

I. POLICY AND PROCEDURES FOR RESPONDING TO VIOLATIONS OF UNIVERSITY OF LOUISVILLE RESEARCH POLICIES

PURPOSE

It is the research policy of the University of Louisville to comply with all applicable federal and state laws and regulations and obligations the institution has assumed by contract (e.g. assurances, accreditation standards, etc). The University must be prepared to respond fairly and appropriately (1) to violations of law, regulation or University policy relating to research, (2) when questionable or unacceptable research practices occur, or (3) where there is non-compliance with research policy requirements or with reasonable requests for action or cooperation necessary to implement these research policy requirements (collectively referred to as a “violation(s) or non-compliance of research policy (ies).”).

POLICY

The University of Louisville requires that all employees (e.g. investigators, faculty, and staff), key personnel and students involved in research comply with all applicable laws, regulations, statutes, contractual obligations and University policies relating to research. The University may respond with sanctions or other appropriate action (1) to violations of law, regulation, contractual obligation or University policy relating to research, (2) when questionable or unacceptable research practices occur, or (3) where there is non-compliance with research policy requirements or with reasonable requests for action or cooperation necessary to implement these research policy requirements (collectively referred to as a “violation(s) or non-compliance of research policy(ies).”).

ORGANIZATIONAL RESPONSIBILITIES

Knowledge of any violations of or non-compliance with research policies should be immediately reported to the Provost, the appropriate Vice President, Dean, Chair or unit head for the department or unit in which the violation or non-compliance has occurred and, if applicable, any other compliance oversight office of the University. 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 Provost.

Corrective Actions and Sanctions applied pursuant to this policy shall not supersede or impede any regulatory or contractual authority conferred upon compliance oversight offices at the University of Louisville to apply sanctions or take other corrective actions appropriate to their authority. Corrective Actions and Sanctions applied pursuant to this policy do not supersede any sanctions imposed by external regulatory bodies.

CORRECTIVE ACTIONS AND SANCTIONS AVAILABLE

Corrective Actions and Sanctions available to the University in those circumstances where a violation or non-compliance of research policy is proven to have occurred include, but are not limited to:

- Imposition of a requirement to obtain additional appropriate training;
- Mandatory submission to a corrective action plan;
- Imposition of a mandate and timetable for corrective or remediating action;
- Letter of Reprimand placed in personnel file;
- Improperly collected data will be returned or destroyed;

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- Suspension of supervision or mentoring of University of Louisville students, or of students participating in approved projects or programs under the auspices of the University of Louisville;
- Requirement to make financial restitution;
- Return of funds to the sponsoring entity;
- Suspension of laboratory privileges;
- Suspension of some or all research activities;
- Removal as a principal or co-principal investigator on specific or all research activities;
- Suspension of processing of proposals/applications to research sponsoring entities;
- Suspension or withholding of sponsored activity (e.g. grant/contract) or operating funding;
- Any action that may be required by applicable law or regulation;
- Any other disciplinary actions available as corrective action in a case of inappropriate behavior by a student or a faculty member or other employee up to and including termination;
- Where required by law or contract, follow-up action with successor institution in the case of investigator leaving the University for such other institution.
- When appropriate and warranted, a department or unit may be held accountable for fees, charges, fines, or expenses incurred or resulting from or related to any such violation or non-compliance where the unit or department is deemed in whole or part responsible.

In addition to imposing appropriate sanctions, the University of Louisville shall do everything it can to clarify the record, such as:

- Formal notification of sponsoring entities, funding sources, co-authors, co-investigators, collaborators, department, campus and university publications, editors of journals in which fraudulent research was published, state professional licensing boards, other institutions, sponsoring agencies, funding sources with which the individual has been affiliated, and professional societies;
- Public announcements;
- Published retractions and disassociation with published papers;
- Formal withdrawal of pending applications for research support.

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II. PROCEDURES FOR APPLYING THE SANCTIONS POLICY

Knowledge or reasonable suspicion of any violations of or non-compliance with research policies should be promptly reported to the Provost. The Provost, or designee will be responsible for communicating the report to the appropriate vice president, dean, chair or unit head for the department or unit in which the violation or non-compliance has occurred and, if applicable, any other compliance oversight office of the University. The Provost, or designee, will be responsible for conducting an inquiry into the reported violations to determine whether a finding of questionable or unacceptable research practices is warranted.

When warranted, the Provost or designee may empanel an Inquiry Committee to determine whether a finding of questionable or unacceptable research practices is justified. The Inquiry Committee shall be an ad hoc committee consisting of three (3) members. They will have seniority and experience at the University of Louisville, and shall be individuals with no real or apparent conflicts of interest in the case, are unbiased, and possessed of the necessary expertise to evaluate the evidence and issues related to the reported instance of questionable or unacceptable research practices, to interview the principals and key witnesses, and conduct the inquiry. The members may themselves be researchers or subject matter experts, be administrators, have legal training, or be otherwise qualified to serve as committee members. The Provost or designee shall make the appointments, following consultation with the appropriate vice president(s), dean(s) and chair(s).

The purpose of the inquiry is to explore in detail the reported instance of questionable or unacceptable research practices and to examine the evidence in depth, and to determine specifically whether questionable or unacceptable research practices have been committed, by whom, and to what extent. The inquiry will also determine whether there are additional instances of possible questionable or unacceptable research practices that would justify broadening the scope beyond the initial report. This may be particularly appropriate where the reported instance of questionable or unacceptable research practices involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

The inquiry will normally involve examination of all documents including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. At a minimum, the Inquiry Committee should interview the complainant/whistleblower, the respondent, and other individuals who might have information regarding the reported instance of questionable or unacceptable research practices. The inquiry will be conducted in a timely and confidential manner.

The Inquiry Committee will generate a report detailing the outcome of the inquiry and forward it to the Provost or designee. The report should contain the following elements: background information; description of the reported instance of questionable or unacceptable research practices; the inquiry process, findings, conclusions and recommendations regarding each reported instance of questionable or unacceptable research practices; the need, if any, for referral of any issue considered research misconduct to the Research Integrity Ombudsperson; and recommended sanctions or other actions, if any. The report should describe the policies and procedures under which the inquiry was conducted, describe how and from whom information relevant to the inquiry was obtained.

When there is a finding of questionable or unacceptable research practices, the Provost or designee shall determine whether sanctions will be imposed and the nature of those sanctions. The Provost or designee shall consult with legal counsel as needed and any other individuals necessary before reaching a decision as to appropriate action. Campus officials designated by the Provost or designee will implement the approved sanctions provide documentation to that effect.

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