 <b>Children's Hospital of Philadelphia</b> RESEARCH INSTITUTE	<i>Committee for the Protection of Human Subjects (IRB)</i>	<b>Published Date:</b> 12/04/2023 <b>Revised Date:</b> 12/01/2023
<b>SOP 103: Management of IRB Office Personnel</b>		<b>Page: 1 of 4</b> <b>SOP</b>

## 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.

 <b>Children's Hospital of Philadelphia</b> RESEARCH INSTITUTE	<i>Committee for the Protection of Human Subjects (IRB)</i>	<b>Published Date:</b> 12/04/2023 <b>Revised Date:</b> 12/01/2023
<b>SOP 103: Management of IRB Office Personnel</b>		<b>Page: 2 of 4</b> <b>SOP</b>

## 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, documenting 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

 <b>Children's Hospital of Philadelphia</b> RESEARCH INSTITUTE	<i>Committee for the Protection of Human Subjects (IRB)</i>	<b>Published Date:</b> 12/04/2023 <b>Revised Date:</b> 12/01/2023
<b>SOP 103: Management of IRB Office Personnel</b>		<b>Page: 3 of 4</b> <b>SOP</b>

## VII. REFERENCES TO OTHER APPLICABLE SOPS

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

## VIII. RESPONSIBILITIES


Title	Responsibility
Senior Director, HSR	Responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of the IRB staff
Chair, CPHS	Responsible for providing feedback to the Senior Director, HSR regarding observations about resources and staffing of the IRB membership and staff

## 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

 <b>Children's Hospital of Philadelphia®</b> RESEARCH INSTITUTE	<i>Committee for the Protection of Human Subjects (IRB)</i>	<b>Published Date:</b> 12/04/2023 <b>Revised Date:</b> 12/01/2023 <b>Page: 4 of 4</b>
<b>SOP 103: Management of IRB Office Personnel</b>		<b>SOP</b>

**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