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<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.1.D</td>
<td>The University of Louisville has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Boards, as appropriate.</td>
</tr>
</tbody>
</table>

1.1 Description of the Organization, its purpose, and how the HSPP relates to the organization's mission

The University of Louisville, established in 1798, is one of the oldest urban institutions of higher learning in the United States. The University, located in the Commonwealth's largest metropolitan area, serves as Kentucky's premier urban/metropolitan university providing the educational, intellectual, cultural, service, and research needs of the greater Louisville region. It has a special obligation to serve the needs of a diverse population, including many ethnic minorities and place bound, part-time, nontraditional students.

The University of Louisville is a premier, nationally recognized metropolitan research university with a commitment to the liberal arts and sciences and to the intellectual, cultural, and economic development of diverse communities and citizens through the pursuit of excellence in five interrelated strategic areas:

1. Educational Experience
2. Research, Creative, and Scholarly Activity
3. Accessibility, Diversity, Equity, and Communication
4. Partnerships and Collaborations
5. Institutional Effectiveness of Programs and Services.

In conjunction with this mission, the University of Louisville Human Subjects Protection Program works to:

- ensure safety precautions for and obtain the full informed consent of each research participant at the University of Louisville;
- enhance the educational training of all researchers and their staff who conduct research utilizing human subjects to ensure the highest standards of research conduct;
- promote accountability and responsibility among all those involved in clinical research including those serving on institutional review boards (IRBs), institutional officials, researchers, and sponsors;
- ensure support for an effective oversight process; and
- enhance the efficiency and cost-effectiveness of the clinical research oversight system.
1.2 University of Louisville Organizational Chart and the Institutional Official

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.1.B</td>
<td>The University of Louisville delegates responsibility for the Human Subjects Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.</td>
</tr>
<tr>
<td>I.1.D</td>
<td>The University of Louisville has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board, as appropriate.</td>
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The President of the University of Louisville, Dr. James Ramsey, reports to the University’s Board of Trustees. The President of the University delegates responsibility for the protection of human research participants to the Executive Vice President for Research and Innovation. The Board of Trustees of the University of Louisville, the governing body of the University appoints the President and the Executive Vice President for Research and Innovation.

UofL Leadership Team

The President of the University delegates the responsibility for ensuring human subject protections to the Executive Vice President for Research and Innovation. The Board of Trustees of the University of Louisville, the governing body of the University, appoints the Executive Vice President for Research and Innovation (Job Description of the EVPRI).

William M. Pierce, Jr., Ph.D., Executive Vice President for Research and Innovation, is the Institutional Official (I/O), charged by the President of the University to develop and maintain the institutional infrastructure for the proper conduct of all research. The Associate Vice President for Research and Innovation, Pamela W. Feldhoff, Ph.D., oversees the HSPPO.
As the University of Louisville’s Institutional Official, the Executive Vice President for Research and Innovation signs the Federalwide Assurance of Compliance (FWA) on behalf of the institution and is ultimately responsible for:

- Creating, establishing and maintaining the policies and procedures for the HSPP and related research policies and procedures on behalf of the University of Louisville.
- Overseeing the protection of human participants, regulatory compliance, and the implementation of the HSPP for Louisville.
- Ensuring that open channels of communication are maintained between the components of the HSPP
- Ensuring the independence of the IRB, including the authority to act without undue influence.
- Requiring periodic reviews of the HSPP.
- Ensuring that the HSPP is functional, adequately staffed and funded, involving:
  - Annual review of the resources allocated to the HSPP.
  - Participation in the annual budget preparation for the HSPP and incorporation of the HSPP budget into the budget of the University of Louisville.

1.3 Organization of the HSPP

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I.2</td>
<td>The University of Louisville ensures that the Human Subjects Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the University of Louisville conducts or oversees.</td>
</tr>
</tbody>
</table>

The day-to-day operational and oversight responsibility for the HSPP is delegated to the HSPPO Director, a non-faculty, full-time professional/administrative position. The HSPPO Director reports to the Associate Vice President for Research and Innovation, Pamela W. Feldhoff, Ph.D. The HSPPO Director, Rebecca Higgins, has day-to-day operational responsibility for the HSPP. She has over 20 years’ experience at the University of Louisville serving as the IRB administrator, dealing with the Institutional Review Boards and aspects of compliance, and previously, as Assistant Director, HSPPO. She has served as Director since January, 2014.

