

	CONFLICTS OF INTEREST (COI)			
	SECTION	EFFECTIVE DATE	REPLACES POLICY	REPLACES SECTION
	P&P 1.04	02.06.2020	03.25.2020	5.15

I. INTRODUCTION

As defined in the LSUHSC-NO Conflict of Interest policy (CM-35), “Conflict of Interest” means any “Financial Conflict of Interest” and/or any “Non-Financial Conflict of Interest”. A potential or actual Conflict of Interest occurs in the context of Sponsored Projects if:

- there is a chance that an Interest could reasonably appear to affect the project; or
- if there is a chance that research or other LSUHSC-NO activities could reasonably appear to affect the interests of an external entity in which the Investigator (or Immediate Family Member) or the Institution has an Interest.

“Financial Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research and occurs when an Investigator’s or Immediate Family Member(s)’ Financial Interests compromise or have the appearance of compromising, an Investigator’s professional judgment in proposing, conducting, supervising, or reporting research.

“Non-Financial Conflict of Interest” occurs when an Investigator’s or Immediate Family Member’s role in the University or other outside activities compromise or have the appearance of compromising an Investigator’s professional judgment in proposing, conducting, supervising, or reporting research or come into conflict with an Investigator’s primary commitment to maintain scientific objectivity.

Immediate Family Member” means the spouse of the Investigator, dependent children of the Investigator, and any other individual that the Investigator knows or should know maintains an Interest that may be impacted by research or project the Investigator is proposing or conducting. Additionally, any other relationship that a reasonably prudent person might consider as an appearance of a conflict of interest is also included in the definition of “Immediate Family” and should be disclosed as well.

A full description of the LSUHSC-NO’s Conflict of Interest policy is described in Chancellor’s Memorandum 35 (CM35) which is available at the following URL: <http://www.lsuhs.edu/administration/cm/>.

II. INVESTIGATORS AND STUDY TEAM MEMBERS

The LSUHSC-NO Human Subjects Protection Program and IRB expands on this policy as follows and in Section C.:

All study team members are required to submit a Col Attestation form at the time of submission of the initial IRB application and at the time of continuing re-approval. This submission is independent of the source of funding for the human subjects research project. Should any potential Col be identified by the study team member through this document, they must engage the following process and provide a full disclosure to the Office of Research Services.

III. IRB MEMBERS

Cols for IRB Members can occur due to financial interests: anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); or intellectual property rights (e.g., patents, copyrights and royalties from such rights) that would reasonably appear to be affected by or to affect

their consideration or review of the research.

1. As defined earlier, no member with a Col may participate in the discussion of or vote on any item under consideration by the Board.
2. A notice to this effect is made at the beginning of each meeting and is documented in the minutes of the meeting.
3. Members with a Col financial, commitment or otherwise related to any item under consideration by the Board may not act as a reviewer for that item.
4. Such members may provide information at the request of the Board but must be otherwise recused.
5. Any member with a potential Col must disclose such interest through the process described for investigators and study team members in the previous section of this Guidebook.

If a consultant is utilized, the consultant is bound by the Col requirements and restrictions pertaining to IRB members.

IV. INDIVIDUAL COI

Introduction

It is the objective of the Louisiana State University Health Sciences Center-New Orleans (LSUHSC-NO) to enact policies and procedures that ensure the highest quality patient care possible, an excellent teaching environment for training future health care professionals, and an environment that supports transparent medical and scientific research. LSUHSC-NO must ensure that patient care, education, and research are performed under the highest standards of ethical conduct, with integrity and openness, and the rights of human beings are protected.

In addition, these policies and procedures are to protect the credibility and integrity of the LSUHSC-NO's faculty and staff so that public trust and confidence in the LSUHSC-NO's sponsored activities are ensured. LSUHSC-NO understands the increasing complexity of relationships between universities, members of their faculty and staff, federal and state governments, private industry, and the non-profit sector.

LSUHSC-NO encourages faculty, staff, students, house officers and other employees to participate in meaningful professional relationships with industry, government and private entities. These relationships are established for mutually-beneficial reasons and many times produce knowledge and intellectual property that will help the community at large. However, these relationships may create non-financial interests as well as financial interests that may create a bias in decisions related to a sponsored project, such as payments for services, equity interests, or intellectual property rights. The value of the results of funded research to the advancement of health care must not be compromised by any investigator's financial and/or non-financial interest that could bias the design, conduct or reporting of the research.

