



UNIVERSITY OF ILLINOIS SYSTEM

University Senates Conference
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09/28/2026**

August 27, 2026

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Professor Timothy Bretl, Chair
UIUC Senate Executive Committee
Agricultural & Consumer Economics
1301 W Gregory Dr, M/C 644

Re: OT-400: Policy on Financial Conflicts of Interest in Research

Dear Colleagues,

The University Senates Conference is sending forward the attached revisions to the University of Illinois System Policy on Financial Conflict of Interest in Research and Conflict of Commitment in Research (OT-400) as an informational item.

The updated policy responds to new requirements for Financial Conflict of Interest policies at institutions of higher education that were finalized by the United States Department of Energy (DOE) on July 16, 2026. Institutions were required to have changes in place by August 17, 2026. Accordingly, the UI System developed an interim policy that went into effect on that date. The interim policy was reviewed and discussed at the USC Meeting held on August 20, 2026. Due to the tight timeline for compliance with DOE requirements, USC voted at that meeting to share the revision with the senates for information rather than for formal senate feedback. It will be presented for approval as a final policy at the next Board of Trustees Meeting scheduled for September 17, 2026.

Attached are the revised policy, in clean and redline versions, and a summary of changes to the policy. I encourage you to review the changes and welcome any questions you have.

Thank you for your attention to this matter.

Sincerely,

Lynn Fisher, Chair
University Senates Conference

LEF/dmp

cc: Sarah Gantz, Office of the Executive Vice President
Elizabeth Dooley, UIC Senate
Sara Powell, UIS Senate
Jenny Roether, UIUC Senate
Members, University Senates Conference

Summary – FCOIR Policy Changes

Changes to address DOE requirements include:

- Investigators included in term “Covered Individual” and language adapted to apply policy to Covered Individuals.
- Expansion of policy scope to include Conflict of Interest and Conflict of Commitment. Current policy is focused on financial conflict of interest in research that may result in bias in the research. The expanded scope indicates that the policy also serves to mitigate risk because of conflict of interest and conflict of commitment.
- Definitions are expanded to be consistent with terms defined by DOE reg.
- Includes addition of new appendix for DOE SFI definition.
- Policy statement expanded to include mitigating risk from COC and FCOI.
- Disclosure section is expanded to include requirements to disclose commitments and sponsored or reimbursed travel (\$0 de minimus) and to require disclosure for any new Covered Individuals added to project after application is submitted prior to that individual participating in the project.
- Covered Individuals must disclose commitments and SFIs annually and update disclosures to the University as soon as practicable, and in accordance with sponsor requirements after any new or existing actual, apparent, or potential SFI or commitment arises, changes, or is discovered or acquired. DOE requires updating disclosures no later than 15 days of changes. Other sponsors require within 30 days.
- Review procedures expanded to include review obligation time frame consistent with sponsor requirements and review of commitments that could present a Conflict of Commitment. Review section includes additional paragraph to explain the university’s obligation to report to the sponsor COC and FCOI consistent with sponsor requirements.
- Non-compliance expanded to include notification when required by sponsor.
- Training will be required every 2 years.

One change in the revised policy was not required for compliance with DOE policy. On the recommendation of the University of Illinois Records and Information Management Services (RIMS), the records retention requirements was changed from three to six years.

Policy on Financial Conflicts of Interest and Conflict of Commitment in Research

I. Policy Information

Policy Title: The University of Illinois System Policy on Financial Conflicts of Interest and Conflict of Commitment in Research

Policy Owner: Vice President for Academic Affairs

Responsible Official: Vice President for Academic Affairs (System); Vice Chancellor for Research and Innovation (UIUC); Vice Chancellor for Research (UIC); Vice Chancellor for Academic Affairs (UIS)

Approved by: University of Illinois Board of Trustees

Date Approved: ~~01/18/2024~~09/17/2026

Effective Date: ~~01/18/2024~~08/17/2026

Targeted Review Date: ~~01/19/2029~~01/17/2031

Contact: System, coi@uillinois.edu; Chicago, coi@uic.edu; Springfield coi@uis.edu; Urbana-Champaign, coi@illinois.edu

Related Policies:

[Policy on Outside Activities and Conflicts of Commitment and Interest](#)

[Policy on Organizational Conflicts of Interest](#)

II. Purpose

This policy provides a framework for the University of Illinois System (“University”) to comply with conflict of commitment and interest policies established by external sponsors of research. It serves as a complement to the University Policy on Outside Activities and Conflicts of Commitment and Interest and University Policy on Organizational Conflict of Interest.

