

The Research Compliance Program: Charter

The Research Institute at Children's Hospital of Philadelphia (CHOP) maintains a research compliance function for all research conducted at CHOP. This charter sets forth the purpose, governance, authority, and responsibility of the research compliance program at CHOP.

Purpose

CHOP is committed to the highest standards of integrity in all areas of research, so we invest considerable resources—personnel, facilities, funding, and other infrastructure—to support compliance activities throughout the organization. As part of this commitment, the Research Institute established the research compliance program to consolidate and strengthen research compliance and regulatory functions. Through active and close collaboration with the various research compliance oversight committees, other research administrative offices, and the Office of Compliance and Privacy (OCP), the research compliance program promotes the ethical and responsible conduct of research and ensures compliance with regulatory requirements related to human subjects research, animal subjects research, laboratory-based research, and other areas of research compliance. The research compliance program promotes a culture of research compliance throughout the organization that encourages proactive identification of compliance issues and prompt and appropriate responses to compliance concerns.

Governance

The governance of the research compliance program is described in *“The Research Compliance Program: Structure and Governance.”*

The research compliance program is supported by the Research Compliance and Risk Sub-Committee (RCRS), and the VP of Research Compliance & Regulatory Affairs provides periodic updates to the RCRS about the research compliance program.

Authority

The VP of Research Compliance & Regulatory Affairs and the offices reporting to this position have oversight of compliance activities within the Research Institute.

The research compliance program shall have full, free, and unrestricted access to all records, reports, activities, property and personnel, as needed to fulfill their assigned responsibilities.

The VP of Research Compliance & Regulatory Affairs is authorized to:

- Allocate resources, select areas of review, set frequencies, determine scopes of work, and apply the techniques required to accomplish the research compliance program’s objectives
- Obtain the necessary assistance of personnel in other institutional offices as well as contract for other specialized services to accomplish the research compliance program’s objectives

Responsibility

The research compliance program has the responsibility to:

- Develop and maintain a risk-based research compliance program to ensure that research compliance risks are identified and controlled. The research compliance program shall be guided by the elements of an effective compliance program recommended by the Federal Sentencing Guidelines and applicable standards of the Office of Inspector General of Health and Human Services
 - Designation of a compliance officer and compliance committee
 - Development of written compliance policies
 - Development of open lines of communication
 - Appropriate training and education
 - Internal monitoring and auditing
 - Response to detected deficiencies and development of corrective action initiatives through investigations including ensuring that reports are made to regulatory authorities as required
 - Enforcement of disciplinary standards
- The research compliance program includes, but is not limited to
 - A post-approval quality assurance program for human, animal, and laboratory-based research
 - A policy and procedure documentation program
 - An IND and IDE monitoring program
 - An export control program
 - Oversight of the Research Institute's decentralized compliance functions, e.g., clinical research billing, Investigational Drug Service, use of controlled substances in research
- Conduct the annual risk assessment process; coordinate results with CCO, Research Institute executive leadership, and RCRS; track and monitor resulting risk management plans
- Develop and implement annual compliance plans with the input of the CCO and RCRS and approval by the Audit, Compliance, and Risk Committee
- Support management, legal counsel, and institutional committees with any special tasks or projects
- Keep appropriate leadership and key stakeholders informed about research compliance matters including as described in the *"The Research Compliance Program: Structure and Governance."*