OFFICIAL UNIVERSITY ADMINISTRATIVE POLICY

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2 Responsible Conduct of Research and Scholarship (RCRS)

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4 POLICY NUMBER (O*)

5 RES-5.01

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7 INITIAL ADOPTION AND EFFECTIVE DATE (R*)

8 May 23, 2007

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POLICY APPLICABILITY (R*)

This policy applies to faculty, students, trainees, staff, and all other members of UofL's research community, regardless of pay or leave status, hereafter referred to as Scholars/Researchers. This policy applies to UofL employees and students engaged in any facet of research and scholarship, regardless of internal or external support, including (but not limited to):

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- Publishing activities (journal articles, book writing, literary criticism, legal research, technical and institutional research reports, literature reviews, and historical scholarship, among other forms)
- Oral or poster presentations of research/scholarship
- Collection and analysis of data, information, biospecimens or records
- Inclusion as personnel on sponsored research or scholarship grants/awards
- Inclusion as personnel on internally funded research or scholarship grants/awards
- Development and/or leadership of centers that generate new knowledge, research or scholarship
- Media contributions
- Creative expression/performance and visual arts activities (compositions, presentations, performances, exhibits and similar projects)

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REASON FOR POLICY (0*)

The University of Louisville is committed to the highest standards of Responsible Conduct in Research and Scholarship (RCRS). The continued success and positive public image of the University of Louisville depends on the responsible and ethical conduct of all members of the university community.

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37	The purpose of this policy is to articulate this commitment. It is the responsibility
38	of the university community to foster and nurture a culture where integrity in the
39	conduct of Research and scholarly activity is the foremost aim. In addition, all
40	members of the university community are responsible for ensuring their behavior
41	and actions are consistent with this commitment, as well as with university policies
42	and procedures, and applicable federal, state, and local laws, and regulations.

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POLICY STATEMENT (R*)

- Primary assurance of the quality of research and scholarly endeavors arises from 45 the qualifications of individual Scholars/Researchers. All Scholars/Researchers are 46 ultimately responsible for the character, accuracy, and reliability of their output and 47
- for that conducted under their supervision. Each Scholar/Researcher is responsible 48
- 49 for the integrity and originality of their own work. Scholars/Researchers are
- responsible for being familiar with all University policies related to 50
- Research/scholarly output including, but not limited to, policies on: Intellectual 51 52
 - Property, Research Misconduct, and this policy.

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Academic and Research projects must be designed with rigor and conducted with honesty and integrity. The design of an academic/Research project must include appropriate safeguards against bias. All Scholars/Researchers involved in the project and/or Research must follow the ethical principles of RCRS.

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All Scholars/Researchers must complete training in RCRS as defined in related University administrative procedures and/or in alignment with the requirement of external funding agencies.

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VIOLATIONS OF THIS POLICY

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Failure to comply with this or any other research policy of the University will result in the application of Administrative Sanctions for Violations of the University of Louisville Research Policies.

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RELATED INFORMATION (0*)

- 70 America COMPETES Act
- 71 NIH NOT-OD-22-055
- NIH NOT-OD-10-019 72
- 73 NIH NOT-OD-21-152
- NSF PAPPG CH II.C.1.d 74

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- 76 RES-1.01 Guidelines on the Ownership of Data University of Louisville
- 77 Addressing Potential Individual Conflicts of Interest
- 78 <u>Intellectual Property</u>
- 79 Responding to Allegations of Research Misconduct
- 80 Administrative Sanctions for Violations of the University of Louisville Research
- 81 <u>Policies</u>

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STANDARDS (O*)

- Principal Investigators/Project Directors are responsible for ensuring that all
- Scholars/Researchers as well as other applicable members of their team are made
- aware of these requirements.
- Conflict of Interest and Commitment. Researchers/Scholars are expected to avoid conflicts of interest and commitment that appear to directly and significantly:
 - 1. compromise objectivity in carrying out University responsibilities;
 - 2. affect the University's interests; or
 - 3. otherwise compromise the performance of University responsibilities unless such conflicts are managed, reduced, or eliminated. Scholars/Researchers must be aware of, understand, and comply with applicable University policies.