This policy seeks to maintain a reasonable balance between these competing interests, give LSUHSC-NO the ability to identify and manage financial and non-financial interests that may bias the research, and minimize reporting and other burdens on the investigators.

Scope

This policy applies to all LSUHSC-NO faculty members (including part-time, gratis, and visiting faculty),

staff and other employees, house officers, and students (including post-doctoral fellows) who propose, conduct or report research on behalf of LSUHSC-NO, regardless of funding source.

This policy only addresses Conflicts of Interest in Research Projects. There are other areas in which Financial and Non-financial conflicts may arise and other types of conflicts, e.g. conflicts of commitment or other outside activities, which may conflict with LSUHSC-NO obligations.

Policy

An Investigator shall not be permitted to begin any research activity (e.g. design, conduct or reporting of research, educational, or service activities) when there is an actual or potential Conflict of Interest, until a written review of the disclosure has been conducted and a Conflict of Interest Resolution Plan has been developed, if necessary, and has been received by the Investigator from the Vice-Chancellor of Academic Affairs.

Each Investigator is responsible for determining whether he/she or his/her Immediate Family Member has a potential Conflict of Interest.

Investigators and/or Immediate Family Members should evaluate potential Conflicts of Interest not only at the outset of their research and continually throughout the period of the award, but also when a change occurs in their relationship with an outside entity. This may occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.

The Director of Research Services and the Conflict of Interest Review Committee (CIRC) are the institutional official(s) to solicit and review disclosures of Significant Financial Interests from each Investigator planning to participate or participating in research.

Requirements for Disclosure

Investigators shall disclose 1) those Conflicts of Interest that would reasonably appear to be affected by or to affect their research or educational activities; and 2) any Conflict of Interest in entities whose interest would reasonably appear to be affected by or to affect the Investigator's performance of his or her LSUHSC-NO duties, activities and responsibilities. In other words, if an Investigator has a Conflict of Interest, then disclosure shall be necessary if 1) there is a chance that this interest could reasonably appear to affect his or her research, teaching, or other LSUHSC-NO activities; or 2) if there is a chance that his or her research, teaching, or other LSUHSC-NO activities could reasonably appear to affect the interests of the external entity in which the Investigator or Immediate Family Member has a Conflict of Interest. In addition, Investigators are encouraged to disclose any other Conflicts of Interest that could present an actual Conflict of Interest, or might be perceived to present a Conflict of Interest.

Each Principal Investigator or Co-Principal Investigator shall be responsible for ensuring that Investigators under his or her supervision who are involved in proposing, conducting or reporting research on the Principal or Co-Principal Investigator's project shall comply with this policy in identifying and disclosing any potential Conflicts of Interest.

Procedures for Disclosure of Conflicts of Interest

Investigators must disclose any Conflicts of Interest of the Investigator and his/her Immediate Family Members, prior to submitting the research proposal, and the disclosure must be updated annually.

This disclosure must be submitted to the Office of Research Services through completion of the Conflict of Interest Disclosure Form, and the appropriate attachments, including but not limited to PM-11 and/or PM-67 disclosure forms. Conflict of Interest Disclosure Forms must be updated to reflect any new or previously undisclosed Conflicts of Interest within thirty (30) days of discovering or acquiring a new Significant Financial Interest.

All Conflict of Interest disclosures shall first receive an administrative pre-review to assess the circumstances of a potential Conflict of Interest and whether significant financial interest is related to the proposed research by the Director of Research Services or designee.

Investigators may be required to provide additional information for this initial assessment. If the Director determines that a potential Conflict of Interest may exist, the Director shall forward his or her pre-review to the LSUHSC-NO's Conflict of Interest Review Committee (CIRC), which is responsible for reviewing Conflict of Interest disclosures and providing recommendations to reduce, manage or eliminate Conflicts of Interest, as appropriate.

Within sixty (60) days of an Investigator new to participating in an ongoing research project disclosing a Significant Financial Interest; an Investigator who previously did not timely disclose a Significant Financial Interest; or a Significant Financial Interest which was not previously reviewed by LSUHSC-NO, the Director of Research Services shall review the disclosure and determine whether the disclosure must be submitted to the CIRC.

