



1 **POLICY NAME (R\*)**

2 Conflict of Interest and Commitment

3

4 **POLICY NUMBER (O\*)**

5 {TBD}

6

7 **FIRST ADOPTION AND EFFECTIVE DATE (R\*)**

8 {TBD}

9

10 **POLICY APPLICABILITY (R\*)**

11 This policy applies to University Community (trustees, administrators, faculty, staff and students) and affiliates

12

13 **REASON FOR POLICY (O\*)**

14 The University of Louisville and its Affiliates (“University”) expects Covered Persons to conduct University affairs  
15 with high ethical and legal standards and in a manner that supports the University mission. As part of this duty,  
16 Covered Persons must apply their University time and effort correctly and use University assets properly.

17 Use of University assets or University time damaging to the University mission or for personal advantage  
18 represents a conflict of interest. This policy sets standards to reduce or eliminate such conflicts and protect the  
19 financial well-being, reputation, and legal duties of the University.

20 **POLICY STATEMENT (R\*)**

21 **Contents**

22	POLICY APPLICABILITY .....	1
23	REASON FOR POLICY .....	1
24	POLICY STATEMENT .....	1
25	POLICY .....	2
26	CONFLICT OF INTEREST .....	3
27	NEPOTISM .....	3
28	BUSINESS OPERATIONS.....	3
29	GIFTS .....	4
30	TEACHING MISSION .....	4
31	RESEARCH AND CREATIVE MISSION .....	4



# University of Louisville

## OFFICIAL UNIVERSITY ADMINISTRATIVE POLICY

32	CLINICAL MISSION.....	5
33	INSTITUTIONAL OFFICIALS AND TRUSTEES.....	5
34	SMALL BUSINESS CONCERNS (START UP ENTITIES).....	5
35	SPECIAL CONSIDERATIONS FOR THE UNIVERSITY.....	6
36	CONFLICT OF COMMITMENT.....	7
37	DISCLOSURE AND MANAGEMENT.....	8
38	COIC TRAINING.....	8
39	COMPLIANCE.....	8
40	DEFINITIONS.....	9
41	PROCEDURES.....	9
42	DISCLOSURE OF EXTERNAL ACTIVITIES AND INTERESTS.....	9
43	REVIEW OF DISCLOSED EXTERNAL ACTIVITIES AND INTERESTS.....	10
44	MANAGEMENT OF IDENTIFIED CONFLICTS OF INTEREST AND COMMITMENT.....	11
45	RECONSIDERATION.....	12
46	IMPLEMENTATION OF APPROVED MANAGEMENT PLANS.....	12
47	COMPLIANCE WITH POLICY.....	12
48	SPECIAL MANAGEMENT FOR RESEARCH AND SPONSORED ACTIVITY.....	13
49	COIC TRAINING.....	13
50	RESPONSIBILITIES.....	13
51	FORMS/ONLINE PROCESSES.....	14
52	RELATED INFORMATION.....	14
53	RESPONSIBLE AUTHORITY.....	15
54	RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION.....	15
55	HISTORY.....	15

56

57 **POLICY**

58 The University commits to teaching, serving, working, and conducting Research with integrity and free from

59 unmanaged Actual or Apparent Conflicts. Covered Persons have a duty to Support University education, Research,

60 and service missions with their primary commitment of time and intellectual energies. Personal Gain from

61 external ventures or Financial Interests must not influence the decisions or actions of Covered Persons in



62 performing University Responsibilities. Covered Persons must not act or decide for the University if Personal Gain,  
63 Interest, or advantage could influence (directly or indirectly) judgment in performing University Responsibilities.

64 No list of rules can provide direction for all the varied circumstances that may arise. The University reserves the  
65 right to address any internal or external circumstance that creates an Actual or Apparent Conflict with University  
66 Responsibilities. Covered Persons should discuss questions about conflicts with the University Conflict of Interest  
67 and Commitment Office (COIC Office).

68 **CONFLICT OF INTEREST**

69 Conflicts of Interest arise when personal or private considerations (financial or nonfinancial) compromise University  
70 priorities. Covered Persons of the University shall exercise good faith and integrity in all transactions touching  
71 University Responsibilities and University’s property. Covered Persons shall not take part in dealings resulting in an  
72 unresolved Actual or Apparent Conflict. Personal Gain must not unduly influence the decisions or actions of Covered  
73 Persons or the University in fulfilling University Responsibilities.

74 The University will exercise oversight and care in removing or Managing Actual or Apparent Conflicts that arise  
75 because of a Covered Person’s Interest related to their University Responsibilities. The University will not allow  
76 contracts, Gifts, buying, or other dealings causing an unresolved Actual or Apparent Conflict.  
77

78 **NEPOTISM**

79 Covered Persons must comply with the University [Nepotism Policy](#). Additionally, a Principal Investigator (PI) cannot  
80 directly or indirectly supervise a Relative on UofL Research. If a Covered Person’s project needs the unique skills of  
81 a Relative, the Conflict Review Board (CRB) must approve a plan to mitigate the conflict of interest before hire or  
82 assignment.

83 **BUSINESS OPERATIONS**

84 Covered Persons conducting affairs for the University, including hiring and buying, must do so in an objective and  
85 ethical manner. This includes a Covered Persons use of a ProCard for buying goods or services for the University.

86 Covered Persons or Relatives cannot buy, rent, or lease any realty, goods, or services for the University from a source  
87 in which the Covered Person or Relative holds a fiduciary or management role or Significant Financial Interest (SFI).  
88 Further, Covered Persons cannot directly or indirectly recommend, review and/ or approve business transactions  
89 that involve a Relative.

90 Covered Persons, acting in their private capacity, cannot rent, lease, or sell any realty, goods, or services to the  
91 University; this includes engaging a Relative as an independent contractor, subcontractor, or consultant.

92 Covered Persons must not provide an external party access to University programs, services, information, or  
93 technology.



94 Covered Persons making University contract decisions<sup>1</sup> cannot have a link with an individual/ Entity under contract  
95 with the University.

96 COIC Office, Office of Communications and Marketing, and approved University management must review and  
97 approve of Entity marketing<sup>2</sup> involving Covered Persons.

### 98 GIFTS

99 Covered Persons may not seek Gifts, cash or special favors<sup>3</sup> from current or prospective Vendors, current or  
100 prospective subordinate employees, or current or prospective students. Covered Persons should not accept  
101 proffered Gifts when:

- 102 ○ individual or Entity offering Gift has current or future business relationship with University;
- 103 ○ Covered Person receiving the Gift has authority or influence over the current or future individual or Entity  
104 doing business with University;
- 105 ○ Gift offered is cash or cash equivalent of any amount;
- 106 ○ noncash Gift valued above \$25; or
- 107 ○ Gift offered directly to Covered Person's Relative.

### 109 TEACHING MISSION

110 Covered Persons must follow unit<sup>4</sup> guidelines when adopting course materials created by the Covered Person, a  
111 Relative or the Covered Person's Appropriate Authority.

112 Covered Persons must not exploit University faculty, staff, students or administrators for Personal or Private Gain.

113 Covered Persons with leadership roles in nonprofit professional or scientific societies may take part in programs,  
114 meetings, and events that involve Vendor relations. The policies and procedures of the society govern these Vendor  
115 exchanges.

### 116 RESEARCH AND CREATIVE MISSION

117 Covered Persons serving as Investigators or Senior or Key Personnel on University Research may not use or disclose  
118 nonpublic Research information for Personal or Private Gain.

119 University professional presentations must not involve Ghostwriting or Gift Authorship. Anyone named as authors  
120 must qualify for authorship.

121 Covered Persons must report SFI, external interests and foreign affiliations in publications<sup>5</sup>, presentations at  
122 professional meetings, and applications for funding.

---

<sup>1</sup> includes developing specification or procurement standards, rendering advice, investigating, or auditing University contracts

<sup>2</sup> Such as endorsement, commercial, print/digital media, etc.

<sup>3</sup> including cash equivalents, meals, loans, rewards, promises of future employment, services or entertainments

<sup>4</sup> In the cases where no unit guidelines exist, the Covered Person should follow the guidelines of the department in which the course is taught.

<sup>5</sup> including articles, abstracts, manuscripts submitted for publication



123 Covered Persons or Relatives shall not take part in negotiating agreements<sup>6</sup> between the University and an Entity in  
124 which the Covered Person or a Relative has an Interest.

125 Covered Persons cannot serve as PI or equal role on University human subjects Research using their technology and  
126 may not supervise Covered Persons who serve as PI or equal role on these projects.

127 Covered Persons with nonprofit professional and scientific society leadership roles may take part in programs,  
128 meetings, and events that involve Vendor relationships. The policies and procedures of the society govern these  
129 Vendor interactions.

130 **CLINICAL MISSION**

131 Clinical service provided to patients/clients, as well as the educational environment provided for students, must be  
132 free from undue bias and influence of external activities and Interests. Covered Persons supporting the clinical  
133 mission must comply with the [University of Louisville Health Care Policy on Vendors](#).

134 **INSTITUTIONAL OFFICIALS AND TRUSTEES**

135 Members of the University Board of Trustees (“Trustees”) and Institutional Officials (IOs) have a heightened  
136 responsibility to foster an environment that is free from undue external influence. As members of the University  
137 leadership team, Trustees and IOs must take a strict approach to avoiding and recognizing Actual and Apparent  
138 Conflicts. Trustee or IO actions taken for the University must protect against using a position for Personal or Private  
139 Gain. Further, Trustees or IOs must ensure others do not use a Trustee or IO position, whether directly or indirectly,  
140 to claim benefits from the University or its faculty, staff, or students.

141 **SMALL BUSINESS CONCERNS (START UP ENTITIES)**

142 Covered Persons are responsible for separating their University Responsibilities for Research and education from  
143 their personal or private Financial Interests. Covered Persons must separate and clearly distinguish current  
144 University Research from work at the start-up companies or small business concerns (SBC).

145 Covered Persons should serve in advisory or advice-giving roles at the SBC as opposed to roles with management  
146 responsibility. Full-Time<sup>7</sup> Covered Persons wishing to engage in a management role, must reduce UofL  
147 appointment<sup>8</sup>.

148 If the Covered Person elects to serve in any SBC roles, the Covered Person may not engage in any University projects  
149 related to the SBC. The SBC and University must define project personnel, budget, scopes of work and resources.

150 Covered Persons or Relatives cannot negotiate with the University for the SBC. Covered Persons must not use  
151 University assets for the direct benefit of the SBC without a University approved agreement in place.

152 Covered Persons involved with an SBC must fully report SBC dealings and ownership to any students, fellows, or  
153 trainees working on their research.

154 SBCs must have independent capacity to conduct business. SBCs may utilize core facilities as long as the SBCs pay  
155 established service center rates.

---

<sup>6</sup> Research agreements, license agreements, equipment purchases, etc.

<sup>7</sup> Refers to 1.0 FTE

<sup>8</sup> Possible mechanism for this reduction would be entrepreneurial leave.



156 A Covered Person cannot contribute to both SBC and University parts of a single project<sup>9</sup>. Covered Persons may not  
157 serve as both the SBC PI and the University subcontract PI.

158 The University may not subcontract to a Covered Person’s SBC, unless University Trustees grant an exception<sup>10</sup>. The  
159 University may accept Research subcontracts from a Covered Person’s SBC (for example STTR, SBIR programs). The  
160 University cannot serve as a Research or development arm of an SBC.

161 Covered Persons must not involve personnel that they supervise<sup>11</sup> in the SBC’s dealings before review by the CRB.  
162 Covered Persons must avoid circumstances in which junior personnel might feel expected to support the SBC.

163 Personal interests of Covered Persons or commercial Interests of Research sponsors may not impact the training  
164 experience and academic progress of University students, fellows, and trainees. Current students, trainees, or  
165 fellows asking to take a leave of absence to join the SBC should consult the CRB who will offer independent advice.

166 **SPECIAL CONSIDERATIONS FOR THE UNIVERSITY**

167 The University shall not engage in actions that create Institutional Conflicts of Interest (ICOI).

168 Philanthropy is important to the University mission. No charitable donation should be dependent on the result of  
169 University research.

170 The University must not seek or accept gifts that impacts the ability of its researchers to conduct and report results  
171 with the highest scientific, medical, professional, and ethical standards.

172 This policy does not forbid the University from accepting philanthropy from companies that sponsor research or  
173 conduct business with the University. The policy helps the University develop means of identifying and examining  
174 such circumstances and managing conflicts of interest that may result.

175 The Office of University Advancement and external investment managers, cannot discuss nonpublic University  
176 research with members of the University community to influence investment decisions<sup>12</sup>.

177 Individuals must report real or seeming conflicts of interest involving philanthropic practices<sup>13</sup> to the CRB or the  
178 COIO.

---

<sup>9</sup> This includes serving as an employee or holding a management position in the Start-up, serving as Start-up project team or consultant.

<sup>10</sup> per Kentucky Revised Statute 164.821(7)

<sup>11</sup> direct or indirect

<sup>12</sup> Maintaining this robust “firewall” is essential for ensuring the core activities of the University are not affected, or perceived to be affected, by the University’s interests in maximizing the value of its endowment pool.

<sup>13</sup> For example: gifts, solicitation of donations, or management of the endowment pool



179 CONFLICT OF COMMITMENT

180 Covered Persons must comply with institutional requirements regarding work outside the University ([Redbook 4.3.3](#)  
181 [for Faculty](#), [Redbook 5.6 for Staff](#), [PER1.12 for Administrators](#)).

182 Covered Persons may use their expertise to advance and share knowledge through collaboration with the public,  
183 the community, and external Entities. These actions strengthen performance of University teaching, advance  
184 University Research and public service missions, and bring credit to the University.

185 At the same time, the University has a responsibility to ensure that Covered Persons' external dealings do not  
186 inappropriately influence their University actions and decisions.

187 Covered Persons may engage in Non-University Commitments of a professional, personal, or economic nature that  
188 do not conflict or interfere with University interests or with the Covered Person's commitment to the University<sup>14</sup>.

189 Covered Persons must meet the duties and professional activities that fulfill obligations to their units, departments  
190 and programs.

191 Covered Persons may not hold a position<sup>15</sup> at any other postsecondary educational institution, independent research  
192 institutes or nonprofit entities while they are Full-time University Employees <sup>16</sup>unless approved under this policy,  
193 including online teaching. Consulting and joint Research relations are subject to review and prior institutional  
194 approval<sup>17</sup>.

195 When a dual appointment is approved, the Covered Person will list the University as the primary appointment on all  
196 research and scholarly publications, presentations and contact information.

197 Funding or support related to the dual appointment must be reported to the University on the ADF, to OSPA and in  
198 funding proposals as needed. This includes all funding or support from all added sources related to the dual  
199 appointment.

200 Covered Persons cannot use University resources to aid work at the dual appointment<sup>18</sup>.

201 Covered Persons must coordinate travel and coverage of University duties with the Appropriate Authority when dual  
202 appointments compel absence from campus.

203 Covered Persons private interests cannot create a recurring conflict with their University Responsibilities.

---

<sup>14</sup> Including, to the University's students, sponsors, patients, or to other parties to whom the University has a duty

<sup>15</sup> as faculty members, professional staff, or administrators, including honorary titles and uncompensated positions

<sup>16</sup> Faculty on non-12 month appointments must apply these requirements for the term in which they are under contract with the University (9, 10, 11 months respectively).

<sup>17</sup> Similar relationships with External Entities are covered by the E-Leave policy and procedures.

<sup>18</sup> This includes, but is not limited to: use of University funds (including all types of sponsored program funds (e.g. NIH grant funds), research infrastructure funds, endowments accounts, gifts, etc.), non-public or confidential research information or intellectual property, facilities, equipment or personnel, services (e.g. IRB Review) and library subscriptions.



204 Covered Persons may not hold a contractual arrangement<sup>19</sup> with an Entity that interferes with their University  
205 Responsibilities.

206 Covered Persons may not engage in excessive or unauthorized use of University time or resources for professional,  
207 charitable, or community activities.

208 Covered Persons or Relatives must not use the Covered Person's position, University assets or resources for Personal  
209 or Private Gain.

210 Covered Persons must not influence or try to influence the actions of colleagues and subordinates with the intent of  
211 improving the Covered Person's or Relatives' Interests (financial or nonfinancial).

### 212 DISCLOSURE AND MANAGEMENT

213 Timely and accurate submission of the University's Attestation and Disclosure Form (ADF) is a condition of  
214 employment at the University.

215 Covered Persons must disclose to the Appropriate Authority or administrative officer intent to engage in external  
216 activity or employment before such engagement and **before** a contract or transaction takes place.

217 Covered Persons must disclose external Interests at least each year or within 30 days of the discovery or gain<sup>20</sup> of a  
218 new external interest, by the ADF to the COIC Office<sup>21</sup>. Covered Persons will report external interests **before** an  
219 application for sponsored funding as needed by this policy and the sponsoring agency.

220 The University will manage or eliminate Identified conflicts. The Covered Person shall agree in writing to the  
221 approved Management Plan.

222 The approved Management Plan will be in place before any action<sup>22</sup> subject to influence by the external interest.

223 The Board reserves authority to review and approve plans for managing, reducing, or eliminating conflict of  
224 interest and commitment involving potential conflicts involving the president; or potential conflicts arising in  
225 matters that otherwise require Board review and action under KRS 164.830.

### 226 COIC TRAINING

227 All Covered Persons will complete Conflict of Interest and Commitment (COIC) training identified by the University  
228 at least every four years or immediately following one of the three circumstances noted in the procedures.

### 229 COMPLIANCE

230 All Covered Persons are responsible for knowing, understanding, and complying with this policy.

---

<sup>19</sup> Including employment

<sup>20</sup> for example, through purchase, marriage, or inheritance

<sup>21</sup> The COIC Office reports to the Vice President for Risk, Audit and Compliance, who serves as the COI Officer.

<sup>22</sup> any related contract, grant, sponsored project (for example, Research, instruction or outreach), dedicated Gift, or other transaction is carried out, or any relationship is started





231 Covered Persons are responsible for affirming that they have received and read this policy and will adhere to its  
232 conditions.

233 Noncompliance with this policy may be cause for corrective actions, depending on the seriousness of the violation  
234 and management discretion. Noncompliance includes deliberate breach of this policy including, but not limited to,  
235 failure to file or willfully filing a partial, false, or misleading ADF, violations of the guidelines, or failure to comply  
236 with prescribed monitoring procedures, will be addressed in accord with applicable disciplinary policies and  
237 procedures (University Redbook, University Discipline Policy) for each Covered Person.

238 Possible sanctions may include some or all of the following actions:

- 239 ○ termination of the activity that is a conflict of interest or commitment;
- 240 ○ divestiture of the external Interest;
- 241 ○ disciplinary action against the Covered Person up to termination.
- 242 ○ violators may be subject to civil or criminal penalties for a violation of criminal or civil law.

243 Individuals should report concerns of noncompliance with this policy to the COIC Office. University will tell the  
244 Research sponsor of the violation and any corrective action, as needed or required. For Public Health Service (PHS)  
245 Supported projects, University will undertake the Retrospective Review and create any Mitigation Reports, as  
246 needed.

247 The COIC Officer authorizes the COIC Office and CRB to review and address reports of noncompliance with this policy,  
248 a Management Plan, or applicable federal, state or local controls. The COIC Officer will address any concerns not  
249 resolved by the COIC Office or CRB.

250 **DEFINITIONS (O\*)**

251 <insert COI URL>

252 **PROCEDURES (O\*)**

253 **DISCLOSURE OF EXTERNAL ACTIVITIES AND INTERESTS**

254 Procedures describing academic, business, clinical, and Research and scholarly activities may also include extra  
255 reporting. Covered Persons report external Interests and activities on the ADF<sup>23</sup>. Covered Persons complete the  
256 ADF yearly and throughout their Term of Appointment. The reporting period for the ADF includes the previous 12  
257 months and the coming 12 months. Annual disclosures follow the following standards:

- 258 • Trustees shall file a disclosure statement yearly and report external Interests as governed by bylaws and  
259 KRS.
- 260 • Institutional Officials shall disclose external Interests by filing an ADF, within 30 days of appointment, yearly  
261 after that, and as described in this policy.
- 262 • Covered Persons shall disclose external Interests by filing an ADF within 30 days of appointment, annually  
263 thereafter, and under circumstances described in this policy. Covered Persons for which a Conflict of

<sup>23</sup> The ADF is located at <https://iris.louisville.edu>



264 Interest or Commitment is identified are required to abide by the requirements of the approved  
265 Management Plan.  
266 • The president or delegate may designate other individuals who shall file a yearly ADF.  
267

268 Newly secured external interests or newly started external affiliations must be reported on an updated ADF. The  
269 updated ADF must be filed within 30 calendar days of a change in external interests or affiliations.

270 All disclosures filed route electronically to the Covered Person’s department or unit head for review. Once the  
271 department or unit head complete review, all disclosures route electronically to the COIC Office. Covered Persons’  
272 ADFs with no disclosures will bypass department or unit head review and route directly to the COIC Office.

273 University will report disclosures made under this policy to governmental agencies or to the general public as  
274 required by law or regulation.

275 Covered Persons reviewing a Request for Proposal/Bid (RFP/B) will complete a confidentiality agreement and ADF  
276 before viewing any Vendor information. COIC Office will review any external activity or Interest and consult the  
277 CRB, as needed. The RFP/B reviewer will be replaced if the review cannot be done timely.

278 **REVIEW OF DISCLOSED EXTERNAL ACTIVITIES AND INTERESTS**

279 The Appropriate Authority, as Primary Reviewer, will review the disclosure of Non-University Commitments and  
280 recommend approval or denial. The appropriate Dean/Vice President, as Secondary Reviewer, will make a final  
281 determination of approval or denial. Covered Person's expertise, the mission of the University and conclusion the  
282 Non-University Commitment does not conflict or interfere with the Covered Person's University Responsibilities will  
283 be the basis for approval.

284 Non-University Commitments needing prior approval include:

- 285 • Non-University consulting for more than the equivalent of one workday a week;
- 286 • Holding office in a scholarly or professional society, for more than the equivalent of one workday a week;
- 287 • Editing a professional journal for more than the equivalent of one workday a week;
- 288 • Any potentially compromising activities for more than the equivalent of one workday a week;
- 289 • Seeking or serving on sponsored projects submitted and Managed through other academic, federal, or  
290 commercial institutions;<sup>24</sup>.
- 291 • Keeping a faculty appointment at another academic institution, federal organization, or Entity;
- 292 • Keeping an employment position at another academic institution, federal organization, or Entity;
- 293 • Directing a program of Research at another Entity; or
- 294 • Seeking buyout of course assignments for Research that involves internal University funds to cover release  
295 time.
- 296

---

<sup>24</sup> This stipulation does not apply to subcontracts awarded to the University; it is not intended to limit a Covered Person’s Participation in multi-site training or Research programs, nor is it intended to apply to circumstances in which the Covered Person's Research requires access to facilities not available at the University.



297 Covered Persons may put forward a reconsideration request in writing within 10 business days of the receipt of  
298 denial to the Provost, or designee. A three-person peer review ad hoc panel<sup>25</sup> will review reconsideration requests.  
299 All member selections must be from within the University community. The panel will make a final recommendation  
300 to the CRB.

301 CRB will review the ADFs, any reviews, the first determinations, and the Reconsideration Request. CRB will have the  
302 right to consult, as needed, with University management. The CRB’s determination shall be final.

303 Disclosed Interests and approved Non-University Commitments will be reviewed by the COIC Office. ADFs submitted  
304 will be screened to ensure:

- 305 a. disclosures made are complete and accurate;
- 306 b. institutional activities engaged in by the Covered Person are correctly identified;
- 307 c. additional information necessary for review of a Covered Person’s disclosures is obtained<sup>26</sup>;
- 308 d. early identification of actual or proposed Research activities involving human subjects in which a  
309 Covered Person may have an identified Conflict of Interest or Commitment<sup>27</sup>.

310  
311 COIC Office will contact the Covered Person, if more information or documentation is needed.

312 CRB will review potential Organizational Conflicts of Interest.

313 FCOI report will be issued for identified COICs meeting Relatedness criteria and involving a PHS project. COIC Office  
314 will directly file report or report will be sent to the prime awardee. Reports are filed at the time the determination  
315 is made.

316 **MANAGEMENT OF IDENTIFIED CONFLICTS OF INTEREST AND COMMITMENT**

317 COIC Office will decide management level to protect the University’s missions to promote objectivity and protect  
318 against COIC. Measures taken in managing COIC include, but are not limited to:

- 319 • Public disclosure of Financial Interests
- 320 • Reformulation of work plan
- 321 • Monitoring of project by an independent review committee
- 322 • Substituting supervisors or personnel
- 323 • Divestiture of Financial Interests
- 324 • Halt or reduce involvement in relevant projects
- 325 • Halt inappropriate student involvement in projects
- 326 • Remove relationships that pose real or potential conflicts

<sup>25</sup> The panel will include one individual selected by the Covered Person<sup>25</sup>, one individual selected by the Covered Person’s Dean or Vice President, and one individual selected by the Provost or designee from outside the Covered Person’s unit.

<sup>26</sup> in order to ensure that the review process and any CRB deliberations concerning the identification, elimination, reduction, or management of any identified Conflicts of Interest or Commitment are as complete and fair as possible

<sup>27</sup> early notification to the Institutional Review Board (IRB) regarding the possibility of such activities, and timely notification to the Covered Person of the rebuttable presumption against such conflicts in human subjects Research and the opportunity available to such individual for demonstrating compelling circumstances in order to overcome the presumption



- 327 • Remove Covered Person from human subject Research in the critical areas of recruitment, inclusion or
- 328 exclusion evaluation, enrollment, and adverse event evaluation and reporting.
- 329 • Naming third-party, for example department or unit head, oversee or control the Gift funds from an
- 330 Entity with which the Covered Person has an identified Actual or Apparent Conflict.

331  
332 Covered Person has the onus of providing information that would help University in reviewing identified COIC.

333 **RECONSIDERATION**

334 Any Covered Person may to seek reconsideration of any final decision under this procedure involving that  
335 individual. Covered Persons must present a written request to CRB Chair within 10 business days of receiving  
336 decision. The request should include, at a minimum, the clause (s) needing change, a reason of why the approved  
337 Management Plan will not work, and a proposed revision to the approved management clause (s).

