



Research Integrity and Compliance

Financial Conflict of Interest in Research

Effective Date: August 24, 2012

INTRODUCTION

The widespread practice of industry-sponsored research raises important ethical questions. On the one hand, healthy academic-industry relationships are generally regarded as having the potential to promote excellence and innovation in research leading ultimately to the development of beneficial healthcare products. On the other hand, if left unregulated, such financial relationships also have the potential to undermine the public's confidence in the objectivity of university-based scientists whose mission is to serve the public at large as impartial arbiters of knowledge. Charles R. Drew University of Medicine and Science (CDU) is committed to promoting innovation, objectivity, and transparency in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by investigators' financial interests.

REGULATIONS

Public Health Service regulations 42 CFR Part 50 and Subpart F and 45CFR94 and National Science Foundation grant requirements.

RATIONAL FOR THIS POLICY

1. Ensure objectivity in all federally-sponsored research projects at CDU, including grants, cooperative agreements, and contracts.
2. Ensure that the design, conduct, or reporting of research projects will be free from bias resulting from Investigator or his/her family members' financial conflict of interest.

SCOPE

This policy and associated procedures apply to,

1. Investigators paid by, under the control of, or affiliated with Charles R. Drew University of Medicine and Science (CDU).
2. Sub-recipients when CDU is the prime awardee and the sub-recipient agrees to comply with CDU's financial conflict of interest policy in accordance with the sub-award agreement.

DEFINITIONS

Conflict of Interest (COI) for the purpose of this policy and procedures refers to a personal, professional, or financial relationship that might compromise an investigator's ability to engage in objective research.

Conflict of Interest Committee (COIC) means the Institution's committee or individual(s) that reviews and makes recommendations to the Responsible University Official (RUO) with regards to conflict of interest matters, including management, mitigation or elimination of conflict of interest.

Disclosure means providing information about conflicts of interest by an Investigator to the University, or the transmission of such information within intra-University channels (e.g., CDU Annual Conflict of Interest Disclosure Questionnaire). Disclosure is the *internal* release of information.

Equity Interest includes stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Family means any member of the Investigator's immediate family, including spouse/domestic partner or dependent children.

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of research.

Financial Interest means anything of monetary value received or held by the Investigator or the Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Institution of Higher Education is defined in [20 U.S.C. 1001(a)] as an educational institution in any State that:

- 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 have completed a secondary school education in a

home school setting that is treated as a home school or private school under State law;

- Is legally authorized within such State to provide a program of education beyond secondary education;
- 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 Secretary;
- Is a public or other nonprofit institution; and
- 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 an agency or association that has been recognized by the Secretary for the granting of pre-accreditation status, and the Secretary 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.

Institutional Responsibilities mean the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Board (IRB) or Data and Safety Monitoring Boards (DSMB).

Investigator means the Principal Investigator or any other person who is responsible for the design, conduct, or reporting of sponsored research or proposals for such funding. Investigator is not limited to those titled or budgeted as Principal Investigator or Co-investigator on a particular proposal, and may include postdoctoral fellows, senior scientists, or graduate students. The definition may also include collaborators, consultants and others as appropriate.

Outside Entity means a company, foundation, contract research organization, or other entity, other than CDU or an agency of the Federal government that sponsors or in some way supports the research in question.

Public Health Service or 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 of the PHS may be delegated. The policy applies to research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. The PHS award component includes the following, but not limited to,

- Administration for Children and Families

- Administration on Aging
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Exception: Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Phase I Applications, **but not** Phase II.

Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship.

Reporting means the release of relevant information about approved conflicts of interest to parties outside the University's conflict of interest review and management processes (e.g., to research subjects or journal editors). Reporting is the *external* release of information.

Research means systematic investigation designed to develop or contribute to generalizable knowledge, such as biomedical, clinical, behavioral, social science, and public health research. Research includes basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Responsible University Official (RUO) means the institutional official who is responsible for implementation of this policy and procedures, and who is the deciding official in all matters related to conflict of interest in research. The RUO at CDU is the Provost and/or designee.

Significant Financial Interests includes a financial interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator's institutional responsibilities. Significant Financial Interests includes monetary value of both the Investigator and his/her immediate family (spouse/partner or dependent children).

- Value of any remuneration received from the **publicly traded entity** in the twelve months preceding the disclosure and the value of any equity interest in the publicly traded entity as of the date of the disclosure, when aggregated, exceeds \$5,000. ***The \$5,000 threshold is for combined remuneration and equity interest value.***
- Value of any remuneration received from **non-publicly traded entity** in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 or

when the Investigator (or the Investigator's spouse/partner or dependent children) holds any equity interest. ***Threshold of \$5,000 for remuneration and \$0 for equity interest.***

- Actual income from licensed intellectual property rights and interests (e.g., patents, copyrights), royalties from such rights and agreements to share in royalties related to licensed intellectual property rights, as well as the right to receive future income under a patent license, copyright, or royalty agreement, where the research is directly related to the licensed technology or work.
- Any **reimbursed or sponsored travel** (i.e., which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. ***There is no de minimis threshold for the disclosure of reimbursed or sponsored travel.***

Exceptions. "Significant Financial Interests" *do not include* the following:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator 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 as defined at 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.
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education as defined at 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.
- Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.

Sub-recipient means sub-awardees, collaborators, contractors, or subcontractors.

POLICY

1. Investigators must disclose known Significant Financial Interests (and the investigator's spouse/domestic partner and dependent children) related to the investigator's institutional responsibilities.
2. Investigators must complete training on Financial Conflict of Interest at least once every 4 years.
3. All Financial Conflict of Interest will be managed, reduced or eliminated.
4. Institution will report Financial Conflict of Interest and noncompliance to the federal agency for PHS- or NSF-funded projects.
5. This policy and procedures will be enforced by appropriate sanctions.

PROCEDURES

Disclosures by the Investigators

1. Annual Disclosures to Administration, Operations and Risk Management
 - a. Web-based CDU Annual Conflict of Interest Disclosure Questionnaire must be submitted by all CDU employees, faculty, students, and affiliates, whether compensated or non-compensated.
2. Initial Disclosures of Significant Financial Interest to the Office of Research Compliance and Integrity (ORIC)
 - a. New Sponsored Research Projects: Investigators must submit a disclosure form before submitting any federally-sponsored grant, cooperative agreement, or contract **or** before being awarded.
 - b. New Research Projects involving Humans or Animals: Investigators must also disclose any conflict of interest to IRB or IACUC before submitting IRB or IACUC application, using the appropriate committee/board approved forms.
 - c. New Research Personnel: Investigators must submit a disclosure form, before being added to an existing research project.
3. On-going Disclosures - New or Additional Significant Financial Interest to ORIC

- a. Investigators must update their disclosure **within 30 days of discovering** or acquiring new or additional Significant Financial Interest (e.g., through purchase, marriage, or inheritance) to the Office of Research Integrity and Compliance for the entirety of the research project.
4. Reimbursed or Sponsored Travel
 - a. Investigators who are funded by PHS must disclose any reimbursed or sponsored travel, unless it is already disclosed in the CDU Annual Disclosure Questionnaire. The disclosure will include, at a minimum, the following information:
 - i. Purpose of the trip
 - ii. Identity of the sponsor/organizer
 - iii. Destination of the trip
 - iv. Duration of the trip
 - v. Monetary value of the trip
 - b. Sponsored travel does not include those sponsored by the following:
 - i. Federal, state, or local government agency
 - ii. An Institution of higher education [20 U.S.C. 1001(a)]
 - iii. An academic teaching hospital
 - iv. A medical center
 - v. Research institute that is affiliated with an Institution of higher education.
5. Additional Information
 - a. Investigators may be required to provide additional information about the disclosure as requested by the RUO or Director of Research Integrity and Compliance. The information may include the nature of the research; more detailed description of the conflict of interest; the compelling circumstances why such research should be approved; and the investigator's proposed plan for ensuring that the research and its associated conflicts of interest are monitored, limited, or otherwise managed. Investigators should respond to such request in writing.
6. Investigators must disclose to appropriate parties external to the University their approved conflicts of interest in order to promote public confidence in the objectivity of research.
7. Investigators must obtain prior approval from their respective deans before conducting research under the following conditions.
 - a. Investigator has a significant financial interest.
 - b. Investigator has other types of conflict of interest

- i. an investigator serving as a non-paid consultant on the board of an outside entity that sponsors the investigator's research
 - ii. an investigator using products manufactured by an outside entity in which the investigator holds stock
 - c. Investigator wishes to assign students or trainees to work on research in which he/she has significant financial interest or other types of interests (non-financial or conflicts in which the financial interests are indirect)
8. As part of the Dean's approval process, the investigator should develop and submit a management plan (including monitoring). Investigators should seek assistance from their respective Deans or ORIC in the development of the management plan.

Review Process

Initial Review

1. Director of Office of Research Integrity and Compliance (ORIC) will review the disclosure to determine whether there is any Significant Financial Interest.
 - a. If there is no Significant Financial Interest, no further action is taken. The disclosure form is filed and the Investigator notified. A report along with a copy of the disclosure form is sent to the Conflict of Interest Committee and to the RUO.
 - b. If a Significant Financial Interest is disclosed that is related to sponsored research, active research involving human subject or animals, or laboratory research, ORIC will request a management plan from the investigator. Both the disclosure and management plan will be forwarded to the COI Committee.

Conflict of Interest (COI) Committee Review

1. COI Committee will review disclosure form to determine whether the Significant Financial Interest is related to research and the Investigator's Institutional responsibilities and if it is a Financial Conflict of Interest.
 - a. If there is no Significant Financial Interest, the COI Committee will notify the Investigator in writing and the research disclosure filed with ORIC. A copy of the meeting minutes will be forwarded to the RUO.
 - b. If there is a Significant Financial Interest, the COI Committee will determine whether Conflict of Financial Interest exists, and if so, how to manage, mitigate or eliminate the conflict before research funds are expended. The COI Committee will review the management plan

- submitted by the investigator and if necessary conduct retrospective review and mitigation report.
- c. Some of the conditions or restrictions that might be imposed to manage an Investigator's Financial Conflict of Interest include, but not limited to
 - i. Public disclosure of Financial Conflict of Interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board);
 - ii. For research projects involving human subjects, research, disclosure of Financial Conflict of Interest directly to research participants;
 - 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 Financial Conflict of Interest; Change in research plan;
 - iv. Modification of the research plan;
 - v. Change of personnel or personnel responsibilities, or disqualifications 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. The institution's management plan should contain a description of the key elements as follows:
 - i. The role and principle duties of the conflicted Investigator in the research project
 - ii. Conditions of the management plan
 - iii. How the management plan is designed to safeguard objectivity in the research;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. How the management plan will be monitored to ensure Investigator compliance
 - e. No external or internal funds will be released until the determination and management plan has been made by the COI Committee and the investigator has signed the management plan.

Human Subject Research Review

1. Investigators must disclose any Significant Financial Interest at the time of submitting an IRB application.

2. If the ORIC Director determines that there is Significant Financial Interest which may pose real or perceived risk to the research participants, the disclosure will be reviewed by the COI Committee.
3. In most cases, the investigator with the Significant Financial Interest in the project or with the sponsor will be disqualified from participating in the research. The COI Committee may make an exception, if the investigator provides compelling justification for being involved in the study, despite having Significant Financial Interest. This may include the investigator being one of the few experts in the field. The COI Committee will make a recommendation that is consistent with the protection of the rights and welfare of the human participants.
4. The IRB may accept or decline the COI Committee's recommendation or impose additional or more stringent conditions as necessary to protect the research participants, including disapproval of the study. The IRB has the ultimate authority to determine whether the financial interest and its management are acceptable for the human subject research to be approved. The COI Committee will be notified of the IRB's final determinations and requirements.

Intellectual Property Review

1. Investigators do not have to disclose any Significant Financial Interest income from intellectual property rights assigned to the institution, in which there is agreement to share in royalties related to such rights. Income may include royalties, license fees, or other forms of revenue.
2. CDU Intellectual Technology Transfer Office will provide report to COI Committee of any intellectual property rights and agreements.
3. COI Committee will review and determine whether a Financial Conflict of Interest exists and whether a management plan is required.
4. Investigators must comply with any such management plan and required to disclose the identified Financial Conflict of Interest.

Review of New or Undisclosed Significant Financial Interests

1. New or undisclosed Significant Interests may be brought to the attention of the COI Committee when,
 - a. New investigator or research personnel discloses Significant Financial Interest.
 - b. Existing investigator in CDU or sub-recipient of the research discloses a new Significant Financial Interest.

- c. University identifies a Significant Financial Interest that was not disclosed by the investigator/sub-recipient or not reviewed by the University during an ongoing research project.
2. COI Committee will review any new or undisclosed Significant Financial Interests **within 60 days** to determine whether,
 - a. It is related to federally sponsored research
 - b. Financial Conflict of Interest exists
 - c. A management plan that has been implemented or will be implemented by the investigator is appropriate
 - d. If Financial Conflict of Interest exists, the Institution will submit an FCOI report to the NIH within this same 60-day period.

Appeals

1. Investigators can appeal the COI Committee's determinations, including management plan by submitting a written request and supporting documentation to the RUO within 14 calendar days (2 weeks) of being notified by the COI Committee.
2. The RUO will review the appeal along with COI Committee's determinations, any additional information or argumentation by the appellant, dean or others and make a final determination, which will not be subject to further appeal.

Monitoring

1. As part of the management plan, the COI Committee may also recommend monitoring of the research. The RUO may appoint a committee of disinterested faculty members, COIC members, or rely on Deans and Department Chairs to perform this function for the RUO and report to the RUO. Monitors shall be free of financial or personal relationships with the investigator whose conflict of interest is being monitored, and should have the appropriate scientific expertise to enable them to exercise meaningful oversight of the research in question.
2. In order to ensure that students and trainees are treated professionally and fairly, the RUO shall monitor all interested individuals who have students or trainees assigned to work on research projects in which interested individuals have conflicts of interest. The RUO (or designated monitors) should meet with students and trainees once a year to ascertain whether they perceive any untoward influence on their own or others' research or education as a result of working for an interested individual. Students and trainees may not be retaliated against for raising such concerns in good faith.

3. All monitoring committees shall keep minutes of their meetings and activities, and shall forward all minutes, along with an annual report, to the RUO. The RUO shall supervise all monitoring committees, answering any questions that may arise during the course of their monitoring activities, resolving conflicts of interest involving committee members, appointing new members as needed, and soliciting minutes and reports from monitoring committees. When monitoring is done by the Deans or Department Heads, an annual report will be submitted to the RUO, which will describe compliance with the management plan.

Record Retention

The Office of Research Integrity and Compliance will retain all records of the research disclosures and the university's review, management plan and written response to each disclosure.

1. PHS-funded projects: Three years from the date the final expenditure report is submitted or other dates specified in 45CFR74.53 (b) and 45CFR92.42(b), where applicable.
2. NSF-funded projects: Three years from the completion or termination of the project.
3. Other federally funded projects: Three years after the completion or termination of the research project.