III. Scope

The Policy on Financial Conflicts of Interest and Conflict of Commitment in Research (FCOI/COCR) applies to Covered Individuals, including Investigators and any other person responsible for or participating in the design, conduct or reporting of funded or human subjects research, including senior/key personnel identified in a grant application or progress or final report of research (~~each an “investigator”~~ hereinafter “Covered Individuals”). The FCOI/COCR Policy applies at the earlier of submission of a funding

proposal or Institutional Review Board (IRB) application and remains applicable through the life of the funding award or study, whichever is longer.

IV. Definitions¹

This policy adheres to the definitions established by the University Policy on Outside Activities and Conflicts of Commitment and Interest and establishes ~~these~~expanded and additional definitions for the purpose of this policy¹.

Conflict of Commitment (COC)²: A situation in which a Covered Individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among the University, multiple employers, or other entities.

Covered Individual (FCOI/COCR): For the purposes of this policy, a Covered Individual includes Investigators and any individual regardless of title or position, who contributes in a substantive, meaningful way to the development or execution of the scope of work or a project funded by a federal sponsor or proposed for funding by a federal sponsor and is designated as a Covered Individual by the federal sponsor.³

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI): ~~A financial conflict of interest (FCOI) exists when the University, through its designated officials, reasonably determines that an~~ Covered Individual or the spouse or a child of the Covered Individual has a Significant Financial Interest or financial relationship, whether with a domestic or foreign entity, that investigator's Significant Financial Interest (SFI) could directly and significantly affect the design, conduct, or reporting or funding of the research, a project, or other federal financial assistance award-related activities.

¹ Defined terms are capitalized throughout this Policy.

² This may include conflicting commitments of time and effort, including obligations to dedicate time in excess of University policies or commitments. Other types of conflicting obligations, including but not limited to, obligations to improperly share information with, or to withhold information from, the University or a federal sponsor, can also threaten research, technology or economic security and integrity.

³ Department of Energy (DOE) designates as Covered Individuals any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co-project director (Co-PD), project manager, and any individual regardless of title that is functionally performing as a PI, PD, Co-PI, Co-PD, or project manager; and persons designated in the applicable Notice of Funding Opportunity (NOFO) or terms and conditions of the federal financial assistance award. Submission of a current and pending support disclosure and/or biosketch/resume for a particular person serves as an acknowledgement that DOE designates that person as a covered individual.

Investigator: Any person who is responsible for the purpose, design, conduct, or reporting of research, or who participates in the purpose, design, conduct, or reporting of research, regardless of title or position.

Other support: Includes all resources made available to a Covered Individual in support of and/or related to all of their professional research (including basic and fundamental research), development, demonstration, and/or deployment efforts, including resources provided directly to the Covered Individual rather than through the University or sub-contracted entity, and regardless of whether or not they have monetary value.

Project: The interdependent activities funded wholly or in part under a Federal financial assistance award. A project has a defined start and end point with objectives described in an application or in an approved scope that, when attained, signify completion and achievement of a specific goal, and creation of a unique product, service, or result. For Federal financial assistance awards that include recipient cost share as part of the approved budget, activities funded with that recipient cost share are included.

Senior/Key Personnel: The Project Director or Principal Investigator and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the funding agency.

Significant Financial Interest (SFI): A financial interest of ~~the Investigator~~ a Covered Individual, their ~~Investigator's~~ spouse, and/or their ~~Investigator's~~ dependent children that reasonably appears related to the ~~Investigator~~ Covered Individual's University Responsibilities based on sponsor defined thresholds (see Appendices).

¹~~Defined terms are capitalized throughout this Policy.~~

V. Statement of Policy

The University seeks to promote objectivity in research to mitigate risk to the research caused by actual, apparent, or potential Conflict of Commitment (COC) and/or Financial Conflict of Interest (FCOI) of the Covered Individual by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from ~~Financial Conflicts of Interest (FCOI)~~ and determining actions that have been or shall be taken to eliminate, or where appropriate, manage or reduce conflicts. This Policy informs ~~investigators~~ Covered Individuals about disclosure requirements of situations that may constitute COCs or FCOIs related to research and provides mechanisms for ~~investigators~~ Covered Individuals and the University to eliminate or manage COCs and FCOIs that arise.

VI. Procedures

The University will adhere to procedures required by a sponsor based on the regulations and award terms and conditions established by the sponsor.

i. Disclosure

~~Investigators~~Covered Individuals must disclose to the University and to the sponsor, when required by the sponsor, any commitments, SFI, and sponsored or reimbursed travel that reasonably appears to be related to or conflicts with the investigatorCovered Individual's University Responsibilities. Disclosure of sponsored or reimbursed travel must include reporting the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Covered Individuals must accept the University's certification statement, sign, and date disclosures. ~~Investigators~~Covered Individuals must disclose commitments and SFIs annually and update disclosures to the University as soon as practicable, and in accordance with sponsor requirements⁴ after any new or existing actual, apparent, or potential SFI or commitment arises, changes, or within 30 days of is discovered~~y~~ or acquisition acquired of a new SFI or a change in an existing SFI.

Any new Covered Individual added to a project after the time of application submission must complete disclosure to the University prior to participating in the project.

ii. Review

Disclosed commitments and SFIs are reviewed by designated officials in each University's Conflict of Interest Office to assess if ~~an~~ commitment or SFI is reasonably related to a University research project. The reviewers take into account the nature and extent of ~~an~~ investigatorCovered Individual's role on a project, the nature and extent of ~~an~~ investigatorCovered Individual's commitment and SFIs, and the nature of the research activity under review. If the commitment or SFI is reasonably related to the research, the reviewers will assess if the commitment or SFI could meet the definition of a COC or a FCOI.

⁴ DOE is no later than 15 days. Other sponsors require within 30 days.

If the reviewer determines that the commitment or SFI(s) may present a COC or FCOI for a research project, the reviewer will refer the COC or FCOI to the applicable Unit Executive Officer (UEO) for review and approval of a management plan. Management of COCs and FCOIs may include, but is not limited to, disclosure to the University, public disclosure of the conflict, disclosure to research participants, appointment of an independent monitor or oversight committee that may take measures to protect the purpose, design, conduct, or reporting of the project against bias resulting from the conflict, impartial review by a non-conflicted plan monitor approved of the management plan, reduction or elimination of the ~~investigator~~Covered Individual's role in all or certain aspects of the ~~study~~project, additional management requirements for clinical studies (see Appendix 4), and additional monitoring, or termination of agreements or other services that create actual, apparent, potential, or real COC or FCOIs.

Reviews and determinations must occur in accordance with sponsor requirements, which may include review prior to submission of the proposal, prior to expenditure of funds for new projects, within 60 days of newly disclosed SFIs or commitments, and within 60 days of the addition of new ~~investigators~~Covered Individuals to projects.

iii. Reporting

When the University determines that an COC or SFI is related to sponsored research, the Responsible Official or their delegate must submit reports as required by the sponsor. The Responsible Official must submit the FCOI Report:

- prior to the expenditure of funds for both managed and unmanaged or unmanageable conflicts;
- within 60 days of identification for an ~~n-investigator~~Covered Individual who is newly participating in the project;
- within 60 days for new, or newly identified, FCOIs for existing ~~investigators~~Covered Individuals.
- After the FCOI Report is initiated, the Responsible Official or their delegate must provide to the sponsor status updates and identify changes in management plans, at least annually, until the completion of the project.

When required by sponsor, the University will report to the sponsor in writing any actual, apparent, or potential COC or FCOI, include any actual, apparent, or potential COC or FCOI reported to the University by the subrecipient, involving any foreign government, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign

government, as well as any measures the University of the subrecipient organization has taken to eliminate or, where appropriate, manage or reduce the conflict.

iv. Non-compliance

The following are examples of non-compliance with the FCOI/COCR Policy:

- a. failure to submit a timely disclosure;
- b. submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- c. failure to disclose information as required by the FCOI/COCR Policy; and
- d. failure to comply with established management plans.

When non-compliance is identified, the Responsible Official or their delegate will implement a management plan within 60 days. When required by the sponsor, the University will promptly notify the sponsor in writing of the failure to comply and of the corrective action taken or to be taken.

In addition, the office of the Responsible Official must conduct a retrospective review of the ~~investigator~~Covered Individual's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, the office of the Responsible Official must promptly notify the sponsor and submit a mitigation report that addresses the impact of the bias on the research and the university's plan of action to eliminate or mitigate the effect of the bias.

If non-compliance is identified related to a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the ~~investigator~~Covered Individual is required to:

1. disclose the FCOI in each public presentation of the results of the research; and
2. request an addendum to previously published presentations.

v. Training

Each ~~investigator~~Covered Individual must complete University-approved conflicts of interest training prior to engaging in sponsored research and thereafter every ~~four~~two years unless immediate retraining is required for any of the following circumstances:

- the University revises the ~~FCOIR Policy~~ and procedures in any manner that affects the requirements of the ~~investigatorCovered Individual~~;
- an ~~investigatorCovered Individual~~ is new to the University or the project;
- the University finds that an ~~investigatorCovered Individual~~ is not in compliance with the ~~FCOIR Policy~~ or with an approved ~~applicable~~ management plan.

Training at each university or the system office is developed and overseen by the respective office of the Responsible Official.

vi. Subrecipient Compliance

If the University carries out the research through use of a subrecipient or subcontractor (“subrecipient”), the University must include language in the subrecipient agreement requiring the subrecipient to comply with either the University’s FCOI/~~COCR~~ Policy or the subrecipient’s ~~FCOIRown~~ policy. If the latter, then the subrecipient must certify that its policy complies with the sponsor’s requirements. The subrecipient agreement must specify deadlines for the subrecipient to submit all SFI disclosures or reports of conflicts to the University so that the University can meet its own reporting obligations.

vii. Public Access to Information

Upon written request, the University must make available to the public within five business days certain information about the SFIs held by senior/key personnel that constitute a FCOI related to the research. The minimal information to be provided is described at 42 C.F.R. § 50.605(a)(5)(ii). The Responsible Official or their delegate will coordinate requests and responses.

VII. Administrative Action and Sanctions

Failure of an ~~investigatorCovered Individual~~ to comply with the requirements ~~for to~~ ~~complete~~ FCOI training, ~~to disclose commitments, to disclose SFI financial disclosure~~, and ~~to manage COC and FCOI management of FCOIs~~ may result in sanctions and administrative actions. Administrative actions may include but not be limited to delay in award execution or suspension of the research project. Sanctions, when necessary, will be consistent with the University *Policy on Outside Activities and Conflicts of Commitment and Interest*.

VIII. Confidentiality

Access to information collected in connection with the FCOI/~~COCR~~ Policy will be limited to those with a need to know and will be shared as required by law and University policies, and upon request to comply with the requirements of a sponsor.

IX. Record Retention

Financial disclosures and management plans must be maintained by the University for the longer of ~~threesix~~ years after termination or completion of the award or the period prescribed by the sponsor or applicable law.

X. Sponsor Oversight

The University will comply with all reasonable requests for additional information or oversight by the sponsor agency.

XI. Related Laws, Guidance, and Policies

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors, 42 C.F.R. part 50 and 45 C.F.R. part 94. Final Rule at 76 Fed. Reg. 53256 (Aug. 25, 2011).

Department of Energy, Chapter IX of title 2 of C.F.R. Part 910, Subpart C, Conflicts of Interest, Conflicts of Commitment, Organizational Conflicts of Interest, and Other Matters of Concern, effective August 17, 2026.

~~Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance, December 20, 2021.~~

Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards

NSF Policy: Proposal and Award Policies and Procedures Guide, effective Jan. 30, 2023.

FDA Regulations: Financial Disclosure by Clinical Investigators, 21 C.F.R. part 54.

Association for the Accreditation of Human Research Protection Programs (AAHRPP), Standard 1-6

State of Illinois Freedom of Information Act, 5 ILCS 140.

Appendix 1

This definition of SFI is applicable to the following sponsors:

Public Health Services, ~~Department of Energy~~

Significant Financial Interest: SFI means a financial interest consisting of one or more of the following interests of the ~~investigator~~Covered Individual (and spouse and dependent children) that reasonably appears related to the ~~investigator~~Covered Individual's University responsibilities with regard to:

- a publicly traded entity if the value of any remuneration received from the entity as of the date of disclosure and in the 12 months preceding the disclosure exceeds \$5,000, when aggregated. Remuneration includes salary, royalties, and other payments for services, such as consulting fees and honoraria paid authorship, equity interests, stock options or other ownership interests, as determined through public prices or reasonable measures of fair market value;
- a non-publicly traded entity, if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000 when aggregated, or when the ~~investigator~~Covered Individual holds any equity interest;
- intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interest; and
- reimbursed or sponsored travel related to ~~investigator~~Covered Individual's University responsibilities if paid by a sponsor other than a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