Depending on the nature of the Significant Financial Interest, the Director of Research Services may determine that interim measures are necessary, and impose interim measures with regard to the Investigator's participation before the CIRC concludes its review.

The CIRC, within sixty (60) days, will review the disclosure of Significant Financial Interest to determine:

- whether it is related to the proposed research
- whether a conflict of interest exists

If a Conflict of Interest exists, the CIRC will consider management of the interest. The CIRC Committee shall include, but is not limited to the following factors in its evaluation of the potential Conflict of Interest:

- Length or nature of the involvement with the Sponsor
- Type of Sponsor, how the Research Project is supported or financed
- Estimated degree of separation between the Research Project's and Investigator's activities
- The nature of the Conflict of Interest and when and where the relationship commenced
- Whether the conditions of the relationship have changed
- Whether the results of the Research Project are likely to be affected by the Conflict of Interest
- The mechanisms to ensure the integrity of the Research Project, such as peer review, other independent research monitors, or controls
- The availability of alternatives to avoid the Conflict of Interest
- Risks to the rights and safety of human subjects research
- Risks to the rights and obligations of students, including fellows, participating in the research
- By whom the study is designed
- Whether LSUHSC-NO is the appropriate site for the Research
- Transparency of relationships

If the CIRC determines that an actual or potential Conflict of Interest exists, then the Committee shall

develop a Conflict of Interest Resolution Management Plan which may impose, singularly or in combination, any of the following:

- Public disclosure of Conflicts of Interest
- Disclosure to subjects through the consent process
- Review of the Research protocol by independent reviewers
- Monitoring of the Research project by independent parties
- Reduction of equity holdings
- Clear separation of Research from paid activities
- Modification or disapproval of the Research plan
- Divestiture of Conflicts of Interest, complete or partial
- Appointment of a non-conflicted Principal Investigator
- Severance of relationships that create actual or potential Conflicts of Interest
- Disqualification of the Investigator with the Conflicts of Interest from participating in all or a portion of the Research
- As the regulations require, a retrospective review and a mitigation report for PHS–funded projects

The Plan may also impose other restrictions which the CIRC deems necessary, to reduce, manage or eliminate actual or potential Conflicts of Interest.

In certain circumstances, the CIRC may determine that the Investigator has presented compelling circumstances to justify allowing research to proceed despite the presence of a Conflict of Interest. Whether the circumstances are deemed compelling shall depend upon the following:

- the nature of the science,
- the nature of the Conflict of Interest
- the amount of the Financial Interest
- how closely the Conflict of Interest is related to the Research
- the degree to which the Conflict of Interest may be affected by the Research, and
- the degree to which the Conflict of Interest can be effectively managed

No “compelling circumstances” will be approved which may violate federal regulations or result in actions detrimental to the LSUHSC-NO and the goals of this policy.

If the CIRC determines that there are compelling circumstances that the Research should go forward despite the Conflict of Interest, then the CIRC may allow the research to go forward, and shall include in the Conflict of Interest Resolution Plan:

- The compelling circumstances which support including the conflicted Investigator in the project
- The stages of the research and the specific activities for which there are compelling reasons for the Investigator’s involvement
- The activities the Investigator will be allowed to perform
- Any restriction plan imposed to prevent the conflict from influencing or appearing to influence the outcome of the project, and strategy to restrict the time of involvement to a minimum

Conflict of Interest Resolution Plans involving human subject research studies shall be submitted to the LSUHSC-NO Institutional Review Board for approval. If the IRB determines that the Plan does not satisfactorily protect human subjects, then the Plan may be returned to the CIRC for further consideration, modification, and re-submitted to the IRB for approval. No Conflict of Interest Resolution Plan involving human subjects research studies shall be implemented without IRB approval.

Conflict of Interest Resolution Plans must be signed by the Principal and/or Co-Principal Investigator, the Investigator with the Conflict of Interest, the Chairperson of the CIRC, Dean of the School of the Investigator with the Conflict of Interest, and the Vice-Chancellor for Academic Affairs.

