ADMINISTRATIVE OVERSIGHT OF THE HRPP

SECTION	EFFECTIVE DATE	REPLACES POLICY	REPLACES SECTION
P&P 1.03	02.06.2020	03.25.2019	2.0-2.3

Institutional Official Authority and Responsibilities

The administration of the LSUHSC-NO has delegated to the IRB the full authority of the Chancellor's Office for the conduct of the program. The Chancellor has designated the Vice-Chancellor for Academic Affairs as the Institutional Official for the IRB. The IO provides oversight and guidance to the HRPP and IRB Chair and exercises functions that require official action. The day-to-day conduct of the program will be the responsibility of the Chair or Vice-Chair of the IRB. While the Chair answers directly to the Vice-Chancellor for Academic Affairs, the Chair has the authority to interact directly with the Chancellor (Chief Executive Officer of LSUHSC-NO) if needed. Specifically, the IO for the administration shall:

A. Maintain active files for all investigators submitting protocols to the IRB for approval

B. Ascertain that all proposals are screened relative to the need for IRB evaluation

C. Allocate resources to provide necessary support services for the IRB and financial and personnel support to assure the HRPP can adequately protect the rights and welfare of study participants

D. As appropriate, transmit to the US Department of Health and Human Services (DHHS) all actions on DHHS-supported activities, and transmit to other federal agencies actions taken on activities supported by those agencies

E. The IO is designated as the Signatory Official on the Federalwide Assurance with OHRP. The Chair completes FWA submissions, updates, and renewals to maintain that institutional policies are in compliance with the U.S. federal regulations for the protection of human subjects in research.

F. Make certain that all recommended actions are initiated pursuant to IRB decisions

G. Present appropriate and ongoing educational opportunities for IRB staff, Board members, investigators and others, concerning human subjects protection, related federal regulations and IRB policies and procedures

H. The IO will evaluate the Chair, and the Chair will evaluate the staff annually to make certain that the professional staff is informed as to the responsibilities of the institution for protection of human subjects, for meeting attendance and minute notes, and accuracy and quality of their IRB work, among other things. Feedback is provided individually regarding any areas for improvement.

I. Develop necessary arrangements with affiliated and other institutions for mutual assurance of protection of human subjects

J. Implement FDA regulations and transmit reports regarding investigational new drugs, devices, and biologics

K. Provide the liaison and channeling of appropriate information among staff, IRB, the administration, and governmental agencies

L. Exercise a continuous surveillance of the IRB program by:

   1. Reviewing all grant applications and clinical trials and research agreements to determine that IRB review has been instituted where required. The functions of the HRPP are separate from Post-award Sponsored Research functions. Those persons who are responsible for business development are not allowed to serve on the IRB or carry out day-to-day operations of review process

2. Maintaining files on IRB actions

3. Reviewing IRB activities to make certain that the guidelines are being implemented to adequately protect subjects

4. Reviewing HRPP activities for Quality Improvement with the goal of assessing compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance, to ensure compliance with all federal, state, and organizational laws, regulations, policies and professional standards. To measure compliance, the HRPP annually plans to assess a certain percentage of research sites and IRB reviews for compliance with regulatory requirements. For example, the program might decide, in a given year, to evaluate 100% of clinical sites conducting FDA-regulated research; a 10% sample of non-clinical studies, or 100% of meeting minutes.

   The HRPP uses site visits and HRPP records to assess compliance and make improvements, as described in Section 4.6 of this Guidebook, under *Post-Approval Monitoring*. The HRPP monitors research based on the complexity of the research, degree of risk, and the qualifications and experience of the research site staff. Periodic site visits enable the HRPP to assess compliance with applicable laws, regulations and policies, and verify that research is conducted in accordance with the IRB-approved protocols. Periodic review of IRB records enables the HRPP to determine compliance with regulations, laws, and policies.

   The HRPP conducts a not-for-cause site visit at selected facilities where clinical research is being conducted at least once per year; the HRPP conducts site visits when the IRB directs an audit to assess compliance (for-cause audits); The HRPP audits a sample of studies on a quarterly basis to monitor the IRB's compliance with regulations. Sample audit activities include auditing meeting minutes for quorum and required regulatory determinations, or consent documents for required disclosures. Results are reported to the IRB.

5. Continually monitoring IRB processes and practices for improvement in the protection of subjects

6. Carrying out an HRPP Quality Improvement plan which periodically assesses the quality, efficiency or effectiveness of the program. Goals of the plan are, for example,
   - to increase the level of quality of research submissions received,
   - to generate fewer requests for changes to applications,
   - to lower the incidence of compliance issues, among other things.

   On an annual basis the HRPP uses the following types of measures to assess whether program performance meets targets (these are examples; actual measures may vary depending on the need to evaluate performance of different aspects of the program, and new measures may be added as required):
   - Time required for review of new FB applications (target=≤3 hours)
   - Time required for Board deliberation of new FB applications (target ≤½ hour)
   - Time required to compose PI memo with Board-mandated changes to new FB study (target ≤1 hour)

- Individual investigators needing to be educated re: submission of new protocols (target <15%)
- Incidence of compliance issues occurring in a quarter (target <2)
- Individual investigators needing to be educated re: compliance (target <5%)

Results are reported to leadership. The program uses the information to design and implement improvement plans.

The program will review national benchmarks annually (such as AAHRPP's published data) and review to determine whether LSUHSC-NO HRPP meets these benchmarks and to help determine whether changes are indicated in HRPP processes and procedures.

In addition, satisfaction surveys are sent to investigators and the study team with each study approval packet, to be returned, if desired, with signed Assurance letters. The results are tabulated periodically and adjustments to the program made as warranted.

7. On an annual basis, a formal evaluation meeting of the Institutional Official, IRB Chair, IRB Vice-Chair, selected members of the IRB, HRPP/IRB staff, and selected PIs and research coordinators is conducted to determine whether resources for the HRPP/IRB are adequate to properly protect the rights and welfare of research participants. The evaluation includes, but is not limited to, the following areas: space, personnel, HRPP education program, legal counsel, Conflict of Interest, quality improvement plan, community outreach and functioning of the IRB. If needs or deficiencies are identified by this group, action is taken to enhance processes, augment resources and rectify deficiencies to enhance participant protection.

8. Evaluation by the Chair, designee or staff, on an annual basis, of the effectiveness of outreach activities with regard to participant recruitment of minority and medically-underserved populations, and educational initiatives in the community. Results are assessed in light of these items and outreach activities are altered appropriately according to the results of the evaluation.

IRB Disapproval

IRB disapproval and other decisions of the IRB cannot be overruled by the Health Sciences Center administration. However, approvals may be overruled by the Chancellor's office if in the best interest of the institution.

Project directors or principal investigators (PI) may appeal IRB disapprovals or restrictions on approvals to the IRB. If the PI wishes to further challenge any decisions made by the IRB, the PI must initiate the process through the Institutional Official, the Vice-Chancellor for Academic Affairs. Such appeals must be filed by the PI within 30 days of action by the IRB.

Research Funding

Funds for any research project may be withheld at the discretion of the administration.