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Owner Lee Seabrooke
Document Area Vice President for Research
Applicability Saint Louis University Campus Wide

Principal Investigator (PI) Policy



Responsible University Official: Interim Vice-President of Research/Ellen Barnidge

Policy Owner: Lee Seabrooke, Associate VP-Research Integrity & Compliance

Policy Contact: Lee Seabrooke, Associate VP-Research Integrity & Compliance

1.0 Reason for Policy

Saint Louis University (SLU) is committed to ensuring that all individuals engaged in research activities understand their roles and responsibilities as Principal Investigators. The Principal Investigator (PI) is charged with conducting objective research that generates independent, high quality, and reproducible results. PIs are responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. Regardless of sponsorship or funding source, the PI is responsible for conducting clinical and non-clinical research activities and projects in a manner that is ethical and compliant with all applicable university and sponsoring agency policies, procedures, and regulatory requirements.

2.0 Policy Statement

PIs are responsible for the direction and oversight of research projects or clinical trials (whether funded or unfunded) including compliance, financial, personnel, and other related aspects of the research project and for coordination with school, department, and central administration personnel to ensure the research is conducted in accordance with federal regulations and university and sponsoring agency policies and procedures.

While the PI may delegate day-to-day administration to staff members in accordance with university policy, the PI accepts ultimate accountability for compliance with Federal, State, University, and sponsor policies and requirements. This also includes knowledge of sponsor regulations regarding any stipulations on rebudgeting and changes in key personnel, scope of work, and subrecipient requests.

PIs are required to review the University's research policies, training requirements, and applicable regulations applicable to their unfunded or funded research projects or clinical trials.

A PI, including students, may not conduct a sponsored research project outside the auspices of University review. As stated in the *Externally Sponsored Proposals and Awards Policy* all proposals and grants are sought in the name and awarded to Saint Louis University and not the PI, unless denoted by the external sponsor. Consequently, the PI or agent may be personally liable for any claims by either the sponsor or subjects of the project and may not be covered by the liability insurance afforded by the University to faculty who are acting as University employees or agents.

A PI conducting a sponsored project for which there is not an approved agreement by the University may not use the facilities, personnel, equipment or the name of the University for such activities. This policy applies to research-related activities only. As such, any activity, such as service-related projects, that do not constitute research do not apply. Any such activity is not a University sponsored or endorsed activity and specific arrangements must be made by the individual to reimburse the University for any property or facilities being utilized in the conduct of that individual's private endeavors.

If no agreement exists between the University and the sponsor of the project, or if the project does not constitute research, such as a service-related project not designed to contribute to generalizable knowledge, the PI or responsible agent is solely and personally liable for necessary accounting reports and for dealing with any audit requested or required by the sponsor, as well as reimbursing the University for any resources used in connection with such reports or audits.

If no agreement exists between the University and the sponsor of the project, and thus, the PI is acting on his/her own behalf, the PI is not entitled to legal or administrative support from the University, should a dispute or problem arise as a result of the project.

It is the expectation that all members of university community will adhere to, and comply with, all applicable policies, procedures, and regulatory requirements concerning the conduct of research, fiduciary responsibilities, and compliance. Any deviation from such adherence should be reported to the staff member or students' department, school/college, or the Office of the Vice President for Research.

All parties submitting or receiving reports of violations or non-compliance will maintain the information in confidence to the extent permitted by law until a final finding has been made.

If the initial report is received by a Vice President, Dean, Chair, or unit head for the department or unit in which the violation or non-compliance has occurred, the individual receiving the report is required to inform all appropriate officials including compliance oversight offices and, up to, and including the Vice President for Research.

3.0 Scope

This policy applies to all operating units of Saint Louis University, including all faculty, staff, students and other workforce members not otherwise identified.

4.0 Procedures

Procedures will be added to the policy as needed.

5.0 Sanctions

Individuals who fail to comply with this policy and the associated procedures may be subject to disciplinary actions guided by applicable regulatory requirements, the University's *Staff Performance Management Policy* or *SLU Faculty Manual (St. Louis Campus)*, as applicable. Non-compliance with this policy may result in disciplinary action, up to and including separation from the university.

6.0 Responsibilities

PIs are defined as an individual who assumes full technical and fiscal responsibility for a sponsored proposal or award, including the supervision of other key personnel, research assistants, students, and staff. A PI must have sufficient experience to responsibly manage the project. PIs at Saint Louis University may be a full-time SLU employee or an SSM-employed clinician with a SLU faculty appointment.