The following financial interests are not considered to be an SFI:

- salary, royalties or other remunerations paid by the University of Illinois System to the ~~investigator~~Covered Individual if the ~~investigator~~Covered Individual is currently employed or appointed by the University, including intellectual property rights assigned to the University and agreements to share royalties related to such rights;
- income from investment vehicles (mutual funds or retirement account that are not managed directly by the individual);
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by

20 U.S.C. § 1001(a), 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 as defined by 20 U.S.C. § 1001(a) (e.g., NIH review panel), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.

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Appendix 2

This definition of SFI is applicable to the following sponsors:

U.S. Department of Energy and the National Nuclear Security Administration (NNSA)

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Covered Individual (and those of the Covered Individual's spouse and dependent children) that reasonably appears to be related to the Covered Individual's University Responsibilities:

(i) With regard to any foreign or domestic 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 disclosure, when aggregated, exceeds \$5,000. 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); 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;

(ii) With regard to any foreign or domestic non-publicly traded entity, a significant financial interest exists if the value of any remuneration, not otherwise disclosed as current, pending, or other support, received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Covered Individual (or the Covered Individual's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); and

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual so that the exact monetary value may not be readily available) related to their University Responsibilities that is not otherwise disclosed in current and pending or other support disclosures, but does not include travel that is reimbursed or sponsored by a Federal, State, or local government agency of the United States; a domestic Institution of Higher Education; or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the University of Illinois to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by the University of Illinois, including intellectual property rights assigned to the University

of Illinois and agreements to share in royalties related to such rights; any ownership interest in the University of Illinois held by the Covered Individual, if the University of Illinois is a commercial or for-profit organization; 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 of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education; or income from service on advisory committees or review panels for a Federal, State, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

Appendix 23

This definition of SFI is applicable to the following sponsors:

National Science Foundation, National Aeronautics and Space Administration (NASA), and any other sponsor that has not implemented COI regulations or adopted PHS regulations

Significant Financial Interest: The term “significant financial interest” means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); venture or other capital financing; and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

SFI does not include:

- a. salary, royalties or other remuneration from the University;
- b. any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR);
- c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- d. income from service on advisory committees or review panels for public or non-profit entities;
- e. an equity interest that, when aggregated for the ~~investigator~~Covered Individual and the ~~investigator~~Covered Individual’s spouse and dependent children, meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity; or
- f. salary, royalties or other payments that, when aggregated for the ~~investigator~~Covered Individual and the ~~investigator~~Covered Individual’s spouse or dependent children, are not expected to exceed \$5,000 during the prior 12-month period.

Appendix 34

This definition of SFI is applicable to the following sponsors:

Centers for Medicare and Medicaid Services

“Significant Financial Interest” means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees and honoraria); equity interest (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, copyright and royalties from such rights).

This term does not include:

- a. salary, royalties, or other remuneration from the applicant organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for PI/PD and the PI/PD’s spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, does not represent more than 5% ownership interest in a single entity; or
- e. salary, royalties or other payments that, when aggregated for PI/PD and the ~~investigator~~Covered Individual’s spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

“Other Interests” means that because of relationships with a parent company, affiliate, or subsidiary organization, the University is unable or appears unable to be impartial in conducting a procurement action involving a related organization.

To comply with the CMS award terms and conditions, significant financial interests and other interests, as identified, must be eliminated prior to spending CMS funding on activities in question.

Clinical Studies Supporting Food and Drug Administration (FDA) Applications

Applicants who submit a marketing application to the FDA for a new drug, biological product, or medical device must include financial disclosures of any clinical investigator directly involved in the conduct of clinical studies covered by 21 C.F.R. part 54 (each a “covered clinical study”). The FDA wants to review the financial interests and arrangements of clinical investigators in cases where they could bias the clinical studies used to support marketing applications. The sponsor of a covered clinical study must obtain financial disclosures from clinical investigators before allowing them to participate in any such study. The university is a sponsor if it provides study funding or if one or more of its employees designs and conducts a covered clinical study, regardless of the funding source. There may be multiple sponsors of a covered clinical study. Where the clinical investigator is not an employee of the sponsor, the investigator must cooperate with the sponsor and provide sufficient accurate information to allow for complete disclosure.