



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 ~~Table of Contents~~

10

11 **POLICY APPLICABILITY (R\*)**

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

13

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

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

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

22 **POLICY STATEMENT (R\*)**

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59 POLICY

60 The University commits to teaching, serving, working, and conducting Research with integrity and free from  
61 unmanaged Actual or Apparent Conflicts. Covered Persons have a duty to Support ~~of the University's mission~~



62 ofUniversity education, Research, and service missions with their primary commitment of time and intellectual  
63 energies. ~~Receipt of~~ Personal Gain from external ventures or Financial Interests must not influence the decisions  
64 or actions of Covered Persons in performing ~~their~~ University Responsibilities. Covered Persons must not act or  
65 decide for the University if Personal Gain, Interest, or advantage could influence (directly or indirectly) judgment in  
66 performing University Responsibilities.

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

71 CONFLICT OF INTEREST

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

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

80 ~~Covered Persons of the University shall exercise the utmost good faith and integrity in all transactions touching~~  
81 ~~University Responsibilities and University’s property.~~

82 ~~Covered Persons shall not take part in dealings resulting in an unresolved Actual or Apparent Conflict.~~

83 NEPOTISM

84 Covered Persons must comply with the University ~~of Louisville~~ Nepotism Policy. ~~A~~Additionally, a Principal  
85 Investigator (PI) cannot directly or indirectly supervise a Relative on UofL Research. If a Covered Person’s project  
86 needs the unique skills of a Relative, the Conflict Review Board (CRB) must approve a plan to mitigate the conflict of  
87 interest before hire or assignment.

88 BUSINESS OPERATIONS

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

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



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

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

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

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

103 GIFTS

104 Covered Persons may not seek ~~or accept gifts~~ Gifts, cash or special favors<sup>3</sup> from current or prospective Vendors<sup>4,7</sup>,  
105 current or prospective subordinate employees<sup>5,7</sup> or current or prospective students<sup>6</sup>. Covered Persons should not  
106 accept proffered Gifts when:

- 107 o ~~an individual or Entity who offering Gift~~ has current or future business relationship with ~~the~~ University
- 108 ~~offers the Gift;~~
- 109 o ~~the~~ Covered Person receiving the Gift has authority or influence over the current or future individual or
- 110 Entity doing business ~~dealings~~ with ~~the~~ University;
- 111 o ~~the~~ Gift offered is cash or cash equivalent of any amount;
- 112 o ~~the~~ noncash Gift valued above \$25; or
- 113 o the Gift offered directly to Covered Person’s Relative.

115 TEACHING MISSION

116 Covered Persons must follow unit<sup>7</sup> guidelines when adopting course materials created by the Covered Person, a  
117 Relative or the Covered Person’s Appropriate Authority.

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

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

<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, ~~cash~~ equivalents, meals, loans, rewards, promises of future employment, ~~favours,~~ services and/or entertainments

<sup>4</sup> ~~current or prospective~~

<sup>5</sup> ~~current or prospective~~

<sup>6</sup> ~~current or prospective~~

<sup>7</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.



122 RESEARCH AND CREATIVE MISSION

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

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

127 Covered Persons must report SFI, external interests and foreign affiliations in publications<sup>8</sup>, presentations at  
128 professional meetings, and applications for funding.

129 Covered Persons or Relatives shall not take part in negotiating agreements<sup>9</sup> between the University and an Entity in  
130 which the Covered Person or a Relative has an Interest.

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

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

136 CLINICAL MISSION

137 Clinical service provided to patients/clients, as well as the educational environment provided for students, must be  
138 free from undue bias and influence of external activities and Interests. ~~It is the responsibility of the units,~~  
139 ~~departments, and divisions conducting clinical activities to establish criteria and processes, as noted, within this~~  
140 ~~section. All Covered Persons who are members of occupations or professions having established standards of~~  
141 ~~conduct shall, in addition to any obligations and responsibilities imposed by this policy, be bound by the standards~~  
142 ~~of conduct applicable to such occupations or professions. Covered Persons supporting the clinical mission must~~  
143 ~~comply with the University of Louisville Health Care Policy on Vendors.~~

144 ~~**Gifts.** Covered Persons may not receive any Gift (financial or otherwise) from Vendors (or their companies)~~  
145 ~~in person, by phone, e-mail, mail, or any other means at University Health Care, the Schools of Dentistry,~~  
146 ~~Medicine, Public Health and Nursing and all other clinical, administrative, educational, and Research venues~~  
147 ~~and activities on the Health Sciences Center (HSC) Campus that is not for services rendered or is not for~~  
148 ~~goods received or that is in excess of fair market value. Displays of products, cash incentive programs for~~  
149 ~~prescribing, product pamphlets, pre-printed prescription pads with product names, and other materials are~~  
150 ~~prohibited.~~

151 ~~While Covered Persons are personally prohibited from accepting any form of Gifts, food, or products (of~~  
152 ~~any type or value) from Vendors or their companies, at University Health Care locations, other forms of~~  
153 ~~professional interaction, employment, and consulting do exist. Although this policy does not call for~~  
154 ~~institutional policing of off-site activities, adherence to the principles outlined in this policy is not reserved~~  
155 ~~for duty hours.~~

<sup>8</sup> including articles, abstracts, manuscripts submitted for publication

<sup>9</sup> Research agreements, license agreements, equipment purchases, etc.



156 Unrestricted educational Gifts from Vendors are allowed for the Support of educational needs as warranted  
157 for patient and medical education and patient care, either in an open (unspecified) manner or with  
158 acknowledgement that it is focused on a specific area of educational focus. These Gifts can be used for  
159 educational related expenses (e.g., staff, resident, faculty lunch based presentations). These educational  
160 events may not involve marketing, detailing, or advertising of brand names or products, and the Vendors  
161 may not select paid lecturers or require the inclusion or exclusion of medications purchased for patient  
162 care. Vendors may restrict the educational grant to cover specific educational topics (e.g., breast cancer or  
163 heart disease) so long as the above listed requirements are met. Recognition of these grants may consist of  
164 attribution (e.g., in brochures for conferences, graduation event agenda, acknowledgement slides in  
165 presentations, and wall plaques of thanks) for contributions received.

