INSTITUTIONAL COMPLIANCE PLAN

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Contents

I. SCOPE OF THE PLAN 2

II. MISSION STATEMENTS 2

A. U of L MISSION STATEMENT 2

B. U of L INSTITUTIONAL COMPLIANCE MISSION STATEMENT 3

III. DEFINED TERMS 3

IV. CODE OF CONDUCT 3

V. COMPLIANCE OVERSIGHT 3

A. GOVERNING AUTHORITY 4

B. U of L COMPLIANCE OVERSIGHT COUNCIL 4
Membership 4
Meetings 4
Role and Responsibilities 4

C. INSTITUTIONAL COMPLIANCE COMMITTEE 5
Membership 5
Meetings 5
Role & Responsibilities 5

D. AVP AUDIT SERVICES AND INSTITUTIONAL COMPLIANCE 5
The AVP Audit Services and Institutional Compliance (AVP) 5
Responsibilities of the AVP 6

E. INSTITUTIONAL COMPLIANCE OFFICER 6
The Institutional Compliance Officer (ICO) 6
Responsibilities of the ICO 6

VI. COMPLIANCE AWARENESS, EDUCATION & TRAINING 7

A. COMPLIANCE AWARENESS 7

B. COMPLIANCE EDUCATION 7
Introduction 7
General Compliance Education Content and Delivery 8
Specific Compliance Education Content and Delivery 8
Education Reporting and Maintenance of Compliance Education Materials 8

C. SUPERVISOR RESPONSIBILITIES 8

D. CORRECTIVE ACTION 9

VII. CRIMINAL BACKGROUND AND SANCTION CHECKS 9

A. EMPLOYEES 9

B. CONTRACTORS/VENDORS 9

VIII. MONITORING & RISK ASSESSMENT 9

A. ROUTINE MONITORING ACTIVITY 9

B. ANNUAL COMPLIANCE RISK ASSESSMENT 9

IX. REPORTING RESPONSIBILITIES & RESOURCES 9

A. REPORTING RESPONSIBILITY 9

B. COMPLIANCE HELPLINE 10

C. NON-RETALIATION POLICY 10

D. CONFIDENTIALITY 10

X. RESPONSE AND CORRECTIVE ACTION 10

A. RESPONSE TO ALLEGATIONS 10

B. CORRECTIVE ACTION & APPEAL RIGHTS 11

APPPENDIX A – INSTITUTIONAL COMPLIANCE ORGANIZATIONAL STRUCTURE 10

I. Scope of the Plan

This document is the compliance plan for the University of Louisville and the University of Louisville Research Foundation, Inc.

II. MISSION STATEMENTS

A. U of L MISSION STATEMENT

The University of Louisville shall be a premier, nationally recognized metropolitan research university with a commitment to the liberal arts and sciences and to the intellectual, cultural, and economic development of our diverse communities and citizens through the pursuit of excellence in five interrelated strategic areas: (1) Educational Experience, (2) Research, Creative, and Scholarly Activity, (3) Accessibility, Diversity, Equity, and Communication, (4) Partnerships and Collaborations, and (5) Institutional Effectiveness of Programs and Services.

B. U of L INSTITUTIONAL COMPLIANCE MISSION STATEMENT

The compliance program shall provide an infrastructure that facilitates on-going assurance that the institution is complying with internal and external Compliance Requirements and U of L policies and procedures as the University moves forward to become a premier, nationally recognized, metropolitan research university.

III. DEFINED TERMS

These terms are defined for purposes of this Plan as follows:

Auditing is a formal, systematic and disciplined approach designed to evaluate and improve the effectiveness of processes and related controls performed by professionals independent of the process being audited.

Compliance Requirements are laws, regulations, rules, guidances, and codes that U of L is subject to in providing teaching, research, service and clinical activities.

Monitoring is an on-going process usually directed by management to ensure processes are working as intended and is usually completed by operations or compliance personnel.

Non-compliance means failure or refusal to follow applicable state or federal laws or institutional policies whether or not such conduct results in financial risk to U of L. It can include acts that constitute fraud and/or violations of law or institutional ethical standards.