PIs are responsible for the compliance with, and adherence to, all applicable university policies and procedures, compliance requirements, and federal, state and local laws and regulations for any and all

research activities conducted at, or under the auspices of, Saint Louis University, including but not limited to the following:

Research Administration (Pre- and Post-Award Operations)

All grant proposals are sought in the name of and awarded to Saint Louis University unless denoted by the external sponsor. The Grant Operation (GO) Centers are responsible for pre-award administration and assist the PIs with securing external funding to support their research, scholarly, programmatic, and other activities. In terms of pre-award responsibilities, the PI will work collaboratively with the GO Center pre-award specialist to initiate and prepare external grant submissions once a funding opportunity has been identified by the PI. These pre-award responsibilities include, but are not limited to, assisting in budget development; advising on the budget justification; defining the scope of work of the project; ensuring all key personnel (internal & external) complete their annual conflict of interest in research disclosures; notifying their department chair or dean of any released time or absences that will result if the proposal is funded; completing and sharing appropriate proposal documents for institutional review (by OVPR AORs), and completing the appropriate Workday requests and approvals.

Just-in-Time (JIT) requests occur after a proposal is submitted to an external sponsor. PIs play an important role with these requests in partnership with GO Center pre-awards specialists. Because this information is typically requested with a tight turnaround time, collaboration is key. PI responsibilities during this phase include, but are not limited to, updating the sponsor requested proposal documents (e.g., budget, justification, biosketch, etc.); addressing any sponsor questions; updating Other Support documents, and sharing appropriate JIT documents for institutional review (by OVPR AORs).

Once a Notice of Award (NoA) has been issued to Saint Louis University on behalf of the PI then the post-award phase begins. The Grant Operation (GO) Centers are responsible for the post-award administration and compliance of all sponsored awards in partnership with the PIs. This is necessary to ensure that the administration of sponsored awards is compliant with award documents, university policies, procedures, and all relevant regulations.

PIs need to ensure they review the NoA in collaboration with the post-award specialists to note any differences between what was requested as part of the proposal and what was awarded. Elements to review include award amount, period of performance, scope of work, etc.

It is imperative during this phase that the PIs develop and submit (if not already done) the appropriate compliance protocols (e.g., Human Subjects, Animals, Biological Agents) needed to complete the scope of the project.

PIs are ultimately responsible for carrying out the scope of a project's work and its daily operation, programmatically and administratively, for grants the sponsor has named them PI.

PIs do not have the authority to enter into legal agreements involving grants, contracts, and cooperative agreements on behalf of the University. These must be signed by a university representative with institutional signature authority. PIs will need to help post-award specialists with any appropriate contract/agreement intake forms to ensure the negotiation and review process of said contract/agreement can occur efficiently.

Throughout the lifecycle of an externally sponsored award, PIs are also responsible for providing financial oversight of their grant funds. These fiscal responsibilities include, but are not limited to the following:

- Understand and comply with sponsor and University policies and procedures
- Regularly review and authorize expenditures charged to sponsored awards only if they are allowable or approved by the sponsor, submitted within the approved period of performance, and are within budget;
- Inform post-award specialist of changes in grant personnel effort, hiring of appropriate grant staff, ending student employment, etc.;
- Approve non-labor transactions within Workday greater than \$500 that are not Banner feeds. PI (or delegate) approves all subcontract invoices greater than \$500;
- Request the purchase of certain direct costs on sponsored awards to the grant administrator or post award;
- Ensure all expenditures are allowable, allocable, and reasonable;
- Ensure sponsor approvals are sought and maintained when an expense was not initially approved in the application budget or when a sponsor's guidelines on expense allowability are unclear;
- Ensure terms and conditions of the sponsoring agency are being met;
- Approve cost transfers greater than \$500 and all cost transfers past 60 days; and
- Utilize the PI Dashboard in Workday, in collaboration with post-award specialist, to identify and resolve errors on grants in a timely manner and certify a monthly review of ledger account transactions for compliance with sponsor and University's sponsored programs policies.

PIs are also responsible for the grant close-out process in collaboration with the GO Center and Sponsored Programs Financial Management. More specific PI responsibilities, procedures, and policies related to research administration (pre- and post-award operations) can be found [here](#).

Human Research Protections Program

PI are responsible for protecting the rights and welfare of human research participants in accordance with federal regulations and university and sponsoring agency policies and procedures. In doing so, he/she must complete, and assure that all key personnel involved in human research, complete and comply with the required education for the protection of human participants in accordance with federal regulations and university and sponsoring agency policies and procedures. He/She must also act as a liaison between the Human Research Protection Office (HRPO) and the sponsor and adhere to all approval requirements of the Institutional Review Board. Additionally, he/she must support and endorse cooperation with university compliance and monitoring efforts related to human participant research and report instances of noncompliance to the appropriate compliance office. More information regarding applicable policies and procedures is available via this [link](#).

Animal Welfare

PIs are responsible for the ethical and responsible use of animals in research. They must oversee the

humane care and use of animals involved in research in accordance with Institutional Animal Care & Use Committee requirements, federal regulations, and university and sponsoring agency policies and procedures. They must assure that all key personnel involved in animal research complete the required education for the humane care and use of animals in accordance with federal, state, and local regulations and university and sponsoring agency policies and procedures. Additionally, PIs must support and endorse cooperation with university compliance and monitoring efforts related to animal welfare requirements and report instances of noncompliance to the appropriate compliance office. More information regarding applicable policies and procedures is available via this [link](#).

Environmental Health & Safety

PIs are responsible for adhering to all federal, state, and local regulations and university and sponsoring agency policies and procedures instituted to protect the health and safety of research participants, personnel, and the environment. As such, he/she must assure that individuals handling hazardous or regulated materials are well trained in proper safety procedures and complete the required environmental health and safety education in accordance with federal, state, and local regulations and university and sponsoring agency policies and procedures. In doing so, he/she shall establish or coordinate with department administrators and university resources to establish and monitor safety programs for department, center, or project in accordance with federal, state, and local regulations and university and sponsoring agency policies and procedures. They must comply with all applicable initial and ongoing approval requirements and safety-related interventions of the Institutional Biosafety Committee and/or Radiation Safety Committee and Department of Environmental Health & Safety, as applicable. Additionally, they must support and endorse cooperation with university compliance and monitoring efforts related to environmental health & safety requirements and report instances of noncompliance to the appropriate compliance office. More information regarding applicable policies and procedures is available via this [link](#).

Human Gene Transfer

PIs are responsible for adhering to all federal, state, and local regulations and university and sponsoring agency policies and procedures governing human gene transfer. In doing so, they must ensure that all key personnel involved in human gene transfer research have met training requirements in accordance with federal, state, and local regulations and university and sponsoring agency policies and procedures. Additionally, they must support and endorse cooperation with university compliance and monitoring efforts related to human gene transfer research and report instances of noncompliance to the appropriate compliance office. More information regarding applicable policies and procedures is available via this [link](#).

Patents & Inventions

PIs are required to disclose and report patent and invention information to the Research Innovation Group (RIG) in accordance with federal regulations and university and sponsoring agency policies and procedures. They must report all inventions promptly to RIG to ensure proper patent protection and coordinate with RIG on the preparation and prosecution of patents. Additionally, PIs must support and

endorse cooperation with university compliance and monitoring efforts related to intellectual property, patents, and inventions and report instances of noncompliance to the appropriate university office. More information regarding applicable policies can be found in PolicyStat (IP Ownership Policy (<https://slu.policystat.com/policy/11345907/latest>) and the Management and Commercialization of Intellectual Property (<https://slu.policystat.com/policy/13697202/latest>)).

Individual Outside Interests Program

PIs must remain aware of and adhere to federal regulations and university policies and procedures related to identifying and managing potential conflicts of interest, export controls, and foreign influence. They must assure that all research team members are well trained in federal regulations and university policies and procedures related to conflicts of interest, export controls, and foreign influence and annually submit an individual outside interest disclosure in accordance with regulatory requirements and university policy and comply with recommended management strategies and restrictions. In addition, PIs must disclose international exchanges of information, items, and/or activities as requested and comply with recommended management strategies and restrictions. Additionally, they must support and endorse cooperation with university compliance and monitoring efforts related to individual outside interests and report instances of noncompliance to the appropriate university office. More information regarding applicable policies and procedures is available via [this link](#).

Research Contracts

Contracts for sponsored projects funded by the government, foundations or other non-profits, or private industry that are performed by University faculty or staff at the University or at facilities leased or owned by the University must undergo review and approval by the Research Contracts Office (RCO) prior to project initiation. Similarly, contracts governing unfunded projects or the transfer of the University's research assets (i.e. data, research results, confidential/proprietary information, or tangible materials such as model organisms and biological specimens) must also undergo review and approval by the RCO. PIs will work with their assigned support in the GO Centers to ensure that all such research-related agreements are submitted to the RCO for review, negotiation, approval, and signature process via the University's contract management system, Agiloft, prior to the PI and/or its project staff performing any work or other activities under such agreements. The contract review process can be complicated and lengthy, especially for contracts with private industry or non-routine granting agencies (e.g. Department of Defense, NASA), as contracts can frequently include terms that conflict with University policy or mission, and reaching mutually satisfactory terms requires exhaustive but necessary negotiations. PIs must ensure that contracts are submitted to the RCO for review well in advance of the period of performance start date to allow time for proper processing. PIs are not permitted to begin performing a project without a fully executed agreement absent (i) a signed and fully approved Expense Guarantee form if the project is funded, or (ii) written approval from an authorized OVPR representative if the agreement is unfunded.

