Internal & External Reporting

Purpose

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

Policy

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

- Unanticipated problems that involve risks to participants or others.
- Suspension or termination of Institutional Review Board (IRB) approval of research; and
- 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. The IRB reserves the right to voluntarily report any event that is not associated with federal funding to 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.

- If it appears that an investigation and resolution of the event may take longer, the institutional official may submit an initial report with any information known to date and the time frame necessary to submit a final report.
- 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. However, if the IRB or IRB Chair requires suspension or termination, the incident is reportable under this policy.

The specific procedures for investigating and making pertinent determinations concerning those situations are addressed in the following IRB policies:

- ***Noncompliance: Investigations and Determinations***
- ***Suspensions and Terminations***

- ***Unanticipated Problems and Adverse Events Involving Risks to Research Subjects and Others***

Procedure

Reportable Events

The IRB determines if an event represents an unanticipated problem that involves risks to participants or others; if an even represents serious or continuing noncompliance, and the need to suspend or terminate the research.

Report Content

Following a complete investigation of the situation or incident, the Director of Clinical Research Compliance is to prepare a final report that includes the following:

1. An overview of the situation or incident.
2. A description of the manner in which the investigation was conducted.
3. The findings of the investigation.
4. A full explanation as to why and how the incident occurred.
5. The actions taken, including any corrective actions.
6. Any sanctions taken.

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.

The Institutional Official makes the final determination regarding the report's content.

Report Recipients

A copy of the final report will be shared with government agencies as applicable, sponsors to the extent legally and contractually required, and with other applicable bodies under the sole discretion of the Institutional Official. Possible recipients of the full report, excerpts or summaries, include:

- Office of Human Research Protections (OHRP) if federally funded,
- Food and Drug Administration (FDA) when the research is subject to regulation by the FDA.
- Funding agency when funded by a government entity (e.g., the Departments of Defense, Education, and Justice require copies of such reports).
- Licensing and accrediting bodies, where the report or some portion thereof implicates standards or regulations administered by those bodies.
- IRB Chair and members.
- Principal investigator (PI).
- PI's Department Chair or supervisor.
- Office of Sponsored Programs when the research is funded by a grant or contract.
- Any other external sponsor, when the research is sponsored.

- Other BCH Departments who require notification (i.e. Pharmacy, Clinical Research Compliance, office of Sponsored programs, Department Chairs/Chiefs).
- Boston Children's Hospital Office of Patient Quality and Safety
- Harvard Medical School, where the findings are requested and relevant to violations of academic standards.

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

Noncompliance: Investigations and Determinations

Suspensions and Terminations

Unanticipated Problems and Adverse Events Involving Risks to Research Subjects and Others

Document Attributes

Title	**Internal and External Reporting**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/1/2005 7/6/2005 5/11/2007 5/1/2015
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2020	**Last Modified**	1/10/2020
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		