166 **Travel.** Travel funds may not be directly given to University faculty, residents, or students, except in the  
167 cases of legitimate reimbursement or contractual services to those Vendors. Travel funds for educational  
168 purposes must be otherwise handled using the accounts established as described above. It is recognized  
169 that members of the faculty may, in the course of their leadership roles in non-profit professional and  
170 scientific organizations, be expected to Participate in programs, meetings, and events that involve Vendor  
171 relationships. Vendor interaction with Covered Persons in the course of representing legitimate  
172 professional organizations will be governed by the policies and procedures of the specific organization.

173 **Marketing.** Vendors may not be allowed to product or brand detail (i.e., in person marketing visits by  
174 Vendors), or market, at University Health Care, the HSC clinics, and all other clinical, administrative,  
175 educational, and Research venues and activities on the HSC Campus. Detailing and marketing at hospitals  
176 and facilities outside of University Health Care and the HSC Campus will be governed by the policies and  
177 procedures of those respective institutions.

178 **Vendors on premises.** Covered Persons may not allow Vendors to enter the following clinical locations:  
179 patient care areas, operating rooms, delivery rooms, emergency rooms, professional student and resident  
180 lounges, and staff elevators except to provide in-service training or assistance on devices and equipment,  
181 for example, in the operating room. In such cases, there must be prior disclosure to and consent by the  
182 patient or surrogate (if the patient is incapacitated) whenever possible, i.e., if it is known ahead of time that  
183 a Vendor will be involved. However, in such cases when a crisis or an emergency treatment with devices,  
184 equipment, etc. from a Vendor is required during an operation or procedure in order to provide the best  
185 care for the patient, and if the patient is incapacitated and no surrogate is available, the requirement for  
186 consent will be waived.

187 **INSTITUTIONAL OFFICIALS AND TRUSTEES**

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



194 SMALL BUSINESS CONCERNS (START UP ENTITIES)

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

~~198 The University may not subcontract to a Covered Person’s SBC, unless University Trustees grant an exception<sup>40</sup>. The  
199 University may accept Research subcontracts from a Covered Person’s SBC (for example STTR, SBIR programs).~~

~~200 Covered Persons must not use University assets for the direct benefit of the SBC. SBCs must have independent  
201 capacity to conduct business. The University cannot serve as a Research or development arm of an SBC.~~

202 Covered Persons should serve in advisory or advice-giving roles at the SBC as opposed to roles with management  
203 responsibility. Full-Time<sup>11</sup> Covered Persons wishing to engage in a management role, must reduce UofL  
204 appointment<sup>12</sup>.

~~205 A Covered Person cannot contribute to both SBC and University parts of a single project<sup>43</sup>. Covered Persons may  
206 not serve as both the SBC PI and the University subcontract PI.~~

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

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

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

~~213 SBCs must have independent capacity to conduct business. SBCs may utilize core facilities as long as the SBCs pay  
214 established service center rates.~~

~~215 A Covered Person cannot contribute to both SBC and University parts of a single project<sup>14</sup>. Covered Persons may  
216 not serve as both the SBC PI and the University subcontract PI.~~

~~217 The University may not subcontract to a Covered Person’s SBC, unless University Trustees grant an exception<sup>15</sup>. The  
218 University may accept Research subcontracts from a Covered Person’s SBC (for example STTR, SBIR programs). The  
219 University cannot serve as a Research or development arm of an SBC.~~

<sup>40</sup> per Kentucky Revised Statute 164.821(7)

<sup>11</sup> Refers to 1.0 FTE

<sup>12</sup> Possible mechanism for this reduction would be entrepreneurial leave.

~~<sup>13</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>14</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>15</sup> per Kentucky Revised Statute 164.821(7)



220 Covered Persons must not involve personnel that they supervise<sup>16</sup> in the SBC’s dealings before review by the CRB.  
221 Covered Persons must avoid circumstances in which junior personnel might feel expected to support the SBC.

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

~~225 Covered Persons must not involve personnel that they supervise<sup>17</sup> in the SBC’s dealings before review by the CRB.~~  
~~226 Covered Persons must avoid circumstances in which junior personnel might feel expected to support the SBC.~~

227 SPECIAL CONSIDERATIONS FOR THE UNIVERSITY

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

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

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

233 This policy does not forbid the University from accepting philanthropy from companies that sponsor research or  
234 conduct business with the University. The policy helps the University develop means of identifying and examining  
235 such circumstances and managing ~~any real or seeming~~ conflicts of interest that may result.

236 The Office of University Advancement<sup>18</sup> ~~and external investment managers~~, cannot discuss nonpublic University  
237 research with members of the University community to influence investment decisions<sup>19</sup>.

238 Individuals must report real or seeming conflicts of interest involving philanthropic practices<sup>20</sup> to the CRB or the  
239 COIO.

240 CONFLICT OF COMMITMENT

241 Covered Persons must comply with institutional requirements regarding work outside the University (Redbook 4.3.3  
242 for Faculty, Redbook 5.6 for Staff, PER1.12 for Administrators).

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

<sup>16</sup> direct or indirect

~~<sup>17</sup> direct or indirect~~

~~<sup>18</sup> and its outside investment managers~~

<sup>19</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>20</sup> For example: gifts, solicitation of donations, or management of the endowment pool





- 246 At the same time, the University has a responsibility to ensure that Covered Persons’ external dealings do not  
247 inappropriately influence their University actions and decisions.
- 248 Covered Persons may engage in Non-University Commitments of a professional, personal, or economic nature that  
249 do not conflict or interfere with University interests or with the Covered Person’s commitment to the University<sup>21</sup>.
- 250 Covered Persons must meet the duties and professional activities that fulfill obligations to their units, departments  
251 and programs.
- 252 Covered Persons may not hold a position<sup>22</sup> at any other postsecondary educational institution, independent research  
253 institutes or nonprofit entities while they are Full-time University Employees <sup>23</sup>unless approved under this policy,  
254 including online teaching. Consulting and joint Research relations are subject to review and prior institutional  
255 approval<sup>24</sup>.
- 256 When a dual appointment is approved, the Covered Person will list the University as the primary appointment on all  
257 research and scholarly publications, presentations and contact information.
- 258 Funding or support related to the dual appointment must be reported to the University on the ADF, to OSPA and in  
259 funding proposals as needed. This includes all funding or support from all added sources related to the dual  
260 appointment.
- 261 Covered Persons cannot use University resources to aid work at the dual appointment<sup>25</sup>.
- 262 Covered Persons must coordinate travel and coverage of University duties with the Appropriate Authority when dual  
263 appointments compel absence from campus.
- 264 Covered Persons private interests cannot create a recurring conflict with their University Responsibilities.
- 265 Covered Persons may not hold a contractual arrangement<sup>26</sup> with an Entity that interferes with their University  
266 Responsibilities.
- 267 Covered Persons may not engage in excessive or unauthorized use of University time or resources for professional,  
268 charitable, or community activities.
- 269 Covered Persons or Relatives must not use the Covered Person’s position, University assets or resources for Personal  
270 or Private Gain.

