

Lamar University
Conflict of Interest Policy
For Sponsored Research Investigators

Researcher Conflicts of Interest in Research and Sponsored Program Activities

01. POLICY STATEMENTS

- 01.01 Expansion of the research mission is a critical priority as Lamar University moves into the future. Promoting public good by fostering the transfer of knowledge gained through research to the private sector is vital to this mission.
- 01.02 Lamar University is an institution of public trust. Researchers (see Section 03. Definitions) must respect that status and conduct their affairs in ways that will not compromise the integrity of the university or impede its mission of research. It is the policy of Lamar that its Researchers conduct the affairs of the university in accordance with the highest legal, ethical and moral standards. Serious challenges arise when actions made during a researcher's university activities are determined by personal gain. Such behavior calls into question the professional objectivity and ethics of the individual, threatens the objectivity of scientific research, and reflects negatively on the university.
- 01.03 In addition to traditional externally Sponsored Programs (see Section 03. Definitions), Researchers may be involved in the commercialization of technologies derived from their research, in university-originated startup companies, and other entrepreneurial activities related to research. It is often appropriate to reward faculty for participation in these activities through consulting fees, royalty sharing from the commercialization of their work, or other non-financial rewards or benefits. Conflicts of Interest (COI) (see Section 03. Definitions) are common and often unavoidable in this research environment.
- 01.04 For purposes of complying with all applicable federal and state regulations and to maintain the integrity of its research mission in accordance with the highest legal, ethical and moral standards, Lamar has established this policy relating to COI in all research, funded and or unfunded, and in all Sponsored Programs regardless of the source of funding. The University has developed administrative procedures for identification, disclosure, review, and mitigation or management of such COI. As these are intended to support and facilitate research achievements, it is incumbent on Researchers to become familiar with, and abide by, the policy and related procedures.
- 01.05 The federal government has established minimum standards for grantees' COI policies and has required compliance from Principal Investigators, Key Personnel, and Institutional Representatives (see Section 03. Definitions). The National Science Foundation (NSF Award and Administration Guide 08-1 January 2008 Chapter IV – Grantee Standards) and Public Health Service, Department of Health and Human Services (42 CFR Part 50, Subpart F) have established requirements.
- 01.06 This policy and resulting administrative procedures are additionally bound to compliance with the Texas Education Code 51.912, The Texas State University System Rules and Regulations, Chapter III Sections 12(16)-12(18), Lamar University HR Policy 5.3, Outside Employment, Dual Employment, and Other Activities, HR Policy 2.23-Code of Ethics, HR Policy 3.9 Employment of Relatives (Nepotism Rule), and Interim Policy- Conflicts of Commitment in Research and Sponsored Program Activities.

02. SCOPE OF POLICY

- 02.01 This policy applies to all research, funded or unfunded, as well as all Sponsored Programs regardless of the source of funding for the activity or the location where the activity will be conducted.
- 02.02 This policy is applicable to all Lamar University Researchers or anyone else conducting research for or on behalf of Lamar University. The term “Researcher” is broadly defined and includes any other person not listed in the definition but specified by a Lamar University Department Chair or Dean.
- 02.03 All Significant Financial Interests (see Section 03. Definitions) will be disclosed by Researchers via a Financial Interest Disclosure (see Section 03. Definitions) form. Filing a Financial Interest Disclosure is **mandatory** for Researchers initiating any Sponsored Program research activity regardless of the source of funding. Filing a Financial Disclosure **may be** required for Researchers conducting any other research activity, unfunded or funded, if deemed necessary by the Institutional Official (see Section 03. Definitions).
- 02.04 Each person completing a Financial Interest Disclosure must list:
- 02.04.1 All his/her Significant Financial Interests and those of his/her Immediate Family (see Section 03. Definitions); and
 - 02.04.2 All his/her interests in or affiliation with any Financially Interested Company (see Section 03. Definitions), including those of his/her family members as defined in HR No. Policy 3.9 Employment of Relatives (Nepotism Rule).
- 02.05 At a minimum, this Financial Disclosure must be updated on an annual basis. The Financial Disclosure must also be updated within thirty (30) days as new reportable Significant Financial Interests are obtained and/or identified.
- When Sponsored Program activity, regardless of the source of funding, is initiated, all principal Researchers, or Key Personnel (see Section 03. Definitions) on the proposal, contract, or agreement will be required to have an up-to-date Financial Interest Disclosure for the current calendar year on file in the Office of Research Compliance (ORC), before submitting a proposal, signing a contract, or finalizing any agreement.
- When the proposal, contract, or other agreement is routed for approval, all Key Personnel on the project will also certify that they have an up-to-date Financial Interest Disclosure for the current calendar year on file in the ORC.
- 02.06 This policy does not apply directly to Conflicts of Commitment, which are situations involving Researcher participation in activities that are external to, and in addition to, their commitment to Lamar University. Conflicts of Commitment may also call into question the professional objectivity and ethics of the individual, threaten the objectivity of scientific research, and reflect negatively on the university. These situations are addressed in a separate policy, Conflicts of Commitment in Research and Sponsored Program Activities.

03. DEFINITIONS

- 03.01 Chief Research Officer: an individual ultimately responsible for the oversight of funded and research and Sponsored Programs at Lamar University. At Lamar, the Chief Research Officer is the Associate Provost for Research and Sponsored Programs (APRSP). The APRSP makes the final decision on resolution, mitigation, or management of all COI.
- 03.02 Conflicts of Interest (COI): a potential or actual Conflict of Interest exists when commitments, professional judgment, obligations to Lamar or to widely recognized professional norms are compromised by a Researcher's other interests or commitments (or those of a member of their immediate family), especially economic, particularly if the Researcher does not disclose those interests or commitments. Federal regulations provide that a conflict of interest exists if a significant financial interest could "directly and significantly affect the design, conduct, or reporting" of federally funded research activities.
- 03.03 Conflict of Interest Review Committee (CIRC): committee appointed by the Institutional Official to review Financial Interest Disclosures and make recommendations regarding management or mitigation of potential or actual COI pertaining to a Researcher's engagement in funded or unfunded research or another Sponsored Programs activity. Other Lamar faculty, staff, or university administration may be asked, as non-voting members, to attend meetings to provide guidance or expertise in a particular subject area. No individual may participate in any review procedures related to a Researcher in their own department, college, or administrative unit.
- 03.04 Financial Interest Disclosure-A document describing :
 - 03.04.1 All Significant Financial Interests of the Researcher and Immediate Family that are, or would reasonably appear to be, directly and significantly affected by or related to funded or unfunded research or Sponsored Programs activities ; or
 - 03.04.2 All significant relationships of the Researcher and Immediate Family to entities whose financial interests are, or would reasonably appear to be, directly and significantly affected by or related to such activities.
- 03.05 Financially Interested Company: a commercial or non-profit entity with financial interests that would reasonably appear to be affected by the conduct or outcome of Lamar University Research or Sponsored Programs activities. This includes any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company ownership, receivership, business or real estate trust, or any other legal entity organized for profit or non-profit purposes. This term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual knows or should know that the financial interests of such a company would reasonably appear to be affected by the research or business at Lamar University. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).
- 03.06 Immediate Family: The Researcher, their spouse/domestic partner, and dependent children.
- 03.07 Intellectual Property: property that can be protected under federal law, including copyrightable works, ideas, discoveries, and inventions.