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Human Subjects. Federal regulations for human subject research are based on three overarching ethical principles, also known as the Belmont Principles. These

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1. Respect for Persons – respecting the autonomy of individuals to make their own decisions and protecting individuals with diminished autonomy;

2. Beneficence – protecting research participants from risk of harm while optimizing possible benefits of the research; and

3. Justice – fairly distributing the benefits and burdens of research. All human subjects research conducted under the auspices of the University must follow relevant policies and regulations.

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Specialized training is required for University Scholars/Researchers conducting Research involving human subjects.

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Animal Subjects. Public and scientific concerns shape the laws that regulate the humane care and use of animals in research, testing, and instruction. These laws are governed by the following ethical mandates, known as "The Three Rs" of animal research:

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- 1. Reduction required proof that the number of animals is reduced to the smallest number possible (respecting the value of each life)
- 2. Replacement required proof that a non-animal model is not available and/or that the species identified is justified (replacing animal use where feasible)
- Refinement required proof that all procedures ensure the highest quality of compassionate care and comfort (applying standards developed to ensure quality of life through minimizing risk and discomfort, adequacy of housing, and advanced veterinary medicine).

Specialized training is required for University Scholars/Researchers conducting Research involving animal subjects.

Safe Laboratory Practices. The Laboratory Manager (defined below) is responsible for informing each staff person and all Scholars/Researchers of applicable federal, state, and local regulations and University policies for conduct of studies involving humans, animals, radioactive and other hazardous materials, and recombinant DNA. Laboratory Managers are responsible for informing personnel and all Scholars/Researchers in their laboratories about existing University policies and these guidelines. The Laboratory Manager is also responsible for explaining and discussing the relevant requirements for RCRS with trainees, fellows, and visiting scientists/scholars in the laboratory, and to ensure that such requirements are met. Specialized training is required for University Scholars/Researchers conducting laboratory research.

Mentor/Mentee Relationships. Mentors are responsible for assuring close supervision of the research of students and trainees, including the design of research protocols, approval by appropriate committees, data gathering and recording, statistical analysis, interpretation of results, preparation of manuscripts, submission, and revision of manuscripts for publication, and presentations at scholarly meetings.

Safe Research Environments. Scholars/Researchers are responsible for ensuring all research practices are equitable and the environments in which research is conducted are also diverse, inclusive, and accessible. All Scholars/Researchers have the right to work in a setting free of mistreatment, harassment, and discrimination.

Collaborative Research. In keeping with the principle of fostering reproducibility in science, novel materials and technology used for experiments should be made

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available or means for obtaining these should be given to other members of the research community upon request and after the execution of a material transfer or data use agreement (as necessary). The Principal Investigator should have the latitude to make a fair and balanced response to requests for all research data and/or materials, including novel compounds and reagents. Additionally, Scholars/Researchers are expected to comply with any applicable data or material sharing requirements set forth by the University, research sponsors, or applicable laws and regulations.

Peer Review. The most effective single process for ensuring research of high quality is peer review, both formal and informal. Informal review occurs through departmental and interest-group seminars and research discussion groups. Each division, department, or program should encourage such informal review procedures. Formal review will be accomplished by existing review committees (e.g., promotion and tenure committees) that are tasked with evaluating the merit and relevance of research.

Data Gathering, Storage, and Retention: Original data must be recorded, preserved, and made accessible to the University. The University retains ownership of all Research data, samples, and materials generated or collected during University Research. Any applicable granting agency requirements or other applicable sponsored research agreement governing the preservation of data must be followed; however, it may be necessary to preserve data for a longer period. For joint Research involving two or more laboratories, the Principal Investigators involved in the Research shall meet and agree upon which of them is to maintain the data. The Principal Investigator shall make the data available for a reasonable period.

Research Misconduct. Principal Investigators bear responsibility for the integrity of Research performed under their supervision. Administrative unit heads must pursue reasonable monitoring to ensure the integrity of the activities conducted under their oversight. The Research Integrity Officer (RIO) is the individual responsible for receiving and assessing allegations of Research Misconduct, assuring that there is a timely response to such allegations, ensuring the timely and thorough execution of relevant processes and proceedings, and disseminating communications to those involved in proceedings such as sponsors and agencies.

Authorship and Publication of Research and/ or Scholarly Works. Each author must make substantial contributions in the conception; design; analysis or interpretation of data; or have drafted the work or reviewed it critically for important intellectual content; AND have approved the submitted version (and any

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- substantially modified version that involves the author's contribution to the
- 194 Research/Scholarship); AND have agreed to be personally accountable for the
- author's own contributions and to ensure that questions related to the accuracy or
- integrity of any part of the work, even ones in which the author was not personally
- involved, are appropriately investigated, resolved, and the resolution documented
- in the literature. Authors must not engage in Unacceptable Authorship Practices
- 199 (defined below).
- No student, trainee, or non-key personnel may publish research results without the
- 201 knowledge and approval of the Principal Investigator. If the Principal Investigator is
- unable to provide approval for personal or professional reasons, the student,
- trainee, or non-key personnel may seek approval from the cognizant Dean / VP of
- 204 the Principal Investigator's home unit.
- 205 International Collaboration & Research Security. UofL recognizes that
- international academic collaborations are an essential part of the research
- 207 community and critical to scientific advancement. However, it is important that all
- 208 personnel engaging in international partnerships are aware of their reporting
- obligations and the concerns associated with research security, including improper
- 210 foreign influence. Researchers should be completely transparent about their foreign
- 211 relationships and activities and fully comply with all reporting requirements
- established by University policy and sponsors of federally-funded research.
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- 214 **Export Controls.** Export control and shipping regulations affect University
- activities at home and abroad. These regulations apply to (but not limited to)
- 216 physical exports of Research materials, samples, data, intellectual property travel
- 217 to certain countries, including foreign nationals residing in the U.S., subject to U.S.
- 218 sanctions, and research projects conducted outside the public domain.
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- 220 **Social Obligation.** Researchers have a social obligation to conduct Research and
- Scholarship work responsibly and with integrity, and to work to ensure that their
- 222 contributions are not misused.
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- 224 **DEFINITIONS (O*)**
- Laboratory Manager(s) or Supervisor(s) means an individual who supervises
- 226 personnel and operations in a laboratory environment.
- 227 **Mentors** means someone who teaches or gives help and advice to a less
- 228 experienced and often younger person.

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- Principal Investigator (PI)/ Project Director (PD) means the individual
- 230 Scholar/Researcher ultimately responsible for the effective and compliant
- 231 management of all ethical, scientific, fiscal, and programmatic aspects of a
- 232 Research project.
- Research and Development. Research means a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. This definition encompasses basic and applied research, including research training activities not
- included in formal instruction and all development activities. Development is the
- 237 systematic use of knowledge and understanding gained from Research, directed 238 toward producing useful materials, devices, data, systems, or methods, including
- the design and development of prototypes and processes. For purposes of this policy, both research and development apply.

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Scholar(s)/Researcher(s) means faculty, students, trainees, staff, employees, visiting scholars, key personnel, project team members, and all other members of UofL's research community, as well as an individual who is responsible for the design, proposal, conduct, and/or reporting of research, irrespective of discipline, regardless of pay or leave status.

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- **Responsible Conduct of Research and Scholarship (RCRS)** means the processes and actions to perform accurate, efficient, rigorous, and reproducible research and scholarship. RCRS encompasses all aspects of the Research and Scholarship enterprise, including, but not limited to the following topics:
- 1. conflict of interest personal, professional, and financial and conflict of commitment, in allocating time, effort, or other research resources;
- 2. policies regarding human subjects, live vertebrate animal subjects, and safe laboratory practices;
- 3. Mentor/mentee responsibilities and relationships;
- 4. safe Research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment);
- 5. collaborative Research including collaborations with industry and Researchers and institutions in other countries;
- 6. peer review, including the responsibility for maintaining confidentiality and security in peer review;
- 7. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks;
- 8. secure and ethical data use; data confidentiality, management, sharing, and ownership;

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- 9. research misconduct and policies for handling misconduct;
- 269 10. responsible authorship and publication;
- 270 11. research security;
- 271 12. export controls; and,
- 13. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of biomedical and social science research
 - 14. the Scholar/Researcher as a responsible member of the profession
 - 15. academic freedom

Research Record means any data or results, in any media or format, which embodies the information resulting from Research. A Research Record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; medical charts; participant research files; computer code; musical scores; musical composition; and choreography.