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<sup>21</sup> Including, to the University’s students, sponsors, patients, or to other parties to whom the University has a duty

<sup>22</sup> as faculty members, professional staff, or administrators, including honorary titles and uncompensated positions

<sup>23</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>24</sup> Similar relationships with External Entities are covered by the E-Leave policy and procedures.

<sup>25</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.

<sup>26</sup> Including employment



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

273 **DISCLOSURE AND MANAGEMENT**

274 Timely and accurate submission of the University’s Attestation and Disclosure Form (ADF) is a condition of  
275 employment at the University.

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

278 Covered Persons must disclose external Interests at least each year or within 30 days of the discovery or gain<sup>27</sup> of a  
279 new external interest, by the ADF to the COIC Office<sup>28</sup>. Covered Persons will report external interests **before** an  
280 application for sponsored funding as needed by this policy and the sponsoring agency.

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

283 The approved Management Plan will be in place before any action<sup>29</sup> subject to influence by the external interest.  
284 The Board reserves authority to review and approve plans for managing, reducing, or eliminating conflict of  
285 interest and commitment involving potential conflicts involving the president; or potential conflicts arising in  
286 matters that otherwise require Board review and action under KRS 164.830.

287 **COIC TRAINING**

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

290 **COMPLIANCE**

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

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

<sup>27</sup> for example, through purchase, marriage, or inheritance

<sup>28</sup> The COIC Office reports to the Vice President for Risk, Audit and Compliance, who serves as the COI Officer. ~~The Board reserves authority to review and approve plans for managing, reducing, or eliminating conflict of interest and commitment involving:~~

~~• potential conflicts involving the president; or potential conflicts arising in matters that otherwise require Board review and action under KRS 164.830~~

<sup>29</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



294 Noncompliance<sup>30</sup> with this policy may be cause for corrective actions<sup>31</sup>. ~~Individuals should report concerns,~~  
295 ~~depending on the seriousness of noncompliance with the violation and management discretion. Noncompliance~~  
296 ~~includes deliberate breach of this policy to the COIC Office including, but not limited to, failure to file or willfully~~  
297 ~~filing a partial, false, or misleading ADF, violations of the guidelines, or failure to comply with prescribed~~  
298 ~~monitoring procedures, will be addressed in accord with applicable disciplinary policies and procedures (University~~  
299 ~~Redbook, University Discipline Policy) for each Covered Person.~~

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

- 301 o termination of the activity that is a conflict of interest or commitment;
- 302 o divestiture of the external Interest;
- 303 o disciplinary action against the Covered Person up to termination.
- 304 o violators may be subject to civil or criminal penalties for a violation of criminal or civil law.

305 ~~Individuals should report concerns of noncompliance with this policy to the COIC Office.~~ University will tell the  
306 Research sponsor of the violation and any corrective action, as needed-

307 ~~or required.~~ For Public Health Service (PHS) Supported projects, University will undertake the Retrospective Review  
308 and create any Mitigation Reports, as needed.

309 The COIC Officer ~~sanctions~~authorizes the COIC Office and CRB to ~~adjust University dealings to ensure~~  
310 ~~compliance~~review and address reports of noncompliance with this policy, a Management Plan, or applicable federal,  
311 state or local controls. The COIC Officer will address any concerns not resolved by the COIC Office or CRB.

312 DEFINITIONS (O\*)

313 <insert COI URL>

314 PROCEDURES (O\*)

315 DISCLOSURE OF EXTERNAL ACTIVITIES AND INTERESTS

316 ~~The procedures~~Procedures describing academic, business, clinical, and Research and scholarly activities may also  
317 include ~~added~~extra reporting~~conditions~~. Covered Persons report external Interests and activities on the ADF<sup>32</sup>.  
318 Covered Persons~~are~~ complete the ADF yearly and throughout their Term of Appointment. The reporting period for  
319 the ADF includes the previous 12 months and the coming 12 months. Annual disclosures follow the following  
320 standards:

- 321 • ~~Trustees~~-Trustees shall file a disclosure statement yearly and report external Interests as governed by  
322 bylaws and KRS.

<sup>30</sup>~~Deliberate breach of this policy including, but not limited to, failure to file or willfully filing a partial, false, or misleading ADF, violations of the guidelines, or failure to comply with prescribed monitoring procedures, will be addressed in accord with applicable disciplinary policies and procedures (University Redbook, University Discipline Policy) for each Covered Person.~~

<sup>31</sup>~~depending on the seriousness of the violation and management discretion~~

<sup>32</sup> The ADF is located at <https://iris.louisville.edu>



- 323 • Institutional Officials. ~~Within shall disclose external Interests by filing an ADF, within~~ 30 days of  
324 appointment, yearly after that, and as described in this policy, ~~Institutional Officials shall disclose external~~  
325 ~~Interests by filing an ADF.~~
- 326 • Covered Persons. ~~Within shall disclose external Interests by filing an ADF within~~ 30 days of appointment,  
327 annually thereafter, and under circumstances described in this policy, ~~Covered Persons shall disclose~~  
328 ~~external Interests by filing an ADF.~~ Covered Persons for which a Conflict of Interest or Commitment is  
329 identified are required to abide by the requirements of the approved Management Plan.
- 330 • ~~Other Individuals.~~ The president or delegate may designate other individuals who shall file a yearly ADF.  
331

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

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

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

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

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

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

348 Non-University Commitments needing prior approval include:

- 349 • Non-University consulting for more than the equivalent of one workday a week;i
- 350 • Holding office in a scholarly or professional society, for more than the equivalent of one workday a week;i
- 351 • Editing a professional journal for more than the equivalent of one workday a week;~~of;~~i
- 352 • Any potentially compromising activities for more than the equivalent of one workday a week;i
- 353 • Seeking or serving on sponsored projects submitted and Managed through other academic, federal, or  
354 commercial institutions;<sup>33</sup>i.
- 355 • Keeping a faculty appointment at another academic institution, federal organization, or Entity;i
- 356 • Keeping an employment position at another academic institution, federal organization, or Entity;i
- 357 • Directing a program of Research at another Entity;i or

<sup>33</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.



358 • Seeking buyout of course assignments for Research that involves internal University funds to cover release  
359 time.

360  
361 Covered Persons may put forward a reconsideration request in writing within 10 business days of the receipt of  
362 denial to the Provost, or designee. A three-person peer review ad hoc ~~committee~~panel<sup>34</sup> will review reconsideration  
363 requests. All member selections must be from within the University community. The panel will make a final  
364 recommendation to the CRB.

365 CRB will review the ADFs, any reviews, the first determinations, and the ~~reconsideration request~~.Reconsideration  
366 Request. CRB will have the right to consult, as needed, with University management. The CRB's determination shall  
367 be final.

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

- 370 a. ~~external~~ disclosures made are complete and accurate;  
371 b. institutional activities engaged in by the Covered Person are correctly identified;  
372 c. additional information necessary for review of a Covered Person's disclosures is obtained<sup>35</sup>;  
373 d. early identification of actual or proposed Research activities involving human subjects in which a  
374 Covered Person may have an identified Conflict of Interest or Commitment<sup>36</sup>.

375  
376 COIC Office will contact the Covered Person, if more information or documentation is needed.

377 CRB will review potential Organizational Conflicts of Interest.

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

### 381 MANAGEMENT OF IDENTIFIED CONFLICTS OF INTEREST AND COMMITMENT

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

- 384 • Public disclosure of Financial Interests  
385 • Reformulation of work plan  
386 • Monitoring of project by an independent review committee  
387 • Substituting supervisors or personnel

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<sup>34</sup> The panel will include one individual selected by the Covered Person<sup>34</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>35</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>36</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



- 388 • Divestiture of Financial Interests
- 389 • ~~Stop~~Halt or reduce involvement in relevant projects
- 390 • ~~Stop~~Halt inappropriate student involvement in projects
- 391 • Remove relationships that pose real or potential conflicts
- 392 • Remove Covered Person from human subject Research in the critical areas of recruitment, inclusion or
- 393 exclusion evaluation, enrollment, and adverse event evaluation and reporting.
- 394 • ~~Third~~Naming ~~third~~-party, for example department or unit head, oversee or control the Gift funds from
- 395 an Entity with which the Covered Person has an identified Actual or Apparent Conflict.

396  
397 Covered Person has the onus of ~~making~~providing information that would help ~~the~~University in reviewing ~~such~~  
398 ~~conflict~~availableidentified COIC.

399 RECONSIDERATION

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

404 CRB Chair will present ~~reconsideration~~ at the next called meeting of the CRB. CRB will review and decide whether it  
405 has necessary information<sup>37</sup>. CRB will communicate the need for more detail to the Covered Person. CRB will  
406 determine whether the original approved clause (s) will stand or be altered. CRB can accept the resolution proposed  
407 by the Covered Person, or adopt an alternate resolution. ~~Resolution~~CRB resolution is final and must be carried out.

408 IMPLEMENTATION OF APPROVED MANAGEMENT PLANS

409 COIC Office will send the approved plan to the Covered Person and Appropriate Authority for implementation.  
410 Covered Person must acknowledge ~~to COIC Office~~<sup>38</sup> receipt of Management Plan and perform ~~needed~~required  
411 actions, ~~on or before the implementation date, to COIC Office~~. The Appropriate Authority is copied on this  
412 communication. Appropriate Authority will apply all clauses not involved in pending reconsideration  
413 ~~request~~requests.

414 COMPLIANCE WITH POLICY

415 COIC Office will conduct a preliminary ~~investigation~~review to decide whether reported noncompliance concerns are  
416 valid.

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

- 418 1. ~~Examine~~Investigate concerns and make written report of conclusions;
- 419 2. Ask Appropriate Authority to conduct investigation<sup>39</sup> and make written report conclusions; or

<sup>37</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>38</sup> ~~on or before the established implementation date~~

<sup>39</sup> ~~Investigation will, at a minimum, include interview with complainant (if available) and interview with the Covered Person(s). Investigations will be conducted in according to University's Reporting and Investigation Procedures.~~



420 3. Appoint CRB member to conduct investigation<sup>40</sup> and make written report of conclusions.  
421

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

424 Investigations confirming noncompliance may result in corrective action<sup>41</sup> ~~as noted in the Compliance section of this~~  
425 ~~policy.~~ The COIC Officer and Executive Vice President for Research and Innovation have authority to suspend  
426 Covered Person’s Research impacted by Actual or Apparent Conflicts<sup>42</sup>, ~~pending conclusion of an investigation or,~~  
427 ~~on conclusion of an investigation, that they be suspended pending correction of any policy violations.~~

428 SPECIAL MANAGEMENT FOR RESEARCH AND SPONSORED ACTIVITY

429 University presumes Covered ~~Person~~Persons with ~~an~~identified COIC may not conduct the activity in question.  
430 Covered ~~Person~~Persons with ~~an~~identified COIC who ~~wishes~~wish to show reasonable or compelling circumstances  
431 must convince University, ~~through~~ CRB and COIC Officer, that facts rebut the presumption. Covered Person will  
432 present to CRB, in writing, an explanation of reasonable or compelling circumstances to conduct proposed activity.  
433 CRB will review documentation ~~submitted~~ and make final determination. CRB will formally approve the rebuttable  
434 presumption and change the Management Plan, or reject the rebuttable presumption and affirm the approved  
435 Management Plan.

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

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

442 The University does not allow subcontracts or subawards from the University to an external Entity in which a  
443 Covered Person or Relatives hold equity Interest or serve in a fiduciary or management role. Rarely, Covered  
444 Persons ~~can~~may seek University prior approval<sup>43</sup> if only source of materials or expertise lives with external Entity.  
445 Where approval is granted, Covered Person will not, under any circumstances, engage in any project, study, or  
446 transactions for University.

447 COIC TRAINING

448 University will identify suitable COIC training completed by Covered Persons at least once every four years or  
449 immediately after circumstances listed below. Training will tell each Covered Person of policy, Covered Person’s

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~~<sup>40</sup>Investigation will, at a minimum, include interview with complainant (if available) and interview with the Covered Person(s). Investigations will be conducted in according to University’s Reporting and Investigation Procedures.~~

<sup>41</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.

~~<sup>42</sup>pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending correction of any policy violations~~

<sup>43</sup> At time of proposal, via the CRB, COIC Officer and Board of Trustees





450 responsibilities about disclosure and of applicable federal, state and local regulations. Immediate training for  
451 Covered Persons will be required:

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

456 RESPONSIBILITIES (O\*)

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

458 **Covered Persons** are responsible for knowing, understanding, and complying with this policy and procedures.  
 459 Covered are responsible for accurate and timely completion of ADF and updating it as external interests change.  
 460 Covered Persons are responsible for accepting Management Plan, or timely seekseeking changes to Management  
 461 Plan, and agreeagreeing to Management Plan. Covered Persons are responsible for upholding all terms, conditions,  
 462 and actions set forth in Management Plan. Covered Person must respond to calls for information from COIC Office  
 463 or CRB. Covered Person are responsible for complying with corrective actions, enforcement, and sanctions imposed  
 464 by University related to findings of noncompliance.

465 **Department or Unit Heads.** Each department or unit head will ensure that –Covered Persons identified within  
 466 department or unit<sup>44</sup> complete ADF in timely manner<sup>45</sup> as required by this policy. Deans or their designees will  
 467 ensure department or unit heads complete duties related to this policy in timely manner, resolve ambiguities  
 468 Covered Persons identification, and ADFs are filed and sent.

469 **University.** University is responsible for keepingmaintaining this policy, making it available publicly as required by  
 470 law or regulation, and ensuring it complies with applicable federal, state, and local regulations. University will make  
 471 COIC training available to Covered Persons that complies with policy and applicable federal, state, and local  
 472 regulations. University will provide FCOI Reports to Research sponsors as required by federal, state, and local  
 473 regulations, sponsor terms and conditions, or as required by Management Plan. University is responsible for setting  
 474 up enforcement to ensure compliance with policy and federal, state, and local regulations. University will keep  
 475 records about ADFs and University's reviews and determinations.

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

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

481  
482 ~~DEFINITIONS (O\*)~~

<sup>44</sup> either as defined by this policy or as individually determined to be involved in Research by the PI, the department or unit head

<sup>45</sup> ~~(within 30 days of hire and yearly thereafter)~~





483 ~~**Actual Conflict.** Conflict of Interest or Commitment exists as determined by University. This determination warrants~~  
484 ~~management.~~

485 ~~**Apparent Conflict.** Covered Person's activity or Interest may represent actual or potential Conflict of Interest or~~  
486 ~~Commitment, but needs analysis. If Apparent Conflict is ruled nonexistent, perception may still warrant explanation~~  
487 ~~and documentation.~~

488 ~~**Appropriate Authority.** The Covered Person's direct supervisor. Board of Trustees serves as Appropriate Authority~~  
489 ~~for the President.~~

490 ~~**Attestation and Disclosure Form (ADF).** A Covered Person's annual attestation to the Standards of Conduct and~~  
491 ~~disclosure of external activities and Interests to the University.~~

492 ~~**Conflict of Interest or Commitment.** A situation that influences Covered Person's professional judgment in~~  
493 ~~University teaching, Research, outreach, or public service because of external relationship that affects an external~~  
494 ~~Interest of the Covered Person, a Relative, or an Entity. Term also includes situation in which Covered Person~~  
495 ~~engages in a Non-University Commitment that may interfere with fulfillment of obligations to University. Examples~~  
496 ~~may include outside employment, pro bono or volunteer work, and government service in public interest.~~

497 ~~**Conflict of Interest and Commitment Office (COIC Office).** COIC Office reports to the COIC Officer. COIC Office~~  
498 ~~fulfills the following duties:~~

- 499 ~~• preserve files on all disclosures of significant financial interest at University;~~
- 500 ~~• keep databases for tracking disclosures and disclosure dates;~~
- 501 ~~• keep administrative files for CRB;~~
- 502 ~~• screen disclosures for completeness before starting review;~~
- 503 ~~• act as a resource for Covered Persons on general regulatory information, guidance with forms, and aid in~~  
504 ~~preparing ADF;~~
- 505 ~~• provide reports certifications, and assurances for federal, state, departmental and unit-wide surveying of~~  
506 ~~disclosure compliance;~~
- 507 ~~• provide sanctioned reports or certifications for external sponsors or agencies, when necessary;~~
- 508 ~~• preserve information on federal regulations about conflicts of interest in research;~~
- 509 ~~• provide education about the COI process and regulations to the University community;~~
- 510 ~~• provide education opportunities to CRB members; and~~
- 511 ~~• conduct quality assurance and quality improvement for the CRB.~~

512 ~~**Conflict of Interest and Commitment Officer (COIC Officer).** The Vice President for Risk, Audit and Compliance, who~~  
513 ~~is responsible for implementation and enforcement of policy and reports directly to President. COIC Officer is~~  
514 ~~responsible for developing and issuing this policy. COIC Officer is responsible for ensuring compliance with all federal,~~  
515 ~~state and local requirements about conflicts of interest. COIC Officer shall report yearly to President and Board of~~  
516 ~~Trustees under this policy. COIC Officer may delegate responsibilities under this policy to COIC Office.~~

517 ~~**Conflict Review Board (CRB).** Panel named by COIC Officer to evaluate potential COIC, review reconsideration~~  
518 ~~requests, and review information about noncompliance. Members include both faculty and administrative staff.~~  
519 ~~The CRB is chaired by the COIC Director (who only votes to break a tie vote).~~



520 ~~Covered Person.~~ Covered Person includes all employees<sup>46</sup> and individuals (full or part-time, paid or unpaid)  
521 Participating in academic, business, clinical, and Research or scholarly activities for University.

522 ~~Entity.~~ Any domestic or foreign, public or private business, organization, corporation, partnership, proprietorship,  
523 limited liability company, or firm, regardless of whether organized for profit or as a nonprofit entity. The term does  
524 not include University, University Research Foundation, or University Athletic Association.

525 ~~Financial Conflict of Interest (FCOI).~~ Any condition in which an SFI could directly and significantly affect the design,  
526 conduct, or reporting of Research.

527 ~~FCOI Report.~~ A University's report of a financial conflict of interest to a Public Health Service Awarding Component.

528 ~~Financial Interest (FI).~~ Anything of monetary value including, but not limited to: direct or indirect interest in  
529 business consisting of any stock, stock option, or similar ownership interest in such business, but excluding any  
530 interest arising solely by reason of investment in such business by a mutual fund, pension, or other institutional  
531 investment fund over which the Covered Person does not exercise control; or receipt of, or the right or expectation  
532 to receive, any income in one or more of: consulting fee, honorariums, salary, allowance, forbearance, forgiveness,  
533 interest in real or personal property, dividend, royalty gained from licensing of technology, or other processes or  
534 products, rent, capital gain, or any other form of compensation. FI may arise from (nonexclusive examples):

- 535 ● Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;
- 536 ● Consulting, including commercial and professional consulting and service arrangements, scientific and  
537 technical advisory board memberships, or serving as an expert witness in litigation;
- 538 ● Services provided in exchange for honorariums including travel expense repayments;
- 539 ● Research funding or other forms of Research Support;
- 540 ● Investment in the form of stock or bond ownership, including single sector investment only mutual funds;
- 541 ● Business ownership or partnership interests;
- 542 ● Patents, copyrights, and other intellectual property interests;
- 543 ● Seeking or negotiating for prospective employment or business; or
- 544 ● Gifts, including travel.

545 ~~Full-time University Employee.~~ Means 80% or more full-time equivalent and for which employment continues for  
546 six months or more.

547 ~~Ghostwriting.~~ Means person qualifies for authorship but not listed as an author or recognized on a publication.

548 ~~Gift Authorship.~~ Means person does not qualify for authorship but named as an author.

549 ~~Gift.~~ Anything Covered Person receives while not giving equal or greater consideration within 90 days. Term<sup>47</sup>  
550 includes, not limited to,

- 551 ● food or drink,
- 552 ● membership dues,
- 553 ● plants, flowers, floral arrangements,

<sup>46</sup> University faculty, administrators, staff

<sup>47</sup> Term does not include salary associated with private employment, an award, plaque, certificate, or similar personalized item for service, gifts from an Honorarium, or an expense related to an Honorarium event paid to a person or the person's spouse, or gifts from Relatives.



- 554 ● transport and lodging, a preferential rate,
- 555 ● use of property,
- 556 ● forgiveness of a debt,
- 557 ● entrance fees, admission fees or tickets to events, performances, or facilities,
- 558 ● charged services provided free, or
- 559 ● other similar service having an attributable value not already provided for in this definition.

560  
 561 **Honorarium.** Anything of value given to Covered Person for speech or written item<sup>48</sup>. Term does not include  
 562 payments for outside employment or payments for Covered Person’s public duties. Term does not include payment  
 563 of reasonable transport, lodging, registration fee, or food and drink expenses for Covered Person and spouse at  
 564 honorarium event.

565 **Institutional Conflict of Interest (ICOI).** A condition compromising or seemingly compromising Institutional Official  
 566 or University’s decision making. ICOIs may arise when (non-exhaustive list):

- 567 ● Institutional official with significant financial interest in business entity is in position to act for University  
 568 that may benefit business entity;
- 569 ● University licenses invention to business entity and holds royalty or equity interests in entity;
- 570 ● Vendor gives a gift to the University;
- 571 ● University holds investments in business entity that has financial or business affiliation with University;
- 572 ● University enters commercial transaction compromising or seemingly compromising University’s missions,  
 573 or institutional reputation; or
- 574 ● University has significant financial interest in business entity with commercial interests affected by research  
 575 conducted at University.

576  
 577 **Institutional Financial Interest.** Institutional Financial Interests includes, but not limited to:

- 578 ● Royalty arrangements: payments, including royalty payments and licensing fees, resulting from technology  
 579 transfer, licensing, and business activities that exceed \$100,000 in the preceding twelve month period<sup>49</sup>;
- 580 ● Non-publicly traded equity<sup>50</sup>;
- 581 ● Publicly traded equity<sup>51</sup>; and
- 582 ● Gifts above one million dollars from for-profit entity or philanthropic unit associated with for-profit entity<sup>52</sup>.

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<sup>48</sup> other than a book, intended to be published

<sup>49</sup> from a single entity

<sup>50</sup> equity and ownership interests of any amount in any for-profit entity that is not publicly traded

<sup>51</sup> equity and ownership interests valued at greater than \$100,000 in the preceding twelve (12) month period in any publicly traded, for-profit entity, except for equity held in the University’s endowment

<sup>52</sup> Certain other payment or financial benefits: from time to time, the University enters into contractual relationships with outside parties which include a payment or other financial benefit to the University from the contracting party that are based on factors outside the course of business between the University and the contracting party (e.g., number of units sold or new accounts established, philanthropic support for the University). The University recognizes that certain types of these contracts, if not properly managed or disclosed by the University, and which



583 Institutional Financial Interest shall also mean the following non-exhaustive financial or business interests of  
584 Institutional Officials (and those of the Institutional Official's spouse or partner):

