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### 2.1 Sufficient Human and Fiscal Resources

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The provision of adequate human and fiscal resources facilitated through the budgeting process results in a well-functioning and effective HSPP.

**Human Resources:** University of Louisville University demonstrates a high level of institutional commitment to its HSPP in terms of human resources. The HSPP is led by the Executive Vice President for Research and Innovation, pursuant to the authority delegated by the Office of the President (see Delegation of Authority to Institutional Officer). The Director of the Human Subjects Protection Program Office (HSPPO) reports to the Associate Vice President for Research and Innovation.

**Fiscal Resources:** University of Louisville University demonstrates a high level of institutional commitment to its HSPP in terms of fiscal resources, and is committed to providing the HSPPO with adequate means to carry out its mission while keeping the protocols-to-staff-ratio within acceptable boundaries.

**Resource Allocation in support of HSPP:** The HSPPO receives the majority of its annual budget through the Office of the Executive Vice President for Research and Innovation. A portion of the HSPPO budget is derived from IRB review fees billed to corporate sponsors and collected to offset the costs providing appropriate staffing, providing educational opportunities to IRB Chairs, members, and HSPPO staff.

The annual budget is established by a three-phase process:

1. IRB Chairs provide input regarding priorities and resources needed for each academic year. The input is communicated to the Associate Vice President for Research and Innovation during a budget discussion meeting.

2. The HSPPO Director prepares income and expense forecasts for the upcoming fiscal year. Income forecast includes fees collected for the review of protocols on corporate-sponsored clinical research. Expenditure forecast takes into consideration:
   - Adequate number of IRBs
   - Adequate staffing
   - Adequate technology support
   - Adequate funds for educational opportunities for IRB members and IRB staff, including off-site conferences
   - Adequate funds to provide on-going office and logistical support
   - Adequate funds to carry out agreed-upon special projects.
3. These forecasts are converted into a budget ultimately reviewed and approved by Executive Vice President for Research and Innovation. This budget is then integrated by the University Planning and Budget Office into the University’s consolidated budget forecast presented to the Board of Trustees for approval. It takes effect on July 1 of each year.

When unanticipated needs arise, they are communicated by the HSPPO Director to the Associate Vice President for Research and Innovation. These needs are considered in light of their urgency and fiscal implications.

### 2.2 Matching IRBs to Volume and Types of Human Research

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The Biomedical IRB meets the first, third and fourth Thursday of each month.

The Social Behavioral Education (SBE) IRB meets on a monthly basis, if needed. The majority of the research reviewed by the SBE IRB is expedited or exempted based on federal regulations. When a greater than minimal risk study is submitted, a full Board meeting is scheduled the first Wednesday of the month.

The SBE IRB reviews research conducted in the field of human behavior, social sciences, education, anthropology, and other similar areas. This IRB generally will not review protocols with physical interventions, e.g., MRI, venipuncture, or actions that involve the collection or analysis of protected health information.

The HSPPO assesses the levels of activity for both boards at least annually in order to optimize the workflow and IRB load. It considers the ratio of protocols to staff, the number of transactions generated by each protocol, the type of protocols (regular, expedited or exempt), and any other appropriate elements. Input from the IRB Chairs regarding the level of activity and other IRB-related matters are gathered in the IRB annual report that is presented to the Associate Vice President for Research and Innovation. When adjustments are necessary, their financial implications are considered during the budget process outlined above in Chapter 2.1.

New IRBs or new staff positions are created to meet the demands of the workload. Meeting schedules and corresponding protocol submission deadlines are posted on the Human Subjects Protection Program website. Submitted protocols are assessed for completeness before their assignment to an IRB. Once a protocol is assigned to an IRB, the review process can start. This includes a detailed pre-meeting review phase that ensures that substantive issues and compliance requirements are addressed in a timely fashion. See Chapter 7 for information on the review process.

### 2.3 Human Research Protection, Care of Participants, and Safety

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<td>II.3.A</td>
<td>The IRB has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.</td>
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To approve research, the IRB must determine that, where appropriate, there are adequate resources to ensure the care and safety of participants, from the screening and recruitment phases throughout the project. During review of the submitted protocol, the IRB assesses the information in the Study Application and, as necessary, asks for additional details. If the protocol does not provide adequate protection, it will not be approved. See Chapter 7 for information about the review process.

Principal Investigators (PIs) are required to indicate in the Study Application whether investigators:
- will have access to a population that will allow recruitment of the required number of participants;
- will have sufficient time to conduct and complete the research;
- will have adequate numbers of qualified staff; will have adequate facilities; and
- will have medical or psychological resources available that participants might require as a consequence of the research, when applicable.

When the protocol is not funded by a contract or a grant, the availability of resources is affirmed by the Division Chief, Department Chair, School Dean or their designee as part of the review conducted prior to initial submission to the IRB.

PIs should continually monitor the resources allocated for their research and notify the IRB if any change in the availability of resources may adversely impact the rights and welfare of participants.