Enforcement, Sanctions, and Noncompliance

General

Investigators must comply fully with this policy. Noncompliance of the policy includes, but not limited to:

1. Failure to submit the disclosure form within the required time
2. Intentional filing of an incomplete, erroneous, or misleading disclosure form
3. Failure to provide additional information requested by COI Committee, RUO, or ORIC Director.

All relevant research activities may be suspended or other disciplinary action may be taken until the matter is resolved or other action deemed appropriate is implemented, which may include progressive system of sanctions (e.g., warning, withholding of paycheck, revocation of IRB approval, dismissal and termination of employment or affiliation) consistent with employment laws, University disciplinary procedures or applicable sections of the Faculty Handbook.

Federally-Funded Projects

1. Retrospective Review:

- a. The University will complete retrospective reviews within 120 days when Financial Conflict of Interest is not identified or managed in a timely manner, such as
 - i. Failure by the Investigator to disclose a Significant Financial Interest that is determined by the University to constitute a Financial Conflict of Interest,
 - ii. Failure by the Institution to review or manage such a Financial Conflict of Interest, or
 - iii. Failure by the Investigator to comply with a Financial Conflict or Interest management plan.
- b. The COI Committee will determine whether the design, conduct, or reporting of the PHS-funded research was biased during the period of noncompliance.
- c. The COI Committee will document the retrospective review, including, but not limited to the following:
 - i. Project number;
 - ii. Project title;
 - iii. Project Director/Principal Investigator or contact PD/PI if a multiple PD/PI model is used;
 - iv. Name of the Investigator who has financial conflict of interest;
 - v. Name of the entity with which the Investigator has a financial conflict of interest;
 - 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, etc.);
 - viii. Findings of the review; and
 - ix. Conclusions of the review.
- d. If the COI Committee identifies a bias to the design, conduct, or reporting of the PHS-funded research, the University will promptly notify the PHS awarding component and submit a mitigation report.

2. PHS Notification

- a. The Office of Sponsored Programs will submit all FCOI reports to the NIH through the eRA commons FCOI Module for awarded grants and cooperative agreements. The FCOI report must include sufficient information to enable the NIH to understand the nature and extent of

the Financial Conflict of Interest and to assess the appropriateness of the Institution's management plan.

- b. The University will not submit a Financial Conflict of Interest report to the PHS awarding component, if the financial interest has been ***eliminated prior*** to expending the funds.
- c. The FCOI report shall include, but are not limited to, the following:
 - i. Project number;
 - ii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - iii. Name of the Investigator with the Financial Conflict of Interest;
 - iv. Name of the entity with which the Investigator has FCOI;
 - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - vi. 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 statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.
 - vii. A description of how the financial interest relates to the PHS-funded research, and the basis for the University's determination that the financial interest conflicts with such research;
 - viii. A description of the key elements of the University's management plan, including:
 1. Role and principal duties of the conflicted Investigator in the research project;
 2. Conditions of the management plan;
 3. How the management plan is designed to safeguard objectivity in the research project;
 4. Confirmation of the Investigator's agreement to the management plan;
 5. How the management plan will be monitored to ensure Investigator compliance; and
 6. Other information as needed.
- d. Initial reports:
 - i. Prior to the University's expenditure of any funds under a PHS-funded research project, the University will provide to the PHS awarding component a Financial Conflict of Interest report regarding any Investigator's Financial Conflict of Interest and ensure that the University has implemented a management plan.
 - ii. The University will also provide an FCOI report whenever the Investigator does not timely disclose a Significant Financial Interest or whenever the Institution does not review a disclosed

Significant Financial interest and the Institution then determines that the Financial Conflict of Interest exists.

- e. Submission of Initial FCOI reports during an ongoing PHS-funded research:
 - i. The Office of Sponsored Programs will submit an FCOI report within 60 days after COI committee determines and approved by the RUO that the FCOI exists for an Investigator who is new to the project or for an existing Investigator who discloses a new Significant Financial Interest during the award period.
 - ii. The Office of Sponsored Program will submit an FCOI report within 60 days whenever the Investigator does not disclose a previously existing Significant Financial Interest or the Institution fails to review a previously existing Significant Financial Interest during an on-going NIH-funded project. The 60 days includes the review and determination by the COI Committee and RUO that the Financial Conflict of Interest exists and the management plan that have been or will be implemented.
 - iii. The university has 120 days to make determination of noncompliance, completing a retrospective review, and finding that there was a bias. The Office of Sponsored Program must update the FCOI and submit the mitigation report within the same 120 day period if the University determined that there was bias to an ongoing PHS-funded research project.
 - iv. Mitigation Report: The mitigation report will include at a minimum,
 1. Key elements documented in the retrospective review
 2. Description of the impact of the bias on the research project
 3. The university's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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).
 4. Thereafter, the University shall submit Financial Conflict of Interest reports annually.
- f. Annual Conflict of Interest Report:
 - i. Any Financial Conflict of Interest previously reported by the institution, the annual FCOI report will address the status of the financial interest and any changes to the management plan.
 - ii. These annual reports will be required for the duration of the PHS-funded research project, including extensions with or without funds.
 - iii. The annual COI report will specify whether,

1. Financial Conflict of interest is still being managed or
 2. Explain why the Financial COI no longer exists (i.e. conflicting financial interest ceases to exist during the period of award).
- g. In some cases, HHS may determine that a PHS-funded clinical 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 FCOI that was not managed or reported by the University as required. In these cases, the University shall require the Investigator involved
- i. to disclose the FCOI in each public presentation of the results of the research, and
 - ii. to request an addendum to previously published presentations.
3. Other sponsors: The Office of Sponsored Programs will notify any other sponsor of FCOI and management plans imposed, as required by sponsor policy or contractual obligation.

Other Requirements

1. PHS Certification. The appropriate University official will certify on each PHS-funded proposal that the University:
 - a. Has a current, written, and enforced administrative process to identify and manage FCOI
 - b. Promote and enforce Investigator compliance with the requirements of 42CFR50, including disclosure of Significant Financial Interests.
 - c. Manage FCOI and provide initial and ongoing FCOI reports to the PHS awarding component
 - d. Upon request, promptly provide information to HHS with regards to disclosures by the investigator and the University's review and response to such disclosure, whether or not the disclosure is determined to be Financial Conflict of Interest by the University.
 - e. Compliance with 42CFR50 requirements.

Public Accessibility

1. The Office of Research Integrity and Compliance will post and maintain this Policy on a publicly accessible CDU website.
2. Prior to the University's expenditure of any funds supporting PHS-funded research project, the Office of Research Integrity and Compliance will ensure the public accessibility of information concerning any Significant Conflict of Interest disclosed to the Institution that meets the following three criteria:

- a. Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH
 - b. Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
 - c. The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest
3. The University will provide written response within 5 business days of receipt of the request. Written requests may be sent to Charles R. Drew University of Medicine and Science, Office of Research Integrity and Compliance, 1731 East 120th Street, Building F, Los Angeles, CA 90059. This information will also be available on the CDU Office of Research Integrity and Compliance, Conflict of Interest website.
4. The information included in a response to request for information shall include, at a minimum, the following:
 - a. Investigator's name;
 - b. Investigator's title and role with respect to the research;
 - c. Name of the entity in which the Significant Financial Interest is held;
 - d. Name/title of the research project;
 - e. Nature of the Significant Financial Interest;
 - f. The approximate dollar value of the Significant Financial Interest
5. The Office of Research Integrity and Compliance will update the information annually.
6. In addition, the Office of Research Integrity and Compliance will update the information within 60 days of identifying additional FCOI of the Investigator that was not previously disclosed, or when the University determines FCOI for new investigators or research personnel in the research project.
7. Information concerning the FCOI of an individual will remain available via written request for three years from the date that the information was most recently updated.

