIALS