


| | | |
|---|---|--|
|  | Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures | SOP 103 Page: 1 of 3 |
| | Title: Management of IRB Office Personnel | Effective Date: 6/1/2006 Version Date: 09/25/2018 |

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

Director, HSR: 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 Director, Human Subjects Research and the AVP, 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 (HR Policy 4.3: Standard Pay Practices).

B. Ensuring Adequate Resources for IRB Operations

1. The Director, HSR and Chair, CPHS in consultation with the Assistant Vice President, Research Compliance and Regulatory Affairs 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.

| | | |
|---|---|--|
|  | Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures | SOP 103 Page: 2 of 3 |
| | Title: Management of IRB Office Personnel | Effective Date: 6/1/2006 Version Date: 09/25/2018 |

2. The Institutional Official or their designee ensure that the IRB Office has sufficient resources, including staff and space 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 Human Resource policies of CHOP (HR Policy 2.0: Employment; HR Policy 5.0: Employee Relations) determine the policies 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).

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

VII. REFERENCES TO OTHER APPLICABLE SOPS


HR Policy 4.3: Standard Pay Practices

HR Policy 2.0: Employment

HR Policy 5.0: Employee Relations

VIII. RESPONSIBILITIES

| Title | Responsibility |
|---------------|---|
| 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 Director, HSR regarding observations about resources and staffing of the IRB membership and staff |

| | | |
|---|---|--|
|  | Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures | SOP 103 Page: 3 of 3 |
| | Title: Management of IRB Office Personnel | Effective Date: 6/1/2006 Version Date: 09/25/2018 |

IX. ATTACHMENTS

None

XI: REVISIONS:

- 6/9/2010 Revised to clarify roles and include the interval for evaluating resources for the IRB.
- 2/2/2013 Editorial changes.
- 9/25/2018 Updated CHOP logo and editorial changes.

X. APPROVAL:

Director, Human Subjects Research

Date

Chair, Committees for the Protection of Human Subjects

Date