- 585 ~~• Equity or ownership interests in publicly traded, for-profit entities if the value exceeds \$25,000 in the~~  
586 ~~preceding twelve (12) month period. Not included are equity or ownership interests in mutual funds and~~  
587 ~~retirement accounts<sup>53</sup>;~~
- 588 ~~• Equity (including stock, options, warrants), ownership, or founders' interests of any amount in non-publicly~~  
589 ~~traded entities;~~
- 590 ~~• Income, including royalties, equity, consulting fees, honorariums and gifts or other payments, from for-~~  
591 ~~profit entities that, in the aggregate, exceed \$25,000 from entity in preceding twelve month period;~~
- 592 ~~• Fiduciary role with for-profit entity, regardless of compensation or income, such as service on the board of~~  
593 ~~directors, management role in company or partnership (for example, President, CEO, COO, CRO, CSO or~~  
594 ~~Treasurer).~~
- 595 ~~• Fiduciary role with nonprofit entity that could reasonably lead to potential ICOI.~~

596 ~~**Institutional Official (IO).** Means people with direct authority over faculty and staff appointments, salaries,~~  
597 ~~promotions, signatory authority, or division of institutional resources, such as assignment of graduate students or~~  
598 ~~other trainees, progress or promotion of students, funding or space, for faculty who are conducting research. Term~~  
599 ~~includes anyone holding administrator positions, even temporarily. Term includes, but not limited to individuals~~  
600 ~~-serving as: Deans, Associate Deans, and Assistant Deans; Institute and Center Directors; University Counsel;~~  
601 ~~University Compliance Officers; Director of Audit Services; Provost, Vice Provosts, Associate Vice Provosts, and~~  
602 ~~Assistant Vice Provosts; President, Executive Vice Presidents, Senior Vice Presidents, Vice Presidents, Associate Vice~~  
603 ~~Presidents, and Assistant Vice Presidents; Department Heads; Directors of Sponsored Programs, Technology~~  
604 ~~Transfer, Research Integrity, Human Subjects Protection; and chairs of the Institutional Review Board, Institutional~~  
605 ~~Biosafety Committee, Institutional Animal Care and Use Committee, Conflict Review Board, and other similar~~  
606 ~~committees created in the future.~~

607 ~~**Interest.** A Covered Person's direct (ownership) or indirect (receipt by Covered Person of direct financial) gain,~~  
608 ~~benefit, monetary value, right, claim, or share.~~

609 ~~**Instructional Materials.** Includes textbooks, software, courseware, and laboratory equipment.~~

610 ~~**Investigator.** Means person, regardless of title, position, pay, role, or responsibilities, with ability to decide~~  
611 ~~independently design, conduct, or reporting of University Research. Term does not include people who perform~~  
612 ~~only incidental or isolated tasks related to project.~~

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because of the University's unique position and relationships, may create the perception that the University was improperly influenced to enter into the contract or endorses the contracting party as a "preferred provider" or may improperly influence consumer choices by third parties, in particular University students.

<sup>53</sup> as long as the University Official does not directly control the investment decisions made in these investment vehicles



613 ~~Manage.~~ Means taking action to address COIC. Term includes reducing or removing the COIC, to ensure that  
614 affected activity is free from bias.

615 ~~Management Plan.~~ Means written plan for management, reduction, or elimination of identified COIC. Management  
616 Plan shall contain provisions for purposes intended (for example management, reduction, or elimination of conflict),  
617 for identity, nature and any monetary amount of conflict.

618 ~~Mitigation Report.~~ Means written report filed by University when results of Retrospective Review show bias  
619 occurred because of unreported or unmanaged FCOI. Mitigation Report includes

- 620 ● Findings of Retrospective Review;
- 621 ● Description of impact of bias on Research; and
- 622 ● University’s plan of action or actions taken to remove or mitigate effect of bias<sup>54</sup>.

623 ~~Non-University Commitment.~~ Means outside (non-University) consulting or other activity, paid or unpaid, beyond  
624 work assignment of Covered Person’s University Responsibilities or employment.

625 ~~Organizational Conflict of Interest.~~ Means person cannot give unbiased aid or advice to the Government, or the  
626 person’s objectivity in performing the contract work is, or might be, otherwise undermined, or a person has an unfair  
627 competitive advantage.

628 ~~Participate.~~ To be part of the University activity in any capacity, including, but not limited to, serving as the PI, co-  
629 investigator, Research collaborator, or provider of direct services or patient care. Term does not apply to Covered  
630 Persons who provide mainly technical or advisory Support and have no direct access to data or control over its  
631 collection or analysis. Term also does not apply to study participants, unless they are in position to influence study’s  
632 results or have privileged information about results.

633 ~~Personal (or Private) Gain or Benefit.~~ To use University resources for personal or private purposes or personal or  
634 private financial or nonfinancial benefits. Personal or private benefits may include, but not limited to, cash, profits,  
635 securities, Gifts, performed work, or sex.

636 ~~Qualifying Adult.~~ Means person over 18 years old, and, if blood Relative (or Relative by adoption or marriage) must  
637 be of same or younger generation as Covered Person (as used in KRS 391.010), and, must be living in Covered  
638 Person’s household (for at least 12 months), and financially interdependent (for example, have a joint checking  
639 account or a joint mortgage) for 12 months or longer, and be unmarried.

640 ~~Relatedness.~~ Means directly and significantly associated with Covered Person’ Research associated with Research  
641 based on topic, use of products, potential for an increase in the value of SFI, or company in which SFI is held.

642 ~~Relative.~~ Anyone related to a Covered Person in the following ways, and includes those within these categories  
643 who are referred to as adopted, step, foster, grand, half, in-law, spouse of, or great:

- 644 ● parent
- 645 ● child or ward
- 646 ● sibling
- 647 ● uncle or aunt

<sup>54</sup> (for example, extent of harm done, including any qualitative and quantitative data to Support any actual or future harm; analysis of whether Research is salvageable)



- 648 ● first cousin
- 649 ● nephew or niece
- 650 ● spouse, domestic partner, significant other

651

652 ~~**Remuneration.** Means salary or any payment for services not identified as salary<sup>55</sup>; equity interest includes any~~

653 ~~stock, stock option, or other ownership interest, as determined through reference to public prices or other~~

654 ~~reasonable measures of fair market value.~~

655 ~~**Research.** A systematic investigation designed to develop or contribute to generalizable knowledge. Term~~

656 ~~encompasses basic and applied Research, service and testing, and product development that may be published.~~

