I. PURPOSE

The purpose of this policy is to establish guidelines to ensure that the Hospital meets its reporting obligations by identifying the events that require reporting and the responsibility for reporting them.

II. POLICY STATEMENT

It is the policy of Children's Hospital of Philadelphia Research Institute that on behalf of the Hospital, the Institutional Official will ensure that full, accurate, and timely reports are submitted to the appropriate regulatory and funding agencies when required for unanticipated problems involving risks to subjects and others, serious or continuing noncompliance, suspensions of previously-approved research, and terminations of previously-approved research.

III. SCOPE

This policy applies to all members of the research staff, non-traditional research personnel, members of the medical staff, employees of the Hospital, IRB members and any entity that is controlled by or under common control with the Hospital.

IV. DEFINITIONS

Continuing Noncompliance: A pattern of noncompliance with repeated failure to adhere to the federal research regulations or CHOP policies that may affect the rights or welfare of participants. The pattern of noncompliance is assessed by the number of incidents occurring during the course of implementation of a protocol, or across multiple protocols, conducted at CHOP, and whether the same noncompliant action was repeated or many different noncompliant events occurred, especially after a remediation procedure such as training has been provided to the researcher or research staff.

Institutional Official: The individual identified on the Federalwide Assurance with OHRP as authorized leader of the Hospital's human subjects protection program.

Noncompliance: A violation of any federal, state, or local regulation that governs human research; any hospital policy on human research; any deviation from the protocol approved by the IRB or stipulations imposed by the IRB as a condition of approval. Serious Noncompliance: Noncompliance that may affect subject safety, increase risks to subjects, affect the integrity of the data, violate the rights and welfare of subjects, or affect the subject's willingness to participate in research.

Suspension of Previously-Approved Research: An action taken by the IRB to temporarily or permanently withdraw approval for some or all research activities short of permanently withdrawing approval for all research activities. Termination of Previously-Approved Research: An action taken by the IRB to permanently withdraw approval for all research

activities (except for those follow up procedures which are necessary to protect the health or welfare of the subjects).

Unanticipated Problems Involving Risks to Subjects and Others: Any incident, experience, or outcome that meets all of the following criteria:

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to a subject's participation in the research; and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

V. PRINCIPLE

Federal regulations 45 CFR 46.108(a)(4) and 21 CFR 56.108(b) require that institutions have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.

VI. PROCEDURES

A. IRB Reporting Responsibilities To The Institutional Official

1. Depending on the event or stage of IRB review, the CPHS Chair or the CPHS Vice-Chair, or the Director, Human Subjects Research (as a member of the IRB) will report the following events to the Institutional Official or designee (e.g. Director, Office of Research Compliance and Regulatory Affairs):

(a) Terminations of Previously Approved Research, as described in **IRB SOP 410**

(b) Suspensions of Previously Approved Research, regardless of the reason for the suspension, as described in **IRB SOP 410**

(c) Noncompliance determined by the IRB to represent Serious or Continuing Noncompliance, as described in **IRB SOP 901**

(d) Problems determined by the IRB to represent unanticipated problems related to research, in accordance with the **IRB SOP 408** - Unanticipated Problems Involving Risks to Subjects and Others

2. The contents of the report for the Institutional Official (or designee) must include:

(a) name of the institution conducting the research

(b) title of the research project and grant proposal in which the problem occurred

(c) name of the principal investigator on the protocol

(d) number of the research project assigned by the IRB

(e) detailed description of the problem

(f) IRB's findings

(g) actions the IRB is taking or plans to take to address the problem

(h) basis for the action

(i) IND number (when applicable)

(j) any further investigation or action recommended to be taken (if applicable)

B. Institutional Official Reporting Responsibilities

Within fifteen (15) days of the final review by the IRB, the Institutional Official (or designee) is responsible for submitting a formal report for the events identified in this policy to the following:

1. External Recipients

(a) Office for Human Research Protections (OHRP) - if the study is subject to U.S. Department of Health and Human Services (DHHS) regulations

(b) Other federal agencies - when the research is subject to those agencies and the agency requires reporting separate from that to OHRP, including Department of Defense Components (see IRB SOP 107)

(c) Food and Drug Administration (FDA) - when the research is FDA-regulated

(d) Sponsors of the research - as appropriate

(e) Funding source of the research - as appropriate

2. Internal Recipients

(a) Institutional Review Board (IRB)

(b) Director, Research Compliance (when appropriate)

(c) Office of General Counsel (when appropriate)

(d) Office of Compliance and Privacy

(e) Principal Investigator's hospital division/department or service (when appropriate)

(f) Relevant Chief Medical Officer (when appropriate)

VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108(a)(4) and 46.113	21 CFR 56.108(b) and 56.113
Guidance on Reporting Incidents to OHRP (September 9, 2022)	

VIII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 408: Unanticipated Problems Involving Risks to Subjects and Others	IRB SOP 410: Suspensions and Terminations of Previously IRB-Approved Research
IRB SOP 901: Noncompliance with Human Subjects Research	

IX. RESPONSIBILITIES

Title	Responsibility
IRB	Reports events (as identified in this policy) to the Institutional Official.
Institutional Official (IO)	The IO or designee are responsible for submitting a formal report to external and internal recipients within fifteen (15) days of receipt of the final report from the IRB. Maintains formal report for 10 years.

X. REVISIONS:

07-22-2015: Re-assessment; include ORCRA Director as designee of IO

05-02-2016 Updated Internal Recipients, inclusion of IND number for studies conducted under an IND

12-22-2022 Re-assessment; updated to reflect current processes and regulations

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/22/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS