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Effective	3/1/2025
Next Review	2/29/2028
Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

Internal & External Reporting Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy outlines the steps to be taken when an event is determined to be reportable under local, state, and federal regulations.

Boston Children's Hospital complies with all applicable local, state, and federal regulations that pertain to reporting requirements. These regulations require that the following be reported:

1. Unanticipated problems that involve risks to participants or others.
2. Suspension or termination of Institutional Review Board (IRB) approval of research
3. Serious or continuing noncompliance with regulations or the requirements of the IRB.

The same criteria and process for conducting investigations, making determinations about reporting, and actions taken will apply to all research regardless of funding source. Incidents that are determined to be reportable but do not require external reporting will be reported to the Institutional Official.

The IRB reserves the right to voluntarily report any event that is not associated with federal funding to the Office of Human Research Protections (OHRP).

All reporting actions are to occur within the minimal amount of time necessary to conduct complete and conclusive investigations, with a final report goal of no more than **30-days** from the time an event is identified.

1. If it appears that an investigation and resolution of the event may take longer, the Institutional Official (IO) may submit an initial report with any information known to date and the time frame necessary to submit a final report.
2. If federally funded or under the jurisdiction of the FDA, the Institutional Official will submit any report on behalf of the institution.

Reporting to regulatory federal agencies is not required if the Principal Investigator (PI) voluntarily closes a study to new subject accrual or temporarily halts the research procedures. In this situation, the IRB, IRB Chair, or administrative officials may recommend voluntary closure of subject recruitment and/or research activities to the PI. However, the PI makes the decision whether closure is appropriate. If the IRB or IRB Chair requires suspension or termination, the incident is reportable under this policy.

Procedures

Reportable Events

The IRB determines if:

1. An event represents:
    a. An unanticipated problem that involves risks to participants or others;
    b. Serious or continuing noncompliance
2. There is need to suspend or terminate the research.

Report Content

1. Following a complete investigation of the situation or incident, the Senior Director of Clinical Research Compliance is to prepare a final report that includes the following:
    a. An overview of the situation or incident.
    b. A description of the manner in which the investigation was conducted.
    c. The findings of the investigation.
    d. A full explanation as to why and how the incident occurred.
    e. The actions taken, including any corrective actions.
    f. Any sanctions taken.
2. The IRB, IRB Chair, the Institutional Official, the General Counsel, and any other individual(s) deemed appropriate by the IRB are to review the report.
3. The Institutional Official makes the final determination regarding the report's content.

Report Recipients

1. A copy of the final report will be shared with:
    a. Government agencies as applicable
    b. Sponsors to the extent legally and contractually required
    c. Other applicable bodies under the sole discretion of the Institutional Official.
2. Possible recipients of the full report, excerpts or summaries, include:
    a. Office of Human Research Protections (OHRP): If federally funded
    b. U.S. Food and Drug Administration (FDA): When the research is subject to FDA regulation
    c. Funding agency when funded by a government entity which require copies of such reports (e.g. Departments of Defense, Education, and Justice).
    d. Licensing and accrediting bodies: Where the report or some portion thereof implicates standards or regulations administered by those bodies
    e. IRB Chair(s) and members
    f. Principal Investigator (PI).
    g. PI's Department Chair/Chief or supervisor.
    h. Office of Sponsored Programs: When the research is funded by a grant or contract
    i. Any other external sponsor: When the research is sponsored
    j. Other Boston Children's Hospital Departments who require notification (e.g. Pharmacy, Clinical Research Compliance, Office of Sponsored Programs, Department Chairs/Chiefs)
    k. Boston Children's Hospital Office of Patient Quality and Safety
    l. Harvard Medical School: Where the findings are requested and relevant to violations of academic standards.
3. A copy of the report is to be placed in the protocol file, as well as any other files that are maintained during an investigation to determine whether an event is reportable.

Related Content

- IRB Policies (For more information on specific procedures for investigating and making pertinent determinations):
    - Noncompliance: Investigations and Determinations
    - Suspensions and Terminations
    - Unanticipated Problems and Adverse Events Involving Risks to Research Subjects and Others

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
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Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

Boston Children's Hospital- Policies & Procedures