Subject: CONFLICTS OF INTEREST: REQUIRED DISCLOSURE POLICY

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Administration Approval:

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Provost, Health Sciences Division

I. PREFACE
Faculty, staff and students at Loyola University Chicago HSD are encouraged to engage in externally funded research, training and public service projects. The 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 of Chicago ("Institution") Health Sciences Division (LUC HSD) faculty, researchers, trainees, students and staff ("Disclosers"). Disclosure of any and all financial or associational relationships with any non-Loyola entity is mandatory. The process for disclosures is described in the Procedures document appended to this policy.

III. TRAINING, PROCEDURES AND REVIEW PROCESS
A. All LUC HSD faculty, researchers, trainees, staff and students will undergo COI education as determined by Institution. Research-engaged investigators must provide evidence of acceptable and current COI training before engaging in Public Health Service funded research. The details of the training shall be described in the Procedures, and each Investigator shall be compliant with the training.

B. Each Investigator shall be fully compliant with the applicable Procedures appended to this policy.
1. Each Investigator with a Significant Financial Interest (SFI) or associational relationship with a research Sponsor is required to disclose the relationship related to research. The 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 any Public Health Service-funded research.

2. The Investigator's required disclosure shall be evaluated by the Institution to determine whether the SFI relates to PHS-funded research and/or constitutes a Financial Conflict of Interest (FCOI). If it is determined that the Investigator has a FCOI, the Institution shall investigate it, and shall develop a plan to manage, 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.

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

A. 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.

B. 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.

C. 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 University employee is engaged in a particular matter that involves an outside organization which may compromise or appear to compromise the employees' 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 in a non-publicly traded entity, 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 be considered an SFI. This does not include salary or other remuneration from Loyola University Chicago or income from public or nonprofit entities. Refer to NIH FAQ’s at: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3180 for further information.

C. "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.

D. "Associational Relationship" means any relationship with non-Loyola entities, including research sponsors that may create or appear to create a conflict of interest ("ACOI"). This may include, but is not limited to, conflicts of commitment such as serving on advisory panels, Board memberships, and/or teaching.

E. "Reimbursed or Sponsored Travel" shall be 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. The description of the travel that is disclosed shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Refer to NIH FAQ’s at: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3190 for further information.

F. "Investigator" means Loyola faculty, trainees, students or staff who serve as the Principal Investigator or are responsible for the design, conduct, analysis or reporting of research.

G. "Required Disclosure" means a formal report of any financial or associational relationship related to a Loyola University of Chicago faculty member, trainee, staff and/or students’ institutional responsibilities, or to ongoing research or research for which an Investigator is seeking approval.

H. "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 or Data and Safety Monitoring Boards (DSMB), and faculty mentoring.

I. Institutional management of disclosures. Procedures shall be appended to this Policy.

VI. RESPONSIBLE PARTIES
The Provost of the LUC HSD will have the responsibility to ensure that the mechanisms for reporting required disclosure 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 LUC HSD Provost office.

Any employee of the Institution who has information concerning FCOIs or ACOIs that have not been disclosed should communicate this information, preferably in writing, to the LUC HSD Provost.

The Health Sciences Division Provost and the Institution Provost shall ensure that this policy is available on a publicly accessible Web site.
Appendix 1

Required Disclosure Procedures

Required Disclosures:
In order to avoid even the appearance of impropriety, employees are obliged to disclose to the University any affiliation with any outside organization which may lead to the appearance of or actual conflict of interest. Such an affiliation would ordinarily include (a) the holding of the position of officer, director, trustee, partner, employee or regularly retained agent of such organization or (b) the 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. In addition, any affiliation with such an organization by his/her spouse/significant others, dependents and/or family members, from a commercial entity that supports the research must also be disclosed.

Any disclosure involving activities supported by external funding must be made before an application for funding may be submitted and shall be updated as the activity occurs and for as long as funding or proposals for funding continue.

Disclosures must be made via the Loyola Portal under the “Required Disclosures” folder located in the Faculty Information System for LUC faculty. Non-faculty staff will find the Required Disclosure folder under “Mini Apps” located in the Loyola Portal. Required disclosures include all income, travel and associational relationships, and any other interests with an outside agency.

Disclosures must be made as they occur. In addition, Faculty and staff will be required to verify disclosures annually at the time of their performance review.

Determination of Conflict of Interest:
All disclosures shall be reviewed by the Conflict of Interest in Research Committee (CIRC) Chair. The CIRC Chair or designate will review the Disclosure of Financial Interest with the affected employee. Any disclosure that is deemed a significant financial or associational interest will be reviewed by the CIRC. The CIRC will determine whether the disclosure requires any further action, and may take the following additional steps:

- Request and document additional information, if necessary, for determination of the presence or absence of a conflict of interest;
- Determine whether the affected employee’s supervisor should review the gathered information;
- Recommend and take appropriate action to resolve any apparent, potential or real conflict;
- Report the outcome to the Provost, HSD;
- Report any determination of FCOI to the Public Health Service (PHS) as defined in PHS regulations at 42 CFR 50/45 CFR 94.
Appendix 1 (cont.)

Required FCOI Training:
All employees engaged in research must complete the CITI course titled "Conflict of Interest Stage 1" as well as Responsible Conduct of Research (RCR) training modules once every four years. Information on how to obtain this training is available through the IRB office.