Regulatory Oversight Committees/Areas refers to existing and/or future Committees and/or Departments that have responsibility for certain regulatory areas, including, but not limited to, Institutional Review Board, Institutional Animal Care and Use Committee, Institutional Biosafety Committee, Medical Billing Compliance, Privacy Office, Conflict Review Board, Radiation Safety, Human Resources, and Research.

Violation of Law means failure or refusal to follow any applicable state or federal law such that criminal and/or civil penalties may be imposed.

IV. CODE of CONDUCT

In support of this Institutional Compliance Plan, the Code of Conduct provides a non-exclusive summary of ethical and legal principles for members of the U of L community based on Compliance Requirements applicable to U of L's activities. Except as otherwise stated, it does not replace any existing Trustee Rules or U of L policies or U of L faculty or student handbooks.

V. COMPLIANCE OVERSIGHT

U of L has designated the Compliance Committees and appointed Institutional Compliance Officials identified below to assist in the development and oversight of the U of L Institutional Compliance Plan (Plan). These Officials, working with the Compliance Committees are jointly responsible for implementing and monitoring a continuous, collaborative and proactive culture of compliance at U of L (*See* ***Appendix A*** *- Institutional Compliance Organizational Structure*).

A. GOVERNING AUTHORITY

The Board of Trustees (BoT) is vested with final jurisdiction of U of L, as enumerated in KRS 164.830. The President is appointed by the BoT and is responsible for the management and operation of the U of L administration and component institutions, under the direction of the Trustees, as enumerated in Article 2.1 of the U of L Redbook.

B. U of L COMPLIANCE OVERSIGHT COUNCIL

Membership

The Compliance Oversight Council (COC) is appointed and chaired by the Executive Vice President and University Provost. The Council is made up of the following individuals:

- Executive Vice President for Health Affairs
- Executive Vice President for Research
- Vice President for Business Affairs
- Vice President for Finance
- Associate Vice President, Audit Services & Institutional Compliance
- University Counsel
- Faculty Member
- Dean
- Faculty Senate Chair (or designee)
- Vice President for Human Resources

Meetings

The COC shall meet at least four times each year (or more often as necessary).

Role and Responsibilities

The COC's responsibilities include:

a. The COC serves as an oversight committee for the institutional compliance program. The council has decision-making responsibility and authority to establish, staff, and implement compliance initiatives across the entire University.
b. Review and give final approval of the Plan, Code of Conduct, and policies and procedures, and any amendments thereto, related to institutional compliance.
c. Furnish adequate resources for and support of the Plan.
d. Review and evaluate risk assessments prepared by the Institutional Compliance Committee (ICC) and approve compliance monitoring plans.
e. Review confidential final investigative compliance reports presented by the ICO to verify that findings of non-compliance are addressed through appropriate corrective action plans and/or disciplinary action to assist in reducing the risk of similar non-compliance in the future.
f. Enforce consistent application of compliance standards, including fair, equitable and consistent disciplinary action of individual(s) identified as responsible for confirmed non-compliance.
g. Review the annual compliance report presented by the ICO to confirm effective compliance oversight.
h. Provide guidance to the ICO on the operation of the compliance program to prevent and/or detect non-compliance with applicable laws, regulations and policies.

C. INSTITUTIONAL COMPLIANCE COMMITTEE

Membership

The COC shall, based on recommendations for membership, appoint members to serve on the U of L Institutional Compliance Committee (ICC). The membership of the ICC consists of a combination of responsible parties for current compliance high risks (or their designees) and representatives from other stakeholder groups across the University of Louisville. The Institutional Compliance Officer acts as chair. The structure is divided into a leadership team and the full committee. The Leadership team will work to determine the strategic agenda for the ICC on a yearly basis.

Meetings

The ICC meets quarterly or more frequently at the request of the COC or the Institutional Compliance Officer to meet its responsibilities under the Plan. Evidence of the discussions of the ICC and the actions taken by the ICC should be reflected in recorded summary of the meeting. A majority of voting members constitutes a quorum and attendance should be recorded in the meeting summary. The Institutional Compliance Officer shall Chair the meetings.