Monitoring

Whenever a Conflict of Interest Resolution Management Plan is instituted by the CIRC, the Director of Research Services or designee shall monitor compliance with the management plan. Upon activation of the management plan approved by the IRB, a monthly report must be submitted by the PI to the IRB as confirmation of adherence to the plan. These reports will be reviewed by the Chair and administratively approved if appropriate. If any questions arise, the PI will be asked to provide clarification. If this is considered to be inadequate, the research may be halted or suspended until the issues are satisfactorily resolved. If resolution is not forthcoming, employee sanctions may be invoked. These could include warning, reprimand, censure, or suspension, or prohibition from conducting further human subjects research at LSUHSC-NO. Additional action may be taken by the Institution at the discretion of the Chancellor.

Retrospective Reviews--for PHS-funded research only

In cases where a Conflict of Interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest, failure by the Institution to review or manage such a Financial Conflict of Interest, or failure by the Investigator to comply with a Conflict of Interest Resolution Management Plan, LSUHSC-NO shall within one-hundred and twenty (120) days from the determination of non-compliance, conduct a retrospective review of the Investigator's activities and any PHS-funded research project conducted during the time-period of noncompliance for bias in the design, conduct, or reporting of such research.

LSUHSC-NO shall document the review; the documentation shall include, but is not limited to:

- Project number
- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest
- Name of the entity with which the Investigator has a Financial Conflict of Interest
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review
 - Methodology of the review process, composition of the review panel, documents reviewed
- Findings of the review
- Conclusions of the review

If appropriate, based upon the results of the review, LSUHSC-NO shall update the previously-submitted FCol report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If bias is found as a result of the review, LSUHSC-NO shall promptly notify and submit a mitigation report to the PHS Awarding component.

The mitigation report shall include, but is not limited to:

- The key elements documented in the retrospective review noted above

- A description of the impact of the bias on the research project
- LSUHSC-NO's plan of action taken to eliminate or mitigate the effect of bias on the research project
- Extent of harm done, including any qualitative or quantitative data to support any actual or future harm
- Analysis of whether the research project is salvageable

Reporting Requirements—PHS-funded research only

Prior to LSUHSC-NO expenditure of any funds under a PHS-funded research project, LSUHSC-NO shall provide to the PHS Awarding Component a FCOI report regarding any Investigator's Significant Financial Interest found by LSUHSC-NO to be conflicting, and ensure that a Conflict of Interest Resolution Management Plan has been implemented.

For any Significant Financial Interest that LSUHSC-NO identifies as conflicting subsequent to the initial FCOI report, LSUHSC-NO shall provide to the PHS Awarding Component, within sixty (60) days, a FCOI report regarding the Financial Conflict of Interest, and ensure that a Conflict of Interest Resolution Management Plan has been implemented.

Where a FCOI report involves a Significant Financial Interest that was not disclosed timely by an Investigator or was not previously reviewed by LSUHSC-NO, a retrospective review shall be conducted to determine whether any PHS-funded research conducted prior to the identification and management of the Financial Conflict of Interest was biased in the design, conduct or reporting. If bias is found, a mitigation report shall be submitted to the PHS Awarding Component.

A FCOI report shall include, but not be limited to:

- Project number
- PD/PI or Contact PD/PI if a multiple PD/PI model is used
- Name of the Investigator with the Financial Conflict of Interest
- Name of the entity with which Investigator has the Financial Conflict of Interest
- Nature of the Significant Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- Value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- A description of how the Significant Financial Interest relates to the PHS-funded research and the basis for the determination that the interest conflicts with the research; and
- A description of the key elements of the Conflict of Interest Resolution Management Plan, including:
 - Role and principal duties of the conflicted Investigator in the research project
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the Investigator's agreement to the management plan
 - How the management plan will be monitored to ensure Investigator compliance;

Annual Report:

LSUHSC-NO shall provide the PHS Awarding Component an annual FCOI report that addresses the status of the Financial Conflicts of Interest, any changes to the management plan for the duration of the project, whether the Financial Conflict of Interest is still being managed or why the interest no longer exists.

In accordance with the regulations, when LSUHSC-NO identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, LSUHSC-NO shall not submit a FCoI report to the PHS Awarding Component.