Before joining the Office of the Executive Vice President for Research and Innovation, she held positions in the School of Medicine as an IRB manager and served as an alternate member of the University’s Social Behavioral Education IRB. Ms. Higgins holds a Bachelor’s of Science degree in Education in Occupational Training and Development.

The HSPPO Assistant Director, Christina LaDuke has day-to-day operational responsibility for the IRBs. She has six years of experience at the University of Louisville. Ms. LaDuke joined the HSPPO staff in November, 2014.
RBs: There is one biomedical IRB and one social behavioral education IRB. Their authority, membership requirements, and responsibilities are described in Chapter 6. IRBs are responsible for the initial and continuing review, review of modifications, approval of all research subject to the HSPP, determining serious or continuing noncompliance, requiring modifications (to secure approval), disapproving research, and applying applicable ethical standards.

**IRB Chairs/Vice Chairs, Biomedical IRB**
- Laura L. Clark, MD, CIP, Chair
- Julie L. Goldman, MD, CIP, Vice Chair
- Diller B. Groff, MD, CIP, Vice Chair
- Serge A. Martinez, MD, JD, CIP, Vice Chair
- Paula G. Radmacher, PhD, Vice Chair

**IRB Chairs/Vice Chairs, SBE IRB**
- Pete M. Quesada, PhD, CIP, Chair
- Melissa Evans Andris, Ph.D., Vice Chair

The Biomedical IRB (IRB00000251) and the Social Behavioral Education IRB (IRB00000252) are the two University of Louisville IRBs and perform many of the core functions of the HSPP. The Executive Vice President for Research and Innovation appoints the chairs and the members of the IRBs. The IRBs are functionally independent (e.g., of the individuals who are conducting the research) and have ready access to the highest officials of the covered organizations, if needed, to ensure protection for human research participants.

The University of Louisville also participates in the Adult and Pediatric Central Institutional Review Boards (CIRB) Initiative of the National Cancer Institute (NCI). The NCI CIRBs are the IRBs of record for certain adult and pediatric national multi-center cooperative oncology group cancer treatment trials.

### 1.4 Administrative Units, Colleges and Schools, Centers and Institutes
The University of Louisville has twelve academic colleges and schools:

- **College of Arts and Sciences**
- **College of Business**
- **School of Dentistry**
- **College of Education and Human Development**
- **School of Interdisciplinary and Graduate Studies**
- **Kent School of Social Work**
- **Brandeis School of Law**
- **School of Medicine**
- **School of Music**
- **School of Nursing**
- **School of Public Health and Information Sciences**
- **Speed School of Engineering**
The University of Louisville has the following Centers and Institutes:

Anne Braden Institute for Social Justice Research  
Bingham Child Guidance Center  
Birth Defects Center  
Cardiovascular Innovation Institute  
Center for Advanced Surgical Technology  
Center for Arts and Cultural Partnerships  
Center for Asian Democracy  
Center for Career and Technical Education  
Center for Economic Education  
Center for Emerging Market Economies  
Center for Environmental & Occupational Health Sciences  
Center for Environmental Education  
Center for Environmental Genomics and Integrative Biology  
Center for Environmental Policy and Management  
Center for Family Resource Development  
Center for Genetics and Molecular Medicine (CGeMM)  
Center for Geographic Information Systems (ULCGIS)  
Center for Hazards Research and Policy Development  
Center for Health Hazard Preparedness  
Center for Industrial Ergonomics  
Center for Infrastructure Research  
Center for Land Use and Environmental Responsibility  
Center for Mental Health Disparities  
Center for Nursing Practice  
Center for Predictive Medicine  
Center for Regulatory and Environmental Analytical Metabolomics (CREAM)  
Center for Research in Mathematics and Science Teacher Development (CRMSTD)  
Center for Sustainable Urban Neighborhood (SUN)  
Center for Study of Crime and Justice in Black Communities  
Kentucky Institute for the Environment and Sustainable Development (KIESD)  
Kentucky Lions Eye Research Institute  
Kentucky Population Research Center  
Kentucky Spinal Cord Injury Research Center  
Kentucky State Data Center  
Kosair Charities Pediatric Center Research Institute  
Labor Management Center  
Logistic and Distribution Institute (LoDI)  
McConnell Center for Political Leadership  
Muhammad Ali Institute for Peace and Justice  
National Crime Prevention Institute  
Non-Profit Innovation Center  
Center for Transportation Innovation  
Center on Race and Inequality  
Children and Youth Project  
City Solutions Center  
Clinical and Translational Research Institute (CTSI)  
Commonwealth Center for the Humanities and Society  
Commonwealth Institute of Kentucky  
Cressman Center for Visual Arts  
Diabetes and Obesity Center  
Depression Center  
Delphi Center  
Early Childhood Research Center  
ElectroOptics Research Institute and Nantechnology Center  
Family Business Center  
Gheens Center on Aging  
Health Promotion and Prevention Science Research  
Henry Vogt Cancer Research Institute  
Hite Art Institute  
Information Technology Research Center (iTRC)  
Institute for Bioethics, Health Policy and Law  
Institute for Cellular Therapeutics (ICT)  
Institute for Community Security and Public Safety  
Institute for Democracy and Development  
Institute for Molecular Diversity and Drug Design (IMD3)  
Institute of Advance Materials and Renewable Energy  
Institute of Molecular Cardiology  
James Graham Brown Cancer Center  
Keller Child Psychiatry Research Center  
Kentucky Area Health Education Centers (AHEC)  
Kentucky Autism Training Center  
Nystrand Center of Excellence in Education  
Outcomes Research Institute  
Pediatric Sleep Medicine and Apnea Center  
Price Surgical Research Institute  
Rapid Prototyping Center  
Southern Police Institute  
Stream Institute  
Survey Research Center  
University Center for Continuing and Professional Education  
Urban Studies Institute  
Weisskopf Child Evaluation Center  

1.5 Goals and Objectives of the HSPP

The goals of the HSPP are to protect human research participants by ensuring that in all research:

- The rights and welfare of human research participants are adequately protected.
• Such research is guided by the ethical principles of respect for persons, beneficence, and justice as set forth in the Belmont Report, and is conducted with the highest level of expertise and integrity.

• Such research complies with applicable laws.

The objectives of the HSPP include mechanisms to:
• Establish a formal process to monitor, evaluate, and continually improve the protection of human research participants and dedicate resources sufficient to do so;
• Exercise oversight of research protection;
• Educate investigators and research staff about their ethical responsibility to protect research participants;
• When appropriate, intervene in research and respond directly to concerns of research participants.

1.6 Organizations Covered by the HSPP and their Components

<table>
<thead>
<tr>
<th>Organizations/Sites</th>
<th>Key Organizational Representative(s)</th>
<th>Federal-wide Assurances</th>
<th>FWA current through:</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Louisville (All campus sites)</td>
<td>See 1.2 and 1.3 above.</td>
<td>FWA00002211</td>
<td>08/07/2019</td>
</tr>
</tbody>
</table>

University of Louisville maintains a Federalwide Assurance under OHRP (45 CFR 46.103) available to investigators and others involved in human subject research. The University of Louisville has three major campuses: the Belknap Campus, located in the heart of Old Louisville; the Health Sciences Center campus, located in the downtown hospital corridor, houses the Schools of Medicine, Dentistry, Nursing and Public Health and Information Sciences; and the Shelby Campus, located in the northeastern section of Jefferson County, houses the University’s Center for Predictive Medicine, a biosafety level three (BSL3) facility for the development of vaccines and other countermeasures to fight bioterrorism and emerging infectious diseases. The majority of biomedical research involving human subjects is conducted on the Health Sciences Center campus. The majority of the social behavioral education research is conducted on the Belknap Campus and in the Jefferson County Public Schools.