338 CRB Chair will present reconsideration at the next called meeting of the CRB. CRB will review and decide whether it  
339 has necessary information<sup>28</sup>. CRB will communicate the need for more detail to the Covered Person. CRB will  
340 determine whether the original approved clause (s) will stand or be altered. CRB can accept the resolution proposed  
341 by the Covered Person, or adopt an alternate resolution. CRB resolution is final and must be carried out.

342 **IMPLEMENTATION OF APPROVED MANAGEMENT PLANS**

343 COIC Office will send the approved plan to the Covered Person and Appropriate Authority for implementation.  
344 Covered Person must acknowledge receipt of Management Plan and perform required actions, on or before the  
345 implementation date, to CIOC Office. The Appropriate Authority is copied on this communication. Appropriate  
346 Authority will apply all clauses not involved in pending reconsideration requests.

347 **COMPLIANCE WITH POLICY**

348 COIC Office will conduct a preliminary review to decide whether reported noncompliance concerns are valid.

349 COIC Office will tell COIC Officer and University Counsel. COIC Office may:

- 350 1. Investigate concerns and make written report of conclusions;
- 351 2. Ask Appropriate Authority to conduct investigation and make written report conclusions; or
- 352 3. Appoint CRB member to conduct investigation and make written report of conclusions.

353 Investigation will, at a minimum, include interview with complainant (if available) and interview with the Covered  
354 Person(s). Investigations will be conducted in according to University’s Reporting and Investigation Procedures.

355 Investigations confirming noncompliance may result in corrective action<sup>29</sup> as noted in the Compliance section of this  
356 policy. The COIC Officer and Executive Vice President for Research and Innovation have authority to suspend  
357 Covered Person’s Research impacted by Actual or Apparent Conflicts, pending conclusion of an investigation or, on  
358 conclusion of an investigation, that they be suspended pending correction of any policy violations.

---

<sup>28</sup> Requests submitted that impact the design, proposing, conduct, perform or analysis of research may require a hold (including expenditures) to be placed upon the specific project in question until the management issue is resolved.

<sup>29</sup> Possible actions or sanctions could include a letter of reprimand, increased monitoring of the identified Conflict of Interest or Commitment, Management Plan modifications, or other appropriate actions.



359 SPECIAL MANAGEMENT FOR RESEARCH AND SPONSORED ACTIVITY

360 University presumes Covered Persons with identified COIC may not conduct the activity in question. Covered  
361 Persons with identified COIC who wish to show reasonable or compelling circumstances must convince University,  
362 CRB and COIC Officer, that facts rebut the presumption. Covered Person will present to CRB, in writing, an  
363 explanation of reasonable or compelling circumstances to conduct proposed activity. CRB will review  
364 documentation submitted and make final determination. CRB will formally approve the rebuttable presumption and  
365 change the Management Plan, or reject the rebuttable presumption and affirm the approved Management Plan.

366 The COIC Office shares approved Management Plans with IRB. IRB has final authority to decide whether approved  
367 plan protects Research subjects and whether Research may continue. IRB may impose added conditions on Covered  
368 Persons, but may not lift controls approved by CRB.

369 Yearly, the subcontractor or subgrantee must send oversight updates to University for duration of contract period.  
370 The University will report existence of Actual or Apparent Conflict and resulting Management Plans as needed by  
371 sponsors.

372 The University does not allow subcontracts or subawards from the University to an external Entity in which a  
373 Covered Person or Relatives hold equity Interest or serve in a fiduciary or management role. Rarely, Covered  
374 Persons may seek University prior approval<sup>30</sup> if only source of materials or expertise lives with external Entity.  
375 Where approval is granted, Covered Person will not, under any circumstances, engage in any project, study, or  
376 transactions for University.

377 COIC TRAINING

378 University will identify suitable COIC training completed by Covered Persons at least once every four years or  
379 immediately after circumstances listed below. Training will tell each Covered Person of policy, Covered Person's  
380 responsibilities about disclosure and of applicable federal, state and local regulations. Immediate training for  
381 Covered Persons will be required:

- 382 • When University makes revisions to policy that impacts Covered Person’s responsibilities;
- 383 • When Covered Person is new to University; or
- 384 • When University finds Covered Person noncompliant with policy or with approved Management Plan.