Recognizing that contract administration cannot be performed without guidance from the PI (as it is the PI that best understands the scope of the project, the effort committed to it by faculty and staff, the relationship of that project to other past or current projects, whether such project uses existing

intellectual property and/or will generate new intellectual property, publication goals, and other characteristics that are crucial to informing the terms of the contract(s) related to that project), the RCO utilizes intake forms to obtain guidance and other valuable information from PIs. PIs will complete the RCO intake forms truthfully and accurately to the best of their knowledge at the time the intake form is completed, taking care to notify the RCO of material changes discovered after the fact.

Only RCO staff are authorized to negotiate the terms and conditions of research-related agreements with external parties, though PIs may negotiate the scope of work or other programmatic terms directly with project funders. Throughout their contact with external parties, PIs will not act in a manner that undermines the University's position on acceptable terms and conditions, such as accepting restrictions on publication or waiving intellectual property rights.

PIs are not authorized to sign contracts on behalf of the University. Research-related contracts signed by the PI instead of an authorized University signatory will have no binding effect on the University. In most instances, the PI will sign research-related contracts in a 'Read and Acknowledged' capacity to signify that the PI has read the terms of the contract, understands the terms applicable to the PI as the primary responsible party for the project, and agrees that the PI can comply with those terms. The PI is responsible for informing all relevant members of its project team and staff of any contractual terms that apply to such personnel, such as confidentiality provisions or the completion of ancillary forms.

7.0 References

University Policies Including But Not Limited To:

- [Non-Retaliation Policy](#)
- [Reporting Concerns of Misconduct Policy](#)
- [Staff Performance Management Policy](#)
- [SLU Research Compliance Education Program Policy](#)

University Resources Including But Not Limited To:

[SLU Faculty Manual \(St. Louis Campus\)](#)

External Resources Including But Not Limited To:

- [2 CFR §200 Subpart E - Cost Principals](#)
- [2 CFR §200.308 - Revision of budget and program plans](#)
- [2 CFR §200 Subpart F - Audit Requirements](#)
- [2 CFR §200.413 - Direct Costs](#)
- [42 CFR 50, Subpart F- Responsibility of Applicants for Promoting Objectivity in Research for](#)

Which PHS Funding Is Sought

- [45 CFR §46 – 2018 Common Rule](#)
- [21 CFR §312 – Investigational New Drug Application](#)
- [21 CFR §812 – Investigational Device Exemptions](#)
- [21 CFR §50 – Protection of Human Subjects](#)
- [21 CFR §56 – Institutional Review Boards](#)
- [HIPAA Privacy Rule](#)
- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)
- [42 CFR §50, Subpart F – Promoting Objectivity in Research](#)
- [PHS Policy on Humane Care and Use of Laboratory Animals](#)

8.0 Definitions

Just In Time (JIT) Requests: A JIT request is when an awarding agency requests further information for a proposal after it has passed peer review, but before it is granted funding.

Principal Investigator (PI): individual who assumes full technical and fiscal responsibility for a sponsored proposal or award, including the supervision of other key personnel, research assistants, students, and staff. A Principal Investigator must have sufficient experience to responsibly manage the project. PIs at Saint Louis University may be a full-time SLU employee or an SSM-employed clinician with a SLU faculty appointment.

Sponsor: Any governmental agency, private foundation, corporation, or association that provides financial project support.

Sponsored Award: A sponsored award, also known as a sponsored project or grant, is a financial award granted to an individual or organization for the purpose of carrying out a specific research, educational, or other project. The award is typically provided by a government agency, private foundation, corporation, or other organization, and is given with the expectation that the recipient will use the funds for a specific purpose that aligns with the goals and objectives of the sponsor. Sponsored awards may cover a wide range of expenses, such as research materials, equipment, salaries, and other costs associated with carrying out the project. The terms and conditions of a sponsored award are typically spelled out in a formal agreement between the sponsor and the recipient, and may include reporting requirements, intellectual property rights, and other provisions designed to ensure that the project is carried out in accordance with the sponsor's expectations.

9.0 History

This is a new university policy.

Approval Signatures

Step Description	Approver	Date
Chief Policy Officer hold before ULC to make required edits	Michael Reeves	Pending
Policy Review Committee	Michael Reeves	9/13/2024
Policy Review Committee	Lee Seabrooke	9/9/2024
Chief Policy Officer review before PRC	Michael Reeves	9/5/2024

Applicability

SLUCare, Saint Louis University

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