Role & Responsibilities

The ICC assists and supports the COC in fulfilling its oversight responsibilities. The ICC is the keystone to the structure for implementing the University of Louisville's compliance program. The ICC is charged by the COC to oversee the University's compliance activities and programs and to ensure they are reasonably designed, implemented, enforced and generally effective in detecting and minimizing risk of violations of university policies, regulations or laws. The ICC shall:

a. Serve as the working committee of the COC to assist the Council in fulfilling its responsibilities
b. Review the results of institutional compliance risk assessments to identify emerging risk areas and high risk activities within the institution and recommend to the COC those high risks which require executive oversight.
c. Review summary report of confidential reporting and investigation activity and recommend institutional process modifications to address operational issues.
d. Provide guidance to the COC in the development of policies and standards related to compliance awareness, training, monitoring, and response (including corrective action, sanctions and enforcement) to identify, avoid and/or minimize non-compliance with applicable laws, regulations and policies.

D. AVP AUDIT SERVICES AND INSTITUTIONAL COMPLIANCE

The Associate Vice President Audit Services and Institutional Compliance (AVP)

The AVP serves as U of L's Chief Compliance Officer (CCO) and has overall responsibility for the implementation and effectiveness of the U of L Institutional Compliance Plan. The AVP reports functionally to the Audit Committee of the Board of Trustees and administratively to the Executive Vice President and University Provost. The AVP shall be given adequate resources and authority to carry out such responsibility and shall report on the implementation and effectiveness of the Plan directly to the COC.

Responsibilities of the AVP

The AVP shall:

a. Serve as the University's Chief Compliance Officer, including voting membership on the Compliance Oversight Council.
b. Oversee and monitor implementation of the U of L Institutional Compliance Plan.
c. Provide periodic reporting of Institutional Compliance activities to the Audit Committee of the U of L Board of Trustees.
d. Supervise operations of the Institutional Compliance Offices.
e. Serve as a primary liaison to the COC for significant external audits, reviews, and investigations regarding potential non-compliance and assist other regulatory oversight areas, as requested, in addressing government audits of their areas.

E. INSTITUTIONAL COMPLIANCE OFFICER

The Institutional Compliance Officer (ICO)

The ICO reports administratively to the AVP and is responsible for operations of the University's Institutional Compliance Office and Conflict of Interest Office. As Chair of the ICC, the ICO also reports to the COC regarding ICC project status. The ICO is also the University's designated Conflict of Interest (COI) official and serves as the Chair of the Conflict Review Board (CRB). The ICO shall be given adequate resources and authority to carry out such responsibility and shall report on the implementation and effectiveness of the Compliance Plan directly to the AVP, the ICC, and the COC. The responsibilities of the ICO include the following:

Responsibilities of the ICO

The ICO shall:

a. develop and implement the U of L Institutional Compliance Plan as directed by the COC, including providing oversight and monitoring of its implementation and periodic review;
b. chair the ICC and meet regularly with University compliance officials;
c. assist COC and ICC in the establishment of institutional level policies and procedures to help ensure compliance with all federal, state, local and other laws and regulations applicable to U of L;
d. maintain, distribute, and promote the University's Code of Conduct;
e. maintain, distribute, and promote the University's COI policies and procedures;
f. develop and maintain process to solicit & review COI disclosures from Covered Individuals addressed in University COI policies;
g. chair the CRB, including oversight of review process and approval of COI management plans;
h. implement and publicize a "Compliance Helpline" program for employees to report suspected non-compliant activities and/or seek compliance guidance;
i. make periodic reports regarding institutional compliance matters directly to the AVP and/or the COC and/or the ICC as considered necessary;
j. develop and maintain a University-wide compliance awareness and training program that educates employees of the importance of general compliance and the institutional compliance program;
k. review high-risk compliance areas for effectiveness in reducing the likelihood of noncompliance with applicable laws, regulations, and policies.
l. maintain current knowledge of laws and regulations, keeping abreast of recent changes that may affect the University policies, procedures and processes through personal research,

