



CONFLICT OF INTEREST IN RESEARCH (CIRC)

Standard Operating Procedure for the Health Sciences Campus of Loyola University Chicago

I. PREFACE

Faculty, staff and students of the Loyola University Chicago (LUC), Health Sciences Division (HSD) are encouraged to engage in externally funded research, training, and public service projects. Loyola University has a responsibility to assure its stakeholders that university activities are undertaken in a manner that is free of potential or real conflicts of interest.

Conflict of interest (COI) refers to situations in which personal or financial considerations may compromise or have the appearance of compromising professional judgment in conducting or reporting of research. For example, such conflicts may result in not only a bias affecting collection, analysis and interpretation of data, but also the hiring of staff, procurement of equipment and materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

II. APPLICATION

This policy applies to all Loyola University Chicago (“Institution”) Health Sciences Division (LUC-HSD) faculty, researchers, trainees, students and staff. Disclosure applies to financial or associational relationships with any non-Loyola entity as it relates to Institutional responsibilities or ongoing research.

The process for disclosure is described in the **Required Disclosure Procedures** document appended to this policy.

This policy reflects the information on financial conflict of interest regulation for the promotion of objectivity in research established by the National Institutes of Health (NIH) and can be found at <https://grants.nih.gov/grants/policy/coi>.

III. TRAINING, DISCLOSURE, AND REVIEW PROCESS

- A. All LUC-HSD investigators, who could be faculty, researchers, trainees, staff, and students, will undergo COI education as determined by the Institution. Research-engaged investigators must provide evidence of acceptable and current COI training before engaging in funded research.

Details of the training are described in the **Required Disclosure Procedures** document appended to this policy.

- B. Each Investigator shall disclose the nature of the interest, the name of the entity with which the Investigator has the relationship, the value of the Investigator's financial interest, and a description of how the relationship relates to research. During the period of award disclosures should be made within 30 days of acquiring or discovering a new SFI. All financial disclosures to the institution must be updated on an annual basis and within 30 days of acquiring or discovering a new SF.

Each Investigator shall be fully compliant with the applicable disclosure procedures stated in the **Required Disclosure Procedures** document appended to this policy.

- C. The Investigator's required disclosure will be evaluated by the Institution to determine whether there is a Significant Financial Interest (SFI) that constitutes a Financial Conflict of Interest (FCOI). If it is determined that the Investigator has a FCOI, the Institution will investigate it, and shall develop a management plan to reduce and/or eliminate the FCOI. This may include barring an Investigator from conducting a particular research project or serving in specific roles for the conduct of that research.

Institutional management of SFI's is described in the **Required Disclosure Procedures** document appended to this policy.

IV. REPORTING TO THE PUBLIC HEALTH SERVICE / NATIONAL INSTITUTES OF HEALTH

- A. All investigators seeking or spending Public Health Service funding will adhere to all aspects of this policy including B, C, D below.
- B. Before Public Health Service funds are spent to support research, information regarding Investigators' and/or senior/key personnel FCOIs related to the Public Health Service-funded research will be compiled by the Institution.
- C. The Institution will provide information regarding Investigators' and/or senior/key personnel FCOIs in writing within five days of the written request when requested to do so by any member of the public.
- D. Information disclosed publicly, and to the Public Health Service, will include not only the name of the Investigator with the FCOI and the grant/contract number, but also:
 1. The nature of the FCOI;
 2. The name of the entity with which the Investigator has the FCOI;
 3. The value of the Investigator's financial interest;
 4. A description of how the financial interest relates to the Public Health Service-funded research; and
 5. The key elements of the Institution's FCOI management plan.

V. DEFINITIONS

- A.** “Conflict of Interest” (COI) is defined as a situation in which a LUC-HSD employee is engaged in a particular matter that involves an outside organization which may compromise or appear to compromise the employee’s commitments or obligations to the University, or the employee has an interest or relationship, or an interest or relationship exists, that may be imputed to the employee that may be compromised by an interest in or commitment to an outside entity.
- B.** “Significant Financial Interest” (“SFI”) means any gift, investment, fee, honoraria, consulting fee, equity interest, intellectual property right, royalty interest, royalty, enrollment bonus, and/or payment, loan, paid authorship or other financial arrangement of at least \$5,000.00, or any equity interest, that may be associated with research and that flows to the Investigator or his/her spouse/significant others, dependents and/or family members, from a commercial entity that supports the research or any of the Investigator’s Institutional responsibilities. For purposes of this policy, any reimbursed or sponsored travel received by an Investigator shall also contribute to the determination of an SFI. This does not include salary or other remuneration from Loyola University Chicago. For further information refer to NIH FAQ’s at: https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3180.
- C.** An SFI is defined as an aggregate of \$5000 or more from the same source obtained within the 12 months preceding the disclosure of the COI.
- D.** “Financial Conflict of Interest” (“FCOI”) means a situation where the financial interests of the faculty, trainees, students, or staff might affect or appear to affect their actions, including the research process, design, conduct, review, data interpretation, or oversight of the research.
- E.** “Associational Relationship” (“ACOI”) means any relationship with non-Loyola entities, including research sponsors that may create or appear to create a conflict of interest. This may include, but is not limited to, conflicts of commitment such as serving on advisory panels, board memberships, and/or teaching.
- F.** “Sponsored Travel” is travel 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. For further information refer to NIH FAQ’s at: https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3190.
- G.** “Investigator” means Loyola faculty, trainees, students, or staff who serve as the Principal Investigator or are responsible for the design, conduct, and analysis, or reporting of research.
- H.** “Subrecipient” means a legal entity that receives a subcontract from a pass-through entity to carry out a portion of a sponsored program. A subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether

objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through entity.

- I. “Required Disclosure” means a formal report of any financial or associational relationship related to a LUC-HSD faculty member, trainee, staff and/or students’ institutional responsibilities, or to ongoing research, or research for which an Investigator is seeking approval.
- J. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the Institution, which include, but are not necessarily limited to, activities such as research, teaching, professional practice, institutional committee memberships, service on boards such as the Institutional Review Board (IRB) or a Data and Safety Monitoring Board (DSMB), and faculty mentoring.

VI. RESPONSIBLE PARTIES

The LUC-HSD Provost will have the responsibility to ensure that the mechanisms for reporting required disclosures are in place and active, and that the procedures for the oversight and management of conflicts are up-to-date, active, and compliant with all applicable laws and regulations. Questions regarding this policy should be directed to the office of the LUC-HSD Provost.

Any employee of the Institution who has information concerning FCOI’s or ACOI’s that have not been disclosed should communicate this information, preferably in writing, to the LUC-HSD Provost.

The LUC-HSD Provost and the Institution Provost shall ensure that this policy is available on a publicly accessible web site.

APPENDIX

CONFLICTS of INTEREST in RESEARCH

**REQUIRED DISCLOSURE
PROCEDURES**

A. TRAINING

All employees engaged in research must complete the required FCOI training modules:

1. The CITI course entitled “Conflict of Interest Stage 1” and
2. “Responsible Conduct of Research (RCR)” training.

These required training modules are to be completed:

1. Within 90 days of beginning employment at LUC;
2. Within 30 days of having been found non-compliant with the Required Disclosure Policies and Procedures;
3. And one every four years after completing the training.

Information on how to obtain CITI training is available through the Institutional Review Board (IRB) office or their website at https://hsd.luc.edu/research_services/irb.

B. DISCLOSURES

Required Disclosures: In order to avoid even the appearance of impropriety, LUC-HSD employees are obliged to disclose to the University any affiliation with any outside organization which may lead to the appearance of or an actual conflict of interest.

Such affiliations include, but is not limited to, the following. More information can be obtained on the NIH website <https://grants.nih.gov/grants/policy/coi/coi> .

1. Holding of the position of officer, director, trustee, partner, employee or regularly retained agent of such organization;
2. Holding of a significant financial interest in an organization that stands to benefit from research, educational or public service activities influenced by the affected employee;
3. Receipt of any gift, investment, fee, honoraria, consulting fee, equity interest, intellectual property right, royalty interest, royalty, enrollment bonus, and/or payment, loan, paid authorship or other financial arrangement;
4. Holding of equity interest in an entity that is associated with the stated research;
5. Travel, reimbursed or sponsored (covered) by the research affiliated entity;
6. Associational relationships such as serving on advisory panels, board memberships, and/or teaching within the outside entity;
7. Any other interests with an outside entity.

Any affiliation by the spouse/significant others, dependents and/or family members, of the Investigator from a commercial entity that supports the research must also be disclosed.

Description of the travel that is disclosed shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration of the trip, and the financial amount.

Process of Disclosure:

1. Any disclosure involving activities supported by external funding must be made before an application for funding is submitted, and before submission of a project to the IRB for review and approval. The COI form is located in the Research Channel linked to the specific project under the associated LU #.
2. In addition, all faculty and non-faculty staff must submit disclosures within 30 days of acquiring or discovering a new SFI.
 - a. Disclosures are made via the “Loyola Application Portal” under the “Annual Disclosure Statement” tab. Faculty may also disclose under the “Faculty Information System” tab in the “Required Disclosures” folder.
 - b. Disclosures are to be updated as the activity occurs and for as long as funding or proposals for funding continue. Date of occurrence must accompany each disclosure.
3. Faculty and staff are required to verify disclosures annually at the time of their performance review.
4. Records related to disclosures and the management of any COI will be maintained for three years from the completion of the research.

C. EXEMPTIONS FROM DISCLOSURE

Exemptions from disclosure are limited to travel reimbursements obtained from the following:

1. An institution of higher education;
2. A federal/state/local government;
3. An academic teaching hospital;
4. A medical center;
5. A research institute affiliated with an institution of higher education.