657 ~~Term includes any such condition for which Research funding is available through grant, cooperative agreement, or~~

658 ~~contract, such as Research grant, career development award, center grant, individual fellowship award,~~

659 ~~infrastructure award, institutional training grant, program project, or Research resources award or gift. Term also~~

660 ~~includes Research activities that are not funded or sponsored. Gifts may be considered Research projects needing~~

661 ~~COIC management when used for purposes related to Covered Person's Interests.~~

662 ~~**Retrospective Review.** Means review conducted by University when Investigator fails to report SFI in timely manner~~

663 ~~or when noncompliance with PHS regulation or approved Management Plan is discovered.~~

664 ~~**Senior or Key Personnel.** Means project director or PI and anyone identified as Senior or Key Personnel in grant~~

665 ~~application, progress report, or report filed by law or regulation.~~

666 ~~**Significant Financial Interest (SFI).** Means FI consisting of one or more of following Interests of Covered Person<sup>56</sup>~~

667 ~~related to University Responsibilities:~~

- 668 1. ~~For publicly traded Entities, value of any Remuneration received from Entity in 12 months preceding~~
- 669 ~~disclosure combined with value of Equity Interest in Entity as of date of disclosure, when totaled,~~
- 670 ~~exceeds \$5,000;~~
- 671 2. ~~For non publicly traded Entities (including but not limited to private "start-up" companies, closely held~~
- 672 ~~corporations, partnerships or sole proprietorships), if either:~~
- 673 a. ~~the value of any Remuneration received from the Entity in the 12 months preceding the~~
- 674 ~~disclosure, when totaled, exceeds \$5,000; or~~
- 675 b. ~~the Investigator holds any Equity Interest (i.e., there is no de minimis amount for Equity~~
- 676 ~~Interests in a non-publicly traded Entity) in the Entity;~~
- 677 3. ~~Income from intellectual property rights and interests (for example, patents, trademarks, copyrights)~~
- 678 ~~that exceeds \$5,000 in previous 12 months; or~~
- 679 4. ~~Repaid or sponsored travel exceeding \$5,000 from Entity in 12 months preceding disclosure<sup>57</sup>.~~

680 ~~**Statutory Affiliates.** University Research Foundation, and University Athletic Association and any other affiliates~~

681 ~~added in the future.~~

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<sup>55</sup> (e.g., consulting fees, honoraria, paid authorship, travel reimbursement)

<sup>56</sup> (and those of the Covered Person's spouse or partner and dependent child[ren])

<sup>57</sup> however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a Research institute that is affiliated with an American Institution of higher education does not need to be disclosed as an SFI



682 ~~**Supervisory Relationship.** Exists when a Covered Person is directly or indirectly through span of control responsible~~  
683 ~~for supervising, directing, evaluating, or influencing the work activities, or job performance of another Covered~~  
684 ~~Person.~~

685 ~~**Support.** Providing anything of value (for example, funds, supplies, equipment, staff, etc.), regardless of whether~~  
686 ~~restricted or unrestricted.~~

687 ~~**Term of Appointment.** The duration of a Covered Person’s University employment, status as a student, or affiliation~~  
688 ~~with the University.~~

689 ~~**Travel.** Repaid or sponsored Travel related to Covered Person’s University Responsibilities, when combined with~~  
690 ~~other Remuneration from Entity meets \$5,000 reporting threshold. Covered Persons do not disclose Travel repaid~~  
691 ~~or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20~~  
692 ~~U.S.C. 1001(a), academic teaching hospital, medical center, or Research institution affiliated with Institution of~~  
693 ~~higher education.~~

694 ~~**University Responsibilities.** A Covered Person’s duties and responsibilities for the University<sup>58</sup>.~~

695 ~~**Vendor.** Entities and individuals who provide goods and services to the University. This term includes~~  
696 ~~pharmaceutical company and medical equipment representatives, as well as equipment and service providers.~~

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

698  
699 [Attestation and Disclosure Form](#)

700 **RELATED INFORMATION (O\*)**

701 **UOFL POLICIES**

- 702 [Code of Conduct](#)
- 703 [Digital Media Policy](#)
- 704 [De Minimis Gifts Policy](#)
- 705 [Ethics in Purchasing](#)
- 706 [Health Care Policy on Vendors](#)
- 707 [Nepotism Policy](#)
- 708 [Public Information](#)
- 709 [Work Outside the University \(Per 1.12\)](#)

710 **REDBOOK**

- 711 [Ethical Considerations – 2.5.8](#)
- 712 [Annual Work Plan and Presence at the University – 4.3.1](#)

<sup>58</sup> The activities outlined in an Covered Person’s annual assignment or position description may include administration, teaching, Research (regardless of whether or not it is funded), Research consultation, and creative activities, course preparation, curriculum development, lectures, evaluation of student efforts, academic advising, committee meetings and memberships, service on panels such as University review boards or data and safety monitoring boards, public service to include service on advisory committee’s or review panels, and any other activity assigned by the Covered Person’s Appropriate Authority in accordance with University policies.





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

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

715 **BOARD of TRUSTEES BYLAWS**

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

717 **GOVERNING LAWS, REGULATIONS, STANDARDS**

718 [42 CFR 50](#)

719 [45 CFR 94](#);

720 [NSF GPM Section 510](#);

721 21 CFR Parts [54](#), [312](#), [314](#), [320](#), [330](#), [601](#), [807](#), [812](#), [814](#), and [860](#); [2 CFR 215](#);

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

723 **KENTUCKY REVISED STATUTES (KRS)**

724 [45A.340](#),

725 [164.367](#),

726 [164.390](#),

727 [164.821](#)

728

729 **RESPONSIBLE AUTHORITY (R\*)**

730 Board of Trustees

731

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

733 Conflict of Interest Office

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

735 502-852-7612

736

737 **HISTORY (R\*)**

738 [This policy supersedes the University’s Addressing Individual Conflicts of Interest Policy and Procedures and the](#)  
739 [University’s Addressing Institutional Conflicts of Interest Policy and Procedures. This policy was last approved by](#)  
740 [the Board of Trustees January 2011.](#)

741

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

743 Reviewed Date(s): July 11, 2017

744

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

747

748 **R\* = Required    O\* = Optional**