- 03.08 Institutional Official (IO): an individual with the legal authority to act and speak for the institution and who is responsible for ensuring that Lamar University will effectively fulfill its oversight function in ensuring objectivity in funded and unfunded research and Sponsored Programs.
- 03.09 Management Plan: A plan created on a case-by-case basis with conditions or limitations that will contribute to the elimination, reduction, or management of an actual or potential COI.
- 03.10 NSF: The National Science Foundation, a federal government funding organization that has established minimum standards for grantees' COI policies and has required compliance from Principal Investigators, Key Personnel, and Institutional Representatives. (NSF Award and Administration Guide 08-1 January 2008 IV-Grantee Standards)
- 03.11 PHS: Public Health Service, an operating division of the U. S. Department of Health and Human Services, and any components of the PHS to which it may have delegated authority. The Public Health Service has established minimum standards for grantees' COI policies and has required compliance from Principal Investigators, Key Personnel, and Institutional Representatives. (42 CFR Part 50, Subpart F)
- 03.12 PHS Awarding Component: The organizational unit of the PHS that funds research that is subject 42 CFR Part 50, Subpart F.
- 03.13 Researcher: All Individuals who are engaged in research, whether funded or unfunded, or in Sponsored Programs activities. The term Researchers includes but is not limited to the Principal (Lead) Investigators (PI), Project Directors (PD), but is not limited to the Principal (Lead) Investigators (PI), Project Directors (PD), Co-Investigators, Key Personnel, Assistant Directors, Sub-grantees, Contractors, Collaborators, Post-Doctoral Scholars, Graduate Assistants, and any other individuals having direct responsibility for the design, conduct or reporting of funded or unfunded research or other Sponsored Programs activities funded or proposed for funding by the federal government or other external funder.
- 03.14 Significant Financial Interests: A significant financial interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests), gifts and intellectual property rights (e.g., patents, copyrights and royalties from such rights). IF the value of such interests: 1) exceeds \$10,000 per annum of salary, fees, and other continuing payments; or 2) represents more than a five percent (5%) ownership interest in any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children. Significant financial interest does NOT include income from seminars, lectures, or teaching, and service on advisory committees or review panels, for government agencies or institutions of higher education. Other exclusions from this definition may be determined on a case-by-case basis after review of the CIRC.
- 03.15 Sponsor: Source outside of Lamar providing funds, materials, or other compensation under a grant, contract or other agreement.
- 03.16 Sponsored Programs: All extramurally funded activities, including but not limited to, research, training, instruction and/or public service projects involving funds, materials, or other compensation from sources (Sponsors) outside of Lamar University, under a grant, contract or other agreement that meets any of the following conditions:

- 03.16.1 Lamar University is bound to a line of scholarly or scientific inquiry specified to a substantial level of detail. Such specificity may be indicated by a plan, by the stipulation of requirements for orderly testing or validation of particular approaches, or by the designation of performance targets;
 - 03.16.2 The Sponsor requires or the proposal submitted for consideration contains a line-item budget or modular budget. A line-item budget details expenses by activity, function, or project period. The designation of overhead (or indirect costs) qualifies a budget as the Sponsor requires financial and/or programmatic reports;
 - 03.16.3 The Sponsor requires that the services performed, the funds awarded, or the materials supplied under the agreement are subject to internal and/or programmatic reports;
 - 03.16.4 The Sponsor requires that the services performed, the funds awarded, or the materials supplied under the agreement are subject to internal and/or external audit; OR,
 - 03.16.5 The agreement provides for the disposition of either tangible (e.g., equipment, records, technical reports, theses or dissertations) or intangible (e.g., rights in data or inventions) properties that may result from activities covered by the agreement.
04. RESPONSIBILITIES
- 04.01 The Associate Provost for Research , as the IO, is responsible for ensuring that COI are reduced or eliminated prior to research, whether funded or unfunded, as well as prior to Sponsored Programs activities being performed or prior to the expenditure of funds.
 - 04.02 It is the responsibility of each Researcher who is planning to participate in funded or unfunded research or in Sponsored Programs activities to ensure that a current Financial Interest Disclosure is on file when a project proposal is initiated, is being routed for review or approval, and when new Researchers join the project.
 - 04.03 When a proposal is being submitted to a potential Sponsor, the Office of Sponsored Programs and Activities (SPA) is also responsible for verifying that current Financial Interest Disclosures are on file in the ORC for all Researchers, prior to proposal submission and for maintaining the proposal records until such time as the Sponsor takes action on the request for funds.
 - 04.04 It the responsibility of the Director of ORC to review each Financial Interest Disclosure and convene the CIRC when a full review is necessary. If a Management Plan is required, the Director of ORC will advise SPA and the Researcher. Work on a funded proposal cannot begin nor can a Sponsored Program account be set up, until the perceived or potential COI has been resolved.