D. REVIEW

All disclosures are reviewed by the **Conflict of Interest in Research Committee (CIRC)** within 60 days of the disclosure. The CIRC Chair or co-Chair will review the financial interest disclosure submitted by the employee. Additional information and/or a meeting with the employee may be requested for clarification to determine if there is a potential conflict of interest related to the research.

Any disclosure that is deemed to be a potential Significant Financial Interest (SFI) or a potential Associational Conflict of Interest (ACOI) will be reviewed by the full CIRC committee.

The CIRC will determine whether the disclosure requires any further action, and may take the following additional steps:

1. Request and document additional information, if necessary, for determination of the presence or absence of a conflict of interest;
2. Determine whether the employee's supervisor should review the gathered information;
3. Recommend and take appropriate action to resolve any apparent, potential or real conflict;
4. Determine whether a management plan should be put in place, which may include oversight and monitoring of the research.

The recommendations of the CIRC will be communicated to the employee and his/her chairperson or supervisor.

E. MANAGEMENT

Management Plans will be documented by the Chair of the CIRC in the relevant CIRC meeting minutes. The minutes of the meeting of the CIRC will be communicated to the LUC-HSD Provost.

The CIRC will take action to resolve any apparent, potential or real conflict. Examples of possible management plans include:

1. Disclosure of the financial conflict on the informed consent document;
2. Modification of the research plan;
3. Change in personnel on the research project or change the personnel responsible for certain aspect of the research;
4. Reduce or eliminate the financial interest;
5. Establish an independent monitor to protect the conduct and reporting of the research against bias.

For a COI, the CIRC will communicate with the IRB (human research) or the IACUC (animal research), as appropriate, to enact the management plan. The CIRC will report the conflict and management plan, as well as the follow up associated with the management plan to the IRB or IACUC as appropriate. The IRB or IACUC as appropriate, will consider the information communicated by the CIRC and decide if the plan is adequate to protect the study subjects. The IRB or IACUC, as appropriate, may ask the CIRC to reconsider a management plan, or may disapprove a study if the members believe that the study subjects may not be protected adequately. The IRB or IACUC as appropriate, will have the final authority in determining whether, in light of a disclosed COI, a study may proceed.

The CIRC will report any determination of FCOI to the Public Health Service (PHS) as defined in PHS regulations at 42 CFR Part 50 (subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought) and 45 CFR Part 94 (Responsible Prospective Contractors), when appropriate.

The CIRC will monitor investigator compliance with the management plan on no less than an annual basis until the completion of the project. The adequacy of the management plan will be determined by the following criteria:

1. Investigator participation and compliance with the plan, as determined by endpoints described in the plan;
2. Subject safety, as determined by adverse events;
3. If indicated, evaluation of research data integrity, as determined by an independent monitor;
4. Modifications to the research plan.

If the CIRC determines that an investigator is not compliant with the management plan, the CIRC may impose additional conditions or restrictions on the research, or may forward the matter to the relevant Department Chair and/or the Dean, who will determine whether additional sanctions, pursuant to the university's policies, are indicated.

If a management plan has been recommended by the CIRC, the LUC-HSD Provost will have the final decision on implementation.

The employee may direct an appeal on the decision directly to the LUC-HSD Provost.

Any employee who fails to adhere to this policy will be subject to disciplinary action as outlined in the Faculty or Employee Handbook, as applicable.

F. SUBRECIPIENT

If the institution carries out the NIH-funded research through a subrecipient, such as a subcontractor or consortium members, the institution must take reasonable steps to ensure that any subrecipient investigator complies with the regulation. These steps, consistent with the Code of Federal Regulations, are as follows:

1. In the written agreement with the subrecipient, you have to incorporate terms that establish whether the FCOI policy of the awardee institution or the FCOI policy of the subrecipient institution will apply to the subrecipient's investigators. Depending on which institutional policy applies, different things will need to happen.
2. If the subrecipient's FCOI policy applies to subrecipient investigators, then the subrecipient will need to certify in the agreement that its policy complies with the regulation. If the subrecipient cannot provide this certification, the agreement must state that subrecipient Investigators are subject to the FCOI policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee institution.
3. Moreover, the agreement must specify time period(s) for the subrecipient to report all identified FCOIs to the awardee institution. These time period(s) must be sufficient for the awardee institution to provide timely FCOI reports to the NIH.
4. If the subrecipient is subject to the awardee institution's FCOI policy. If this is the case, **then** the agreement must specify time period(s) required for the subrecipient to submit all investigator disclosures of significant financial interests to the awardee institution. These time period(s) must be sufficient for the awardee institution to comply with its review, management, and reporting obligations under the regulation

5. The awardee institution will submit any FCOI reports for subrecipient investigators to the NIH
6. Whether the subrecipient is bound by its own institution's policy or that of the awardee institution, the awardee institution in both cases, is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH.