



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

Policy

To assure the safety of Boston Children's Hospital research subjects, it is essential that information regarding adverse events that occur on subjects participating in research be appropriately communicated between the Offices of Clinical Investigation 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 submitted to the Institutional Review Board are also sent to the PPSQ through the electronic protocol review system. These events could involve a death of a research subject, an unexpected or related adverse event, medication or laboratory errors, or other serious events or protocol deviations related to hospital systems must be provided to PPSQ. 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 done. The IRB will ask for a copy of the SERS report for their files.

- 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)

- Any event submitted through SERS that includes the fact that the subject was enrolled on a research protocol should be forwarded to the Institutional Review Board office.
- PPSQ may request and ask for information from the Institutional Review Board office regarding any research protocol for which they have received an event report.
- PPSQ will be responsive to the requests made by the Institutional Review Board 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

Document Attributes

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Approved	<hr/> Susan Kornetsky, MPH Director of Clinical Research Compliance <hr/> Nina Rauscher, Program for Patient Safety and Quality		