Training

Investigators shall complete training regarding the Conflict of Interest in Research policy at least every four years and immediately when any of the following circumstances apply:

- LSUHSC-NO revises the Conflict of Interest in Research policy or procedures in any way that affects the requirements of Investigators
- An Investigator is new to LSUHSC-NO
- An investigator is in non-compliance with the LSUHSC-NO Conflicts of Interest policy or in non-compliance with a Conflict of Interest Resolution Management Plan

Sub-Contracts

If federally-funded research is conducted through collaborators, sub-grantees, or subcontractors, the Principal Investigator and/or Co-Principal Investigator shall ensure that such entities comply with this policy or provide written certification that their entities comply with federal regulations.

If LSUHSC-NO carries out PHS-funded research through a sub-recipient, LSUHSC-NO must take reasonable steps to ensure that any sub-recipient Investigator complies with PHS Conflict of Interest requirements. Any PHS sub-recipient of LSUHSC-NO shall certify as part of the agreement that its Conflict of Interest policy complies with the PHS requirements. Any agreement for PHS sub-recipients shall specify time period(s) for the sub-recipient to report all identified Financial Conflicts of Interest to LSUHSC-NO.

Confidentiality

Appropriate steps shall be taken by LSUHSC-NO to protect the confidentiality of the information provided; however, LSUHSC-NO shall make certain Conflicts of Interest information available when required by law, mandated by sponsoring entities, or determined to carry out the purpose and administration of this Policy.

Records

Records relating to disclosures of actual or potential Conflicts of Interest and determinations, management plans, or retrospective reviews of the CIRC shall be maintained by the Vice-Chancellor for Academic Affairs for at least three (3) years after the date of the final expenditures report, termination or completion of the Research project, or the resolution of any government action or litigation, whichever is later.

The existence of any Conflict of Interest Resolution Plan must be reported as required by law.

Violations and Sanctions

Violations of this Policy and implementing procedures including, but not limited to, the failure to file timely disclosures, filing incomplete, erroneous or inaccurate disclosures, or failure to comply with prescribed procedures for managing or resolving Conflicts of Interest, will be handled in accordance with applicable LSUHSC-NO policies and procedures and may result in civil or criminal liability.

If the failure of the Investigator to comply with LSUHSC-NO's policy has biased the Research, LSUHSC-NO must promptly notify the funding agency and any other application agencies of the corrective action

taken. If the awarding agency is PHS, LSUHSC-NO agrees to make information on conflicting interests available, and how those interests have been managed, reduced, or eliminated.

If the funding agency determines that a funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a conflicting interest which was not disclosed or managed, LSUHSC-NO must require the Investigator to disclose the conflicting interest in each public presentation of the results of the Research.

Public Accessibility—PHS funded research only

LSUHSC-NO will provide information concerning any Significant Financial Interest disclosed to LSUHSC-NO within five (5) days of written request if the following criteria are met:

1. The Significant Financial Interest was disclosed and is still held by the Investigator
2. LSUHSC-NO has determined that the Significant Financial Interest is related to the PHS-funded research
3. LSUHSC-NO determined that there is a Financial Conflict of Interest

The information provided to the requestor shall include, at a minimum, the following:

- The Investigator's name
- The Investigator's title and role with respect to the research project
- The name of the entity in which the Significant Financial Interest is held
- The nature of the Significant Financial Interest
- The approximate dollar value of the Significant Financial Interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Definitions

“Financial Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research, and occurs when an Investigator's or Immediate Family Members' financial interests compromise, or have the appearance of compromising, an Investigator's professional judgment in proposing, conducting, supervising, or reporting research. A Financial Conflict of Interest depends on the situation and not on the character of the individual.

“Significant Financial Interest” means one or more of the following interests of the Investigator and those of the Investigator's Immediate Family Members that reasonably appears to be related to the Investigator's institutional responsibilities.

- With regard to any publicly-traded entity, a Significant Financial Interest exists if one or more of the following interests of the Investigator and those of the Investigator's Immediate Family Members reasonably appears to be related to the Investigator's institutional responsibilities:
 - any remuneration is received from the entity in the twelve (12) months preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure. 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.

- With regard to any non-publicly traded entity, a Significant Financial Interest exists if any remuneration is received from the entity in the past twelve (12) months preceding the disclosure, or when the Investigator or the Investigator's Immediate Family Members hold any equity interest (e.g. stock, stock options, or other ownership interest); or Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.
- Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided 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.

The term "Significant Financial Interest" does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights, any ownership interest in the Institution held by the Investigator
- 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, 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 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

Please note that the above-mentioned exclusions shall not apply if the compensations or transfer of equity interest is conditioned upon a particular outcome in a research project.

"Non-Financial Conflict of Interest" occurs when an Investigator's or Immediate Family Member's role in the University or other outside activities compromise or have the appearance of compromising an Investigator's professional judgment in proposing, conducting, supervising, or reporting research, or come into conflict with an Investigator's primary commitment to maintain scientific objectivity.

Non-Financial Interest includes, but is not limited to:

Conflicts of Commitment regarding Time and Effort

Using a student to perform services for a company in which the Investigator or Immediate Family Member has an ownership or management role when 1) the student is currently enrolled in the Investigator's or Immediate Family Member's class or 2) the Investigator or Immediate Family Member currently supervise(s) the student in an academic capacity; or 3) the Investigator or Immediate Family Member otherwise has the ability to influence the academic progress of the student.

"Conflict of Interest" means any "Financial Conflict of Interest" and/or any "Non-Financial Conflict of Interest".

"Conflict of Interest Resolution Management Plan" is a written plan developed by the Conflict of Interest

Review Committee and approved by the Vice-Chancellor of Academic Affairs, designed to eliminate, reduce or manage a specific Conflict of Interest of an Investigator.

“Conflict of Interest Review Committee (CIRC)” is a committee appointed by the Vice-Chancellor of Academic Affairs, charged with determining whether potential Conflicts of Interest exist, and if so, developing a Conflict of Interest Resolution Plan for Investigators who have reported Conflicts of Interest to the Office of Research Services.

“FCOI report” is a report of a Financial Conflict of Interest to a PHS Awarding Component.

“Investigator” means any LSUHSC-NO Principal Investigators, Co-Principal Investigators, Project Directors, and any other research personnel, including but not limited to, any other LSUHSC-NO employee, (whether faculty or staff), student, or house officer who is responsible for the design, conduct or reporting of the research activity, regardless of funding, and/or status (e.g., faculty key personnel, research associates, technicians, nurse coordinators, administrators, and students).

“Immediate Family Member” means the spouse of the Investigator, dependent children of the Investigator, and any other individual that the Investigator knows or should know maintains Conflicts of Interest that may be impacted by research the Investigator is proposing or conducting. Additionally, any other relationship that a reasonably-prudent person might consider as an appearance of a Conflict of Interest is also included in the definition of “Immediate Family” and should be disclosed as well.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of LSUHSC-NO.

“Research Project”: means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including basic and applied research, behavioral, and social research, biomedical research, product development and other scholarly activity.

“Related To” refers to the situation where the Director of Research Services and/or the CIRC reasonably determines that the research could directly and significantly affect the design, conduct, or reporting of the project.

V. INSTITUTIONAL COI

Institutional Conflict of Interest (Institutional Col)

An institutional Conflict of Interest describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional Cols are of significant concern when financial interests create the potential for inappropriate influence over the institution’s activities. The risks are particularly acute in the context of human subjects research, when the protection of human subjects and the integrity of the institution’s research may be threatened. The policy is intended to protect against exposure from these risks as they may affect research performed at or under the auspices of the institution.

An institution, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the institution in many forms, including major gifts, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements. In addition, university-industry relationships are essential to

advancing scientific frontiers and enabling the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the institution's primary missions, including the safety and integrity of its research, education, and clinical care. The protection of human research subjects and integrity of the institution must remain of the highest priority.

Definition of Institutional Conflict of Interest

An institution may have a Conflict of Interest ("institutional Col") in human subjects research whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the design, conduct, reporting, review, or oversight of human subjects research.

Identification of Potential Institutional Conflicts of Interest

The following significant financial and fiduciary interests of the institution (greater than \$100,000) warrant formal review of potential institutional Col with respect to human subjects research, as provided in this policy: 1.) Royalty payments received from the licensing of intellectual property (IP) related to human subjects research and owned by the institution, 2.) Non-publically traded equity in a company sponsoring human subjects research such as a start-up company, 3.) Publically traded equity in a company sponsoring human subjects research, 4.) Investment revenue from any of these sources, 5.) Equity interest senior administration may hold in sponsors of human subjects research, or 6.) Donations made to the LSUHSC-NO Foundation or directly to LSUHSC-NO for human subjects research.