05. CONFLICT OF INTEREST REVIEW COMMITTEE PROCEDURES

- 05.01 The CIRC reviews information related to all financial and/or fiduciary arrangements in light of related funded or unfunded research or Sponsored Programs activity and makes recommendations to the IO for dealing with the actual or potential COI.
- 05.02 In its review, the CIRC examines the financial and other potential COIs and considers the risks the proposed activity poses to the integrity of the research or Sponsored Program activity; to the rights and obligations of collaborators and students participating in the research or Sponsored Program activity; to the rights and safety of human research subjects; and to the academic, research and educational missions of the University. The CIRC also considers the impact on the availability of research results to the scientific community and on the integrity of research results. The appearance of a COI is an important factor in the review process.
- 05.03 The CIRC meets as often as necessary to ensure that all Financial Interest Disclosures are reviewed in a timely manner and to ensure that funded or unfunded researches as well as Sponsored Programs activities are not unduly inconvenienced. Understanding that some situations arise quickly, and the usual review process might cause problematic delays, the IO may be asked to make an interim decision pending the next meeting of the CIRC for full review of the case.
- 05.04 The CIRC reviews grants, contracts and other agreements of a Researcher who may have a possible or perceived COI. In grants, contracts or other agreements, including faculty consulting agreements and/or contracts, the CIRC examines the terms and conditions to ensure the freedom of timely and unhindered publication of results, to uphold the rights of students and postdoctoral fellows, and to ensure appropriate reporting of inventions and assignment of Intellectual Property rights. In addition, CIRC requires that the ORC receive certification of all Financial Interest Disclosures reviewed by collaborating institutions or corporations for any person considered to be playing a key role on subcontracts or sub-agreements that Lamar University may enter into.
- 05.05 Financial interests involving the use of human subjects in research require additional scrutiny by the CIRC because they may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity. Lamar University Researchers are required to report all financial interests related to any human subject research they plan to conduct. Whenever there is more than “minimal risk” to human subjects, it is presumed that individuals (faculty, staff, students, administrators and researchers) may not participate in research projects involving human subjects while they have a Significant Financial Interest in the research project or in a Financially Interested Company. Exceptions may be made in specific cases only when, in the judgment of the CIRC and with the concurrence of the Institutional Review Board (IRB) and the approval of the IO, individuals with a Significant Financial Interest provide a compelling justification for being permitted to simultaneously hold the financial interest and participate in the human subject research project.
- 05.06 The IRB is the designated authority for the oversight of human subjects in research at Lamar University. All Management Plans that involve research with human subjects will be reviewed by the CIRC and the IRB. The IRB is the primary authority at Lamar University responsible for ensuring that human research participants are protected in accordance with federal

- regulations, university policies and ethical principles. The IRB may require additional provisions which may exceed those recommended by the CIRC to ensure protection of human subjects.
- 05.07 Upon completing its review, the CIRC will issue a report that will detail its findings and will recommend to the IO how the COI should be resolved. The IO will review the report and issue an electronic copy of the report to the Researcher. If the Researcher wishes to respond to the report, he/she will have ten (10) working days following the transmittal of the email to submit or transmit a response to the IO. Upon timely receipt of the Researcher response the IO will submit the report plus the Researcher response to the AVPR, who will determine what action, will be taken to resolve the conflict.
- 05.08 For COI involving human subjects, the CIRC will confer with the IRB prior to issuing its report. The IRB will instruct the CIRC as to what actions the IRB wants to be included in the report to ensure compliance with IRB regulations. The IRB actions shall become a separate section in the CIRC report.
- 05.09 The CIRC may recommend that management of the COI be implemented using, for example, one or more of the following:
- 05.09.1 Disclosure: Disclosure is typically required in every case including:
 - 05.09.1.1 Public disclosure of the financial interests of the Researcher and of Lamar University, if applicable, in all relevant publications and presentation (whether or not academic presentations), including presentations at the level of the Researcher's primary department or higher,
 - 05.09.1.2 Disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and
 - 05.09.1.3 Disclosure on human subject consent forms.
 - 05.09.2 Restriction on Equity: Placement of stock in escrow until a time specified by the CIRC, or requirement that options, warrants and similar instruments not be exercised without the prior approval of the CIRC;
 - 05.09.3 Limiting the Role of the Researcher with a Financial Interest: Requiring that the role of the Researcher with the financial interest be limited in some way (e.g., the Researcher may not be allowed to serve as principal investigator, analyze data or results, or solicit consent from human research subjects);
 - 05.09.4 Oversight: Appointment of a disinterested individual or group to monitor the relevant research or Sponsored Activity. An oversight committee may be charged with ensuring that the research is conducted and reported according to scientific and ethical standards and that COI management measures are observed. In cases concerning a Dean or Associate Dean, the individual or group monitoring the activity shall be appointed by and report to the APR.
 - 05.09.5 Divestiture: The sale or disposal of specified financial interests to eliminate or reduce the financial COI by a certain date;
 - 05.09.6 Severance of Relationships That Heighten or Create Actual or Potential Conflicts: For example, relinquishing a seat on a board or directors or terminating a consulting arrangement with an outside entity in order to reduce the financial or fiduciary COI.
- 05.10 The CIRC may recommend other conditions or limitations on the proposed arrangements if, in its view, such conditions or limitations will contribute to the elimination, reduction or management of the conflict.