Training Requirements

1. Initial Training: Investigators will be informed and trained on the Institutional Financial Conflict of Interest policies, which includes the Investigator's responsibilities regarding disclosure of Significant Financial Interests and the PHS

Federal regulations on FCOI. All Investigators must complete initial FCOI training before beginning work on any research project.

2. Continuing Training: Investigators will be required to satisfy FCOI training every four years, and immediately under the following circumstances:
 - a. Future revisions to the FCOI policies or procedures affect the requirements of the Investigator.
 - b. Investigator is not in compliance with the policy or management plan.
3. Office of Research Integrity and Compliance will provide and track required training. Training can be done in person, CITI, NIH training material, or other appropriate training modules.

Sub-recipients (sub-awardees, collaborators, contractors, or subcontractors)

1. The University will take reasonable steps to ensure that any sub-recipient Investigator on a federally funded research complies with the Financial Conflict of Interest requirement:
 - a. Through written agreement that the sub-recipient are required to abide by the following terms:
 - i. Certify that the sub-recipient's Financial Conflict of Interest policy complies with the applicable Federal regulations.
 - ii. Ensure compliance of their investigator to their Financial Conflict of Interest policy
 - iii. Agree to report all identified FCOI to CDU within 30 days or other time period specified, so that CDU as prime awardee can submit Financial Conflict of Interest Report to the Federal agency.
 - b. Provide FCOI interest reports to the Federal agency regarding all FCOI of sub-recipient Investigator (i.e., prior to the expenditure of any funds and within 60 days of any subsequently identified FCOI).
2. If the sub-recipient does not have its own FCOI policy or cannot certify compliance with the Federal regulations, the agreement with the sub-recipient will:
 - a. Require the sub-recipient's investigators to comply with CDU policy.
 - b. Specify time period(s) for the sub-recipient to submit all investigator disclosures of Significant Financial Interests to CDU. There should be sufficient time for CDU to comply with its review, management, and reporting obligations.
 - c. CDU COI Committee will review the sub-recipient's disclosure for any Financial Conflict of Interest, and implementation of any management and monitoring plan.

RESPONSIBILITIES

Responsible University Officer (RUO)

Institutional Official who is responsible for implementation of this policy and procedures and who is the deciding official in all matters related to financial conflict of interest (fCOI) in research. The RUO at CDU is the Provost or his/her designee.

All appeals for fCOI in research will be adjudicated by the RUO, which will not be subject to further appeal.

CDU Conflict of Interest (COI) Committee

As part of the responsibilities, CDU Conflict of Interest Committee will review disclosure to determine whether financial conflict of interest exists and review management plan, and conduct retrospective review. The Committee's determination and recommendations will be written by the Chair of the COI Committee and sent to the RUO for review and implementation.

Office of Sponsored Programs (OSP)

OSP is responsible for filing any fCOI report to PHS or NSF and any other sponsors through policy or contractual obligation, as well as management plan and any mitigation report.

Office of Research Integrity and Compliance (ORIC)

ORIC will serve as an administrative support for RUO, facilitate communication among various department/individuals to resolve and/or report any fCOI, assist in monitoring fCOI management plan, assist in any investigation, conduct training, and to maintain documentation. Director of ORIC will pre-review all financial conflict of interest in research disclosure form to determine whether it requires COI Committee review and to ensure that appropriate management plans are included before submitting to the COI Committee. All activities regarding conflict of interest in research will be reported to RUO and COI Committee.

Deans

Investigator should report any new or existing financial conflict of interest to his/her Dean and together develop an appropriate management plan. The Investigator should promptly submit the financial conflict of interest in research disclosure form along with their management plan and submit to Office of Research Integrity and Compliance.

CONTACT PERSON ABOUT THIS POLICY

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REFERENCES

Public Health Service regulations 42 CFR Part 50 and Subpart F and 45CFR94
National Science Foundation grant requirements