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Scholarship means the creation of new knowledge or the creation of novel expressions of knowledge in any form.

Unacceptable Authorship Practices means publication processes that detract from professional and societal advancements. The University considers the following practices are considered by the University to be unethical and unacceptable:

- 1. Ghost Authorship Authors who contributed to the work but are not listed, generally to hide a conflict of interest from editors, reviewers, and readers.
- 2. Guest/gift/honorific authorship Individuals given authorship credit who have not contributed in any substantive way to the research but are added to the author list by virtue of their stature in the organization.
- 3. Orphan authorship Authors who contributed materially to the work but are unfairly omitted from the author list by the drafting team.
- 4. Forged authorship Unwitting authors who had no part in the work but whose names are appended to the paper without their knowledge to increase the likelihood of publication.

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- 5. Coercive authorships exertion of seniority or supervisory power by a person to be conferred authorship when appropriate authorship criteria are not otherwise met.
 - 6. Self-plagiarism the re-publication of one's own work or substantial and substantive portions thereof without citation to the original work. The threshold of whether the reuse of one's own work rises to the level of self-plagiarism shall be determined by the relevant journal standard, or if none exists, the relevant standard in the industry/field.
 - 7. Use of papermills or other similar commercial enterprises to purchase manuscripts with the intent of representing them as original work.
 - 8. Use of AI tools or technology that do not follow the requirements of UofL policy, the journal publisher, and Council on Publication Ethics.

PROCEDURES (O*)

RES 5-01a Training in the Responsible Conduct of Research and Scholarship (RCRS)

320 RES 5-01b Resolution of Authorship and Publication Disputes in Research and

321 Creative Activity

RESPONSIBILITIES (O*)

Institutional Officials

It is the responsibility of the University and its officials to provide training and maintain records of training in RCRS. The training provided shall be of sufficient quality and frequency to allow achievement and maintenance of certification. The University will also provide templates and mechanisms to track completion of the training requirement. The University and its officials shall consult with faculty, administrative, and/or research staff for guidance on the content and delivery of the educational materials and other program requirements; publicize the research education program to all faculty, staff, and students; and track and maintain information on participation in RCRS education activities and assess the ongoing effectiveness of the research education program.

Unit Heads or Designee

It is the responsibility of the applicable Unit Head or their designees to ensure all Scholars/Researchers and other applicable Research personnel complete RCRS training requirements appropriate to their career stage and/or as required by sponsors or the University; publicize the RCRS training program to faculty, staff, and students in college or unit; and provide advice and guidance for the RCRS training program.

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344	Directors and Department Heads
345 346	Departments and other administrative units are responsible for providing information regarding accepted standards of professional integrity and quality,
340 347	including aspects specific to their own disciplines. Notices sent from the Office of
348	Research & Innovation, or its designee, through the Deans, Directors, and
349	Department Heads should serve as an effective reminder to all faculty, staff and
350	students. Ensure all Scholars/Researchers complete RCRS training requirements
351	appropriate to their career stage and/or as required by sponsors or the University;
352	Publicize the RCRS training program to all faculty, staff and students in their
353	department; and Monitor completion of requirements by all faculty, staff and
354	students, as needed.
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356 357	Faculty, Staff and Students Scholars/Researchers shall complete RCRS training requirements as outlined in Res
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360	RESPONSIBLE AUTHORITY (R*)
361	Executive Vice President, Research and Innovation
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363	RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION (R*)
364	Office of Research Integrity
365	300 E Market, Suite 300, Louisville, KY 40292
366	Phone: 1-502-852-2454
367	Email: ori@louisville.edu
368	
369	HISTORY (R*)
370	Revision Date(s): May 23, 2007; June 17, 2016; Sep 2022
371	Reviewed Date(s): 2016
372	
373	The University Policy and Procedure Library is updated regularly. In order to
374	ensure a printed copy of this document is current, please access it online at
375	http://louisville.edu/policies.
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277	$R^* = Required O^* = Ontional$