06. MANAGEMENT PLANS

- 06.01 The APR, after reviewing the recommendations of the CIRC, will decide what actions need to be taken to resolve the COI. The IO can request that the CIRC outline a Management Plan in accordance with federal, state and Lamar regulations. All Management Plans are to be created in consultation with the Researcher.
- 06.02 The final Management Plan must be approved by the IO. Once the Management Plan is finalized, the CIRC will obtain the signature(s) of the Researcher(s). The Management Plan may be subject to internal audit or further review to assess compliance at any time during the covered project period.
- 07. GRADUATE STUDENTS AND POSTDOCTORAL SCHOLARS
 - 07.01 Graduate students and postdoctoral scholars may not be involved in a company in which their advisor or faculty mentor has a Significant Financial Interest. Involvement means they may not be employed in the company, undertake training in the company, or do their dissertation research in the company.
 - 07.02 Graduate students and postdoctoral scholars may undertake educationally related research activities at companies as long as:
 - 07.02.1 Their faculty advisor does not have a Significant Financial Interest in the company;
 - 07.02.2 The company places no confidentiality or non-disclosure restrictions on the student and permits the student to freely discuss and publish the results of work without delays; and
 - 07.02.3 Any company patent agreement the student is required to sign is reviewed and approved by the University.
 - 07.03 Graduate students and postdoctoral scholar participation in on-campus industry-sponsored research is encouraged as long as:
 - 07.03.1 The participation furthers the student's educational program; and
 - 07.03.2 The student's faculty adviser and the Researcher directing the project do not have a Significant Financial Interest in the company sponsoring the campus research project.
 - 07.04 Researchers must not allow outside activities or interests to prevent them from meeting their responsibilities to students as teachers, mentors or supervisors of research.
- 08. DISSEMINATION
 - 08.01 This policy is made available to all faculty, staff, students, and all entities interested in collaborating with such, in funded or unfunded research as well as Sponsored Program activities. Periodic notices sent faculty, staff and students about the university's Sponsored Program administration will include information about the procedures and responsibilities and will refer individuals to designated offices or officials for additional information.
 - 08.02 ORC in collaboration with SPA is responsible for disseminating information on the duty to submit timely, accurate and complete Financial Interest Disclosures.
 - 08.03 Education and training will be provided as necessary to Researchers regarding this policy and any conduct that could constitute a violation of this policy. Information, updates, and tutorials will be available.
 - 08.04 ORC in collaboration with SPA will maintain all records received and created pursuant to this policy as well as all records of actions taken with respect to each significant financial interest for:
 - 08.04.1 At least three (3) years beyond the termination or completion of the Research or award,
 - 08.04.2 For as long as is required under federal or state law,
 - 08.04.3 For as long is required by any agreement covering unfunded or funded research or a Sponsored Program activity or

08.04.4 Until resolution of any action by a granting agency or Sponsor involving the records, whichever is longer.

09. NON-COMPLIANCE

- 09.01 Lamar University requires that all Researchers comply fully, truthfully and in a timely manner with this policy. Instances of deliberate breach, including failure to submit required Financial Interest Disclosures, statements or updates thereof; failure to provide additional information requested by the CIRC or the IO knowingly filing an incomplete, erroneous or misleading disclosure; knowingly violating applicable laws, Texas State University System regulations or this policy; or failure to comply with prescribed conditions or restrictions that have been imposed pursuant to this policy, will subject the Researcher to disciplinary action under policies of Lamar University and the Texas State University System, and if applicable, the federal government. Such action could result in a formal reprimand, non-renewal of appointment, termination of appointment, or other enforcement action.
- 09.02 If the failure of a Researcher to comply with this policy has biased the design, conduct or reporting of funded or unfunded research or Sponsored Programs activities, Lamar University will promptly notify the appropriate granting agency, Sponsor or other appropriate agency of the incident and corrective action will be taken.