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**Boston  
Children's  
Hospital**

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Owner Susan Kornetsky:  
Manager  
Department Research  
Applicability Boston Children's  
Hospital-  
Guidelines

## Coordination Between the Institutional Review Board (IRB) and the Program for Patient Safety and Quality (PPSQ) Guideline

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

This guideline applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the guideline also applies to foundation practices leasing space at hospital-licensed locations.

### Guideline Statements

This guidance describes the measures that are taken to ensure the safety of Boston Children's Hospital research subjects.

It is essential that information regarding adverse events that occur with subjects participating in research be appropriately communicated between the Institutional Review Board (IRB) and Program for Patient Safety and Quality (PPSQ).

- Both, the IRB and the PPSQ have processes and criteria for reporting events; therefore, it is possible that an event will be submitted through one or both reporting mechanisms.
- Once an event is reported internally, it is essential that information about the event be communicated to both offices so that they can meet their oversight and regulatory reporting

responsibilities.

- If required, remedial action plans may be coordinated between the two offices.

## Process Steps

The following guidelines should be followed to assist in this coordination of efforts.

### Institutional Review Board

1. Copies of any unanticipated problems for Boston Children's Hospital research subjects submitted to the IRB are also sent to the PPSQ through the electronic protocol review system.
2. These events must be provided to PPSQ and will include any remedial action plans to be taken or already implemented:
  - a. Results that could involve a death of a research subject
  - b. An unexpected or related adverse event
  - c. Medication or laboratory error
  - d. Other serious events, or protocol deviations related to hospital systems
3. The IRB, the IRB Chair, the Institutional Official (Vice President of Research Administration), or the Senior Director of Clinical Research Compliance may request that the PPSQ review an event, series of events, or concerns raised that may impact research subject safety.
4. For any incident reported to the IRB, the IRB may acquire access to any PPSQ documents that may exist regarding the event, including any remedial action plans implemented.
5. The IRB will require that all events that meet the reporting requirements for Safety Event Reporting System (SERS) be submitted through SERS, if not already completed.
6. The IRB will ask for a copy of the SERS report for their files.
7. When incidents rise to the level of required regulatory reporting, the draft report will be submitted to PPSQ for review of accuracy of any information they have regarding the event.

### Program for Patient Safety and Quality (PPSQ)

1. Any event submitted through SERS that includes the fact that the subject was enrolled on a research protocol should be forwarded to the IRB office.
2. PPSQ may request and ask for information from the IRB office regarding any research protocol for which they have received an event report.  
PPSQ will be responsive to the requests made by the IRB office as listed above.
3. As appropriate and necessary, both offices will work together and coordinate efforts for resolution of the issues raised and any additional required corrective action plans.

## Approval Signatures

**Step Description**

**Approver**

**Date**

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## Applicability

Boston Children's Hospital- Guidelines

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