seminars, peer contact, and bench-marking compliance monitoring practices and implementation strategies with other institutions;

m. provide advice and guidance to administration, faculty, and staff to facilitate compliance with statutory, regulatory, and University policy requirements;
n. assist COC in the provision of processes to help ensure no retaliation for employee good faith reporting of non-compliance;
o. work with COC and ICC to help ensure that appropriate compliance incentives for all employee are developed and maintained (e.g. employee evaluation process includes an ethics and compliance component);
p. work with COC to help ensure that appropriate consistent disciplinary action is taken regarding compliance violations,
q. provide oversight of institutional policies and procedures for exercising due diligence in hiring/screening employees, vendors, and affiliates against appropriate governmental exclusion/debarment/suspension lists to ensure eligibility for hire and/or to participate in University programs;
r. ensure that a compliance risk assessment is completed by the institution at least annually and report results and recommended areas of focus to control or manage the identified risks to COC;
s. work collaboratively with ICC and compliance officials, with input from Audit Services to identify high risk compliance areas;
t. investigate and respond to all complaints and/or reports received in the ICO regarding suspected non-compliance, including coordination/cooperation with other University compliance officials as deemed appropriate.

VI. COMPLIANCE AWARENESS, EDUCATION & TRAINING

A. COMPLIANCE AWARENESS

The Code of Conduct will be provided to all U of L employees who will be required to attest to their understanding and agreement to abide by the Standards of Conduct outlined in the Code.

The ICO shall post this Plan and the Code of Conduct on the U of L Institutional Compliance Office website. The ICO shall periodically publish information in various resources regarding the Plan, Code of Conduct, and related policies to raise awareness regarding general and specific compliance issues.

B. COMPLIANCE EDUCATION & TRAINING

Compliance education and training is a critical element of an effective compliance program. U of L is committed to providing general and specific compliance education and training so that U of L employees understand their obligations and responsibilities in accordance with applicable laws, regulations, and policies.

Introduction

Employees are expected to complete required compliance education and training within the time frames and frequencies established by the department or committee requiring and/or providing the compliance education. Notification of compliance education requirements will be communicated through various means, including, but not limited to supervisors, written memorandum, internet/intranet and/or e-mail.

General and Specific Compliance Education and Training programs and related information shall be periodically reviewed and updated to address current risk areas and improvement opportunities. A variety of educational methods, materials, and tools, will be utilized to present General and Specific Compliance Education and Training programs.

General Compliance Education & Training Content and Delivery

The ICO shall be responsible for developing the content for and delivery of general compliance education and training for U of L. The content of general compliance education and training will include, but is not limited to, the U of L Code of Conduct, the U of L Compliance Plan, U of L risk areas, roles & responsibilities and other information necessary to maintain an effective general compliance education and training program. General compliance education and training requirements shall be published on the Institutional Compliance website and advertised through other resources as necessary to communicate the information.

Specific Compliance Education & Training Content and Delivery

It will be the responsibility of the individual, department or committee having regulatory compliance oversight to develop the content and deliver specific compliance education and training related to their area of regulatory oversight responsibility. The content of these educational and training programs shall include those areas mandated by law, regulation and/or policy and may include a review of relevant Compliance Requirements applicable to that regulatory compliance area, identified or potential risk areas, responsibilities, and methods to improve compliance. The scope of specific compliance education and training includes, but is not limited to the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biohazard Committee (IBC), Safety, Radiation Safety, Human Resources, Medical Billing Compliance, Privacy, Conflicts of Interest, and other education as may be required by Compliance Requirements and/or U of L policy. Specific compliance education and training requirements shall be communicated by the department or committee responsible for the content and delivery of the Specific Compliance Education.

Completion Reporting and Maintenance of Compliance Education and Training Materials

Records of completion of required compliance education and training shall be maintained by the department or Committee responsible for delivery of the education and training in accordance with institutional/regulatory guidelines. Summary reports of compliance with mandatory compliance education and training requirements shall be compiled by the department responsible for the education and training at least annually or more often as necessary and be made available for review, upon request, by the ICC, AVP or ICO.