When a human subjects research application is submitted to the IRB, the Chair of the IRB requests that the Director of the Office of Research Services make inquiries as to whether any potential institutional Col exists as follows: 1) The Director contacts the LSUHSC-NO Office of Technology Management to determine if the Institution holds any patents or licenses related to the research project. (Note that any royalties being received by an investigator for such IP must be disclosed through the LSUHSC-NO CM35 individual Conflict of Interest policy as described earlier), 2) The Director contacts the Vice-Chancellor for Administration and Finance to determine whether the Institution holds any equity interest in the sponsoring company (either publically or non-publically traded) or whether the Institution is receiving any investment revenue related to any of these holdings, and 3) The Director contacts the LSUHSC-NO Office of Sponsored Projects to ascertain whether the Institution has received any donations related to the research of the proposed project and contacts the LSUHSC-Foundation for similar information.

For any study where no institutional Col is determined to exist, the Director of the Office of Research Services will make an annual inquiry as described previously to determine that no new institutional Col has developed.

Review and Management of Institutional Conflict of Interest

Note that many policies of the LA State Ethics Code, LSU Board of Supervisors as denoted in the LSU Bylaws and Regulations, and by LSU System Permanent Memoranda preclude institutional Col. For example, any state employee holding significant financial interest in a company is prohibited from executing any contractual relationship with that company. Further, senior institutional officials must provide a yearly financial disclosure to Legislative Auditors and must recuse themselves when they hold equity in any company wanting to contract with the Institution.

Any donations made to the Institution or to the LSUHSC-NO Foundation are only accepted absent any *quid pro quo* and are not accepted if directed to a specific human subject research project.

Also, any royalty payments, income from investments, or revenues from equity holdings are managed by the Chancellor's office and do not flow down to specific investigator activities.

Since LSUHSC-NO has adopted AAUP policies on CoI and academic freedom as expressed in the LSUHSC-NO Faculty Handbook investigators cannot be pressured with regard to the conduct of their specific research activities by senior administration or others. Such attempts to influence human subjects research must be reported to the office of Compliance Programs for evaluation.

When a potential institutional CoI that involves a human research project is identified, the Director of the Office of Research Services notifies the CoI committee for an evaluation of the potential CoI and a determination as to whether a conflict resolution plan must be developed. The Director does not notify the full IRB during IRB deliberations of the protocol and must recuse himself/herself for the deliberations and vote on that project if serving in a voting capacity on the IRB.

If the CoI committee determines that the conflict creates a real institutional CoI, then the committee must develop a CoI resolution plan that either eliminates, reduces or manages the conflict. The conflict resolution plan may include one or more of the following, or other approaches, depending on the circumstance:

- a. Disclosure of the institutional CoI in the informed consent process;
- b. Where the institutional CoI involves a senior official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues.
- c. Where the institutional CoI involves a senior official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator can address institutional CoI-related concerns;
- d. External monitoring of the study, particularly endpoint assessments;
- e. Use of an external DSMB or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
- f. Disclosure of the institutional CoI in public presentations and publications;
- g. Disclosure of the institutional CoI to other centers in a multi-center trial.

Following deliberations of the IRB concerning the protocol, the CoI resolution plan is presented to the IRB for a determination as to whether the plan adequately addresses the safety and welfare of study participants.

The conflict resolution plan as developed by the CoI committee and approved by the IRB must be reviewed and approved by either the Vice-Chancellor for Academic Affairs or the Chancellor if one or the other is a subject of the CoI.

Implementation and Monitoring of the Resolution Plan

The Director of the Office of Research Services is responsible for implementing the conflict resolution plan and monitoring adherence to the plan. On a quarterly basis the Director will make inquiries as previously described to determine if additional elements of conflict have developed, such as new equity interest

obtained by the Institution in a sponsoring company. Such circumstances may require an enhancement of the conflict resolution plan through reconsideration by the Col committee.

References:

State Code of Ethics

LSU Board of Supervisors Bylaws and Regulations

LSUHSC-NO Faculty Handbook

AAUP Policies on Col and Academic Freedom

LSUHSC-NO Foundation Policies

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