386 RESPONSIBILITIES (O\*)

387 The first responsibility for compliance lies with the Covered Person directly involved.

388 **Covered Persons** are responsible for knowing, understanding, and complying with this policy and procedures.  
389 Covered are responsible for accurate and timely completion of ADF and updating it as external interests change.  
390 Covered Persons are responsible for accepting Management Plan, or timely seeking changes to Management Plan,  
391 and agreeing to Management Plan. Covered Persons are responsible for upholding all terms, conditions, and actions  
392 set forth in Management Plan. Covered Person must respond to calls for information from COIC Office or CRB.  
393 Covered Person are responsible for complying with corrective actions, enforcement, and sanctions imposed by  
394 University related to findings of noncompliance.

<sup>30</sup> At time of proposal, via the CRB, COIC Officer and Board of Trustees



395 **Department or Unit Heads.** Each department or unit head will ensure that Covered Persons identified within  
396 department or unit<sup>31</sup> complete ADF as required by this policy. Deans or their designees will ensure department or  
397 unit heads complete duties related to this policy in timely manner, resolve ambiguities Covered Persons  
398 identification, and ADFs are filed and sent.

399 **University.** University is responsible for maintaining this policy, making it available publicly as required by law or  
400 regulation, and ensuring it complies with applicable federal, state, and local regulations. University will make COIC  
401 training available to Covered Persons that complies with policy and applicable federal, state, and local regulations.  
402 University will provide FCOI Reports to Research sponsors as required by federal, state, and local regulations,  
403 sponsor terms and conditions, or as required by Management Plan. University is responsible for setting up  
404 enforcement to ensure compliance with policy and federal, state, and local regulations. University will keep records  
405 about ADFs and University's reviews and determinations.

406 **Initiating Authority.** Vice President for Enterprise Risk, Audit and Compliance serves as Conflict of Interest and  
407 Commitment Officer (COIC Officer) and charged with oversight of this policy and procedures. Executive Vice  
408 President for Research and Innovation (EVPRI) shares a joint responsibility with the COIC Officer, for complying with  
409 FCOI reporting for federal regulations about sponsored programs.

410 For questions, added detail, or to seek changes to this policy, please contact the COIC Office.

411

412 **FORMS/ONLINE PROCESSES (O\*)**

413

414 [Attestation and Disclosure Form](#)

415 **RELATED INFORMATION (O\*)**

416 **UOFL POLICIES**

417 [Code of Conduct](#)

418 [Digital Media Policy](#)

419 [De Minimis Gifts Policy](#)

420 [Ethics in Purchasing](#)

421 [Health Care Policy on Vendors](#)

422 [Nepotism Policy](#)

423 [Public Information](#)

424 [Work Outside the University \(Per 1.12\)](#)

425 **REDBOOK**

426 [Ethical Considerations – 2.5.8](#)

427 [Annual Work Plan and Presence at the University – 4.3.1](#)

428 [Work Outside the University – 4.3.3](#)

429 [Work Outside the University – 5.6](#)

---

<sup>31</sup> either as defined by this policy or as individually determined to be involved in Research by the PI, the department or unit head



430 **BOARD of TRUSTEES BYLAWS**

431 [Article 4, Section 4.1 Conflict of Interest](#)

432 **GOVERNING LAWS, REGULATIONS, STANDARDS**

433 [42 CFR 50](#)

434 [45 CFR 94](#);

435 [NSF GPM Section 510](#);

436 21 CFR Parts [54](#), [312](#), [314](#), [320](#), [330](#), [601](#), [807](#), [812](#), [814](#), and [860](#); [2 CFR 215](#);

437 AAHRPP Standards: [I-6](#), [II-1](#), [III-1](#).

438 **KENTUCKY REVISED STATUTES (KRS)**

439 [45A.340](#),

440 [164.367](#),

441 [164.390](#),

442 [164.821](#)

443

444 **RESPONSIBLE AUTHORITY (R\*)**

445 Board of Trustees

446

447 **RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION (R\*)**

448 Conflict of Interest Office

449 [coi@louisville.edu](mailto:coi@louisville.edu)

450 502-852-7612

451

452 **HISTORY (R\*)**

453 This policy supersedes the University’s Addressing Individual Conflicts of Interest Policy and Procedures and the  
454 University’s Addressing Institutional Conflicts of Interest Policy and Procedures. This policy was last approved by  
455 the Board of Trustees January 2011.

456

457 Revision Date(s): June 27, 1983, January 28, 2013, July 11, 2017 (Reformat only)

458 Reviewed Date(s): July 11, 2017

459

460 The University Policy and Procedure Library is updated regularly. In order to ensure a printed copy of this  
461 document is current, please access it online at <http://louisville.edu/policies>.

462

463 **R\* = Required    O\* = Optional**