C. SUPERVISOR RESPONSIBILITIES

The promotion of and adherence to the Institutional Compliance Plan by University management is considered an integral part of their job performance. Specifically, supervisors shall:

- Complete all required compliance education and training for their respective position.
- Inform employees of required Compliance Requirements specifically related to their job function and appropriately monitor employees to verify compliance with those requirements.

D. CORRECTIVE ACTION

Failure to complete required education and training will result in corrective action, up to and including termination of employment or association with U of L.

VII. CRIMINAL BACKGROUND AND SANCTION CHECKS

A. EMPLOYEES

All new U of L employees undergo a criminal background and sanction checks pursuant to PER 2.04, Employment Applications and ICO-002, Sanction Checks Policy. U of L may prohibit the employment of any person listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federal or state funded programs to maintain compliance with federal and/or state laws.

B. CONTRACTORS/VENDORS

In accordance with ICO-002, Sanction Checks Policy, appropriate University compliance areas shall conduct applicable searches of vendors and contractors against federal and state sanction lists. U of L shall not contract with any individual or entity which is listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federal or state funded programs pursuant to Purchasing Policy 35.00.

VIII. MONITORING & RISK ASSESSMENT

A. ROUTINE MONITORING ACTIVITY

Regulatory Oversight Committees/Areas conduct routine monitoring in accordance with identified risks. The ICO shall review high risk compliance areas' monitoring plans, including activities of Regulatory Oversight Committees/Areas based upon applicable laws, regulations and policies.

B. ANNUAL COMPLIANCE RISK ASSESSMENT

The Institutional Compliance Office shall ensure that a compliance risk assessment is completed at U of L at least annually. This information shall be shared with the Compliance Oversight Council as part of its annual risk assessment activities.

IX. REPORTING RESPONSIBILITIES & RESOURCES

A. REPORTING RESPONSIBILITY

Reporting suspected fraud, violations of law or non-compliance is essential to the effectiveness of the U of L Institutional Compliance Plan. U of L employees and students shall report suspected violations of, or non-compliance with, federal or state laws, and/or U of L policies. There are various methods and resources available to report suspected fraud, violations of law or non-compliance. Any member of the U of L community who has a reasonable basis for believing fraud, violation of law or other non-compliance has occurred has a responsibility to promptly notify his/her supervisor, the appropriate compliance official, or use the external confidential Helpline (See Section B below). Reporting procedures are detailed in ICO-005 Reporting and Investigation.

All employees are expected promptly to report to Audit Services any suspected fiscal misconduct, whether by members of the university community or by persons outside the university, but involving university resources. Reporting procedures are detailed in ICO-004 Fiscal Misconduct Policy

It is a violation of U of L policy to intentionally make or submit false reports of fraud, violations of law or non-compliance. Those found to have made or submitted false reports will be subject to disciplinary action, up to and including termination of employment or association with U of L.

B. COMPLIANCE HELPLINE

1-877-852-1167

University of Louisville employees who have concerns of any kind stemming from possible noncompliance with Compliance Requirements, related University policies, and/or errors or irregularities in the University's financial accounting practices or policies can report them. If you have information about unethical behavior, criminal activity or any other work-related concern, you should first speak with your supervisor or an employee in the University office that has oversight authority for the policy or law. This service is not a substitute for, nor does it supersede, any existing reporting methods or protocols already in place at the University of Louisville for reporting suspected problems or complaints. Instead, the Compliance Helpline provides an additional means of reporting such issues. Any suspected problems or complaints reported via the Compliance Helpline will be reviewed in accordance with current University policies and procedures. All reports of compliance issues will be handled in confidence to the extent practicable. Employees who report concerns in good faith will not be subjected to retaliation, retribution, or harassment.

C. NON-RETALIATION POLICY

Knowledge of or suspicion of misconduct, violations of law, or other wrongdoing must be immediately reported to University management, the Institutional Compliance Office, other University compliance officials, or the University Compliance Helpline. No employee is permitted to engage in retaliation, retribution, or any form of harassment against another employee for reporting compliance-related concerns. Employees cannot exempt themselves from the consequences of wrongdoing by self-reporting, although self-reporting may be taken into account in determining the appropriate course of action. Procedures for the non-retaliation policy are detailed in ICO-001 Non-Retaliation/Non-Retribution Policy.

