I. PURPOSE

The purpose of this standard operating procedure is to describe the administrative functions associated with the management of CHOP IRB staff. The IRB staff provides consistency, expertise, and administrative support to the IRBs, and serves as a daily link between the IRB and the research community. In this capacity, the IRB staff is vital for the effective operation of the CHOP human subjects protection program.

II. POLICY STATEMENT

The CHOP Institutional Official ensures that the IRB Office has sufficient Office staff to support the efficient and effective administration of the IRB and its activities.

III. SCOPE

These policies and procedures apply to all IRB members and staff.

IV. DEFINITIONS

Senior Director, HSR: Senior Director, Human Subjects Research

Chair, CPHS: The Chair functions as the executive chair of all of the IRB committees and subcommittees and provides input for IRB policies and educational training requirements. The Chair works with the Senior Director, Human Subjects Research and the VP, Research Compliance and Regulatory Affairs on procedural matters pertaining to the IRB. The Chair serves as Chair or Vice-Chair for one or more of the CHOP IRBs.
V. PROCEDURES

A. Job Descriptions and Performance Evaluations
The job descriptions for members of the IRB staff will detail the responsibilities expected of their positions. The performance of IRB staff will be reviewed according to current CHOP policy (e.g., HR Policy 4-3: Compensation Standard Pay Practices, HR Policy 5-17: Talent Management for CHOP Leaders).

B. Ensuring Adequate Resources for IRB Operations
1. The Senior Director, HSR and Chair, CPHS review the metrics related to IRB review activities and the required IRB resources and budget at least annually. The reports of these findings are forwarded to the Institutional Official.

2. The Institutional Official ensures that the IRB Office has sufficient resources, including staff and space (as applicable) to support the IRB’s activities. Support requirements will be determined in part, by the volume of submissions to the IRB and the type and complexity of the research.

C. Hiring and Terminating IRB Staff
The policies of CHOP Department of Human Resources determine the policies (found in the CHOP Policy Manager) for recruiting and hiring staff.

D. Documentation
The policies of CHOP Department of Human Resources determine the means of identifying, documentating and retaining formal staff interactions (such as performance reviews, termination procedures, etc.).

VI. APPLICABLE REGULATIONS AND GUIDELINES

| 45 CFR 46.107 | 21 CFR 56.107 |
VII. REFERENCES TO OTHER APPLICABLE SOPS

| Human Resources Policies on Employment, Employee Relations, Compensation, and Talent Management |

VIII. RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Title</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Director, HSR</td>
<td>Responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of the IRB staff</td>
</tr>
<tr>
<td>Chair, CPHS</td>
<td>Responsible for providing feedback to the Senior Director, HSR regarding observations about resources and staffing of the IRB membership and staff</td>
</tr>
</tbody>
</table>

IX. ATTACHMENTS

None

XI: REVISIONS:

- 06-01-2006 Initial approval date
- 06-09-2010 Revised to clarify roles and include the interval for evaluating resources for the IRB.
- 02-02-2013 Editorial changes.
- 09-25-2018 Updated CHOP logo and editorial changes.
- 11-09-2021 Revised to reflect updated job titles and responsibilities
- 12-01-2023 Revised to reflect updated job titles and policy references
X. APPROVAL:

Approval Indicator:  Approved by Amy Schwarzhoff and Barbara Engel on 12/01/2023

Amy Schwarzhoff, Senior Director, Human Subjects Research and Barbara Engel, Chair, CPHS