The University of Louisville does have three major research partners located in the downtown medical corridor: Jewish Hospital St. Mary’s Healthcare (operated by Catholic Health Initiatives); University of Louisville Hospital (with the J. G. Brown Cancer Center, operated by Catholic Health Initiatives); and Norton Healthcare, Inc., (operating Norton Hospital and Norton Children’s Hospital). The University of Louisville does not own or operate its own hospital facility. Faculty research is conducted at the hospitals listed above.

1.7 Essential Functions of the Offices primarily involved in the HSPP

The essential functions of the University of Louisville Human Subjects Protection Program Office are to:

1. assist in preparing agenda for and monitoring IRB meetings;
2. maintain files on all human subjects research (including copies of all correspondence between the IRB and investigators) that takes place at the University of Louisville;
3. maintain databases for tracking studies;
4. prepare meeting minutes;
5. maintain files of minutes of full board and subcommittee meetings;
6. screen research applications for completeness prior to initiating the IRB review process;
7. act as a resource for investigators on general regulatory information, guidance with forms, and assistance in preparing an application for IRB review;
8. maintain the institution’s Federal-wide Assurance and the IRB membership rosters;
9. provide staff support to the IRBs;
10. send notices of approval, study closure (other than closure of the study by the investigator), and termination;
11. generate and sends reminder notices to investigators of upcoming continuing reviews;
12. maintain information on federal regulations relating to human subjects research;
13. provide education regarding the IRB process and regulations to the University community;
14. provide educational opportunities to IRB members;
15. maintain records of IRB membership including training;
16. conduct quality assurance and quality improvement for the HSPP;
17. assist in preparing and providing educational opportunities to subjects, prospective subjects, or their communities, to enhance their understanding of research involving human subjects.

All HSPPO staff are required to complete a non-disclosure agreement and an Attestation and Disclosure Form (COI) on an annual basis.

Other essential functions of the Human Subjects Protection Program in the following EVPRI offices and programs: The Research Integrity Program provides education on the Responsible Conduct of Research. The Sponsored Programs Administration Office provides information and support relating to the negotiation of grants, contracts and sub-agreements with sponsors, including budget review and application approval for submission to outside sponsors, tracking of proposals and awards and services as the official authorized signature authority for sponsored programs grants and contracts from federally funded and non-profit organizations. The Clinical Contracts Division provides information and support to faculty, staff and others engaged in sponsored activities with industry/for-profit organizations and clinical trials (sponsored by any entity, including governmental/non-profit entities). The Office of Technology Transfer assists in preparing Material Transfer Agreements when blood, tissue or data (slides, x-rays, etc.) are being transferred in or out of the institution.

1.8 Laws Applicable to the University of Louisville
The basic legal principles governing human subject research covered by the HSPP and applicable to individual protocols are:
- Federal Policy for Protection of Human Subjects (Common Rule) in 45 CFR Part 46
- Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164.
- ICH-GCP as adopted by the Food and Drug Administration
- Applicable Kentucky law.

1.9 Types of Research Conducted

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>Overall Percentages</th>
<th>Number of Investigators</th>
<th>Number of Protocols</th>
<th>Funding Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical</td>
<td>74%</td>
<td>354</td>
<td>1152</td>
<td>Unfunded 584 51%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Industry 298 26%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Federal 188 16%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Private/Nonprofit 82 7%</td>
</tr>
<tr>
<td>Total Biomedical:</td>
<td></td>
<td></td>
<td>1152</td>
<td>100%</td>
</tr>
<tr>
<td>Social, Behavioral, Educational</td>
<td>26%</td>
<td>226</td>
<td>386</td>
<td>Unfunded 312 81%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Industry 15 4%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Federal 40 10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Private/Nonprofit 19 5%</td>
</tr>
<tr>
<td>Total SBE:</td>
<td></td>
<td></td>
<td>386</td>
<td>100%</td>
</tr>
<tr>
<td>Overall Total:</td>
<td></td>
<td></td>
<td>580</td>
<td>1538</td>
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</table>