D. CONFIDENTIALITY

Insofar as legal and practical, confidentiality of employee concerns will be maintained. Only those personnel who have a need to know will be informed.

X. RESPONSE AND CORRECTIVE ACTION

A. RESPONSE TO ALLEGATIONS

The ICO will maintain a compliance reporting system and initiate a prompt and confidential investigation of questionable practices. Upon receipt of a report of questionable practice, the ICO and/or other University compliance officials will conduct a confidential investigation. The University compliance officials conducting the investigation shall report to appropriate University management and employees the results of the investigation and whether corrective action will be

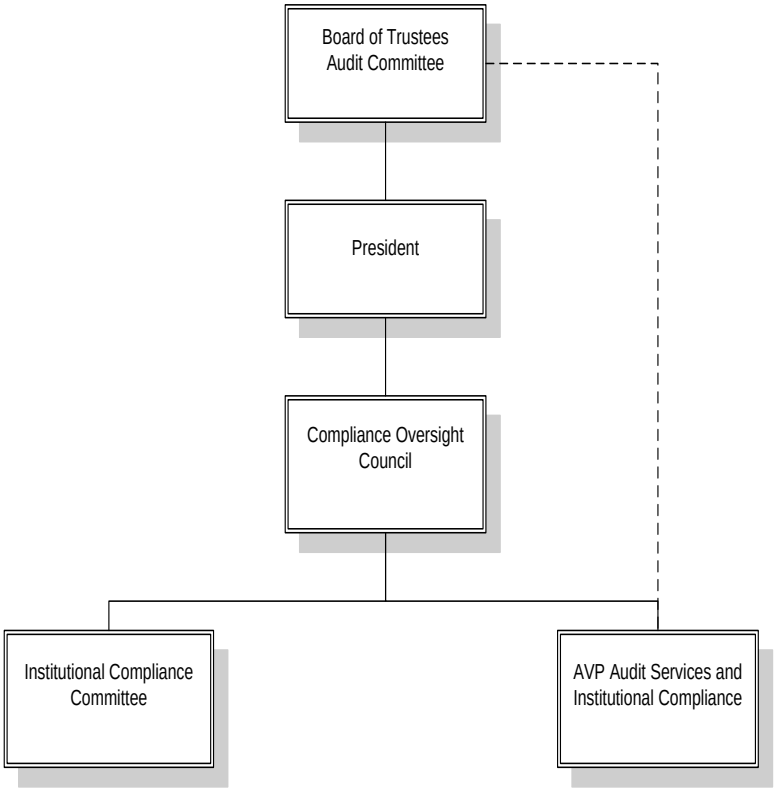
recommended. The AVP may also report the results of the investigation to the COC. U of L students, faculty and staff shall cooperate during any compliance investigation and shall not alter or destroy any documentation during the course of the investigation.

B. CORRECTIVE ACTION & APPEAL RIGHTS

Failure or refusal to comply with this Plan, applicable Compliance Requirements, and/or U of L policies will result in corrective action. An employee's supervisor, Chair, or Dean may also be subject to corrective action when he/she (i) directs or approves the employee's improper actions; (ii) is aware of the improper actions and fails to correct them, or (iii) otherwise fails to exercise appropriate supervision. Corrective action may also be imposed where an employee should have detected, but failed to detect fraud, a violation of law or non-compliance. Correction may include, but is not limited to, any of the following actions

- Mandatory training
- Increased monitoring/auditing
- Reclassification or reassignment of duties
- Suspension of billing privileges for health care providers
- Termination of contractual relationship
- Appropriate disciplinary action, up to and including, termination of employment

Any appeal or grievance rights are those provided in existing policies, including, but not limited to the Redbook, the Student Handbook, and staff personnel policies.

APPENDIX A

University of Louisville
Institutional Compliance Organizational Structure