Coordination Between the Program for Patient Safety and Quality and the Institutional Review Board

Purpose

This policy describes the measures that are taken to ensure the safety of Boston Children's Hospital (BCH) research subjects.

Policy

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

Both offices 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. In addition, if required, remedial action plans may be coordinated between the two offices.

Guidelines

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

Institutional Review Board

1. Copies of any unanticipated problems for BCH subjects submitted to the IRB are also sent to the PPSQ through the electronic protocol review system. These events must be provided to PPSQ: results that could involve a death of a research subject, an unexpected or related adverse event, medication or laboratory error, other serious events, or protocol deviations related to hospital systems. The events will include any remedial action plans to be taken or already implemented.
2. The IRB, the IRB Chair, the Institutional Official (Vice President of Research Administration), or the 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.
3. 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.
4. 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. The IRB will ask for a copy of the SERS report for their files.
5. 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.
3. PPSQ will be responsive to the requests made by the IRB office as listed above.

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.

Related Content

None Identified

Document Attributes

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