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Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Noncompliance: Investigations and Determinations 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.

Definitions

Noncompliance: Any violation of any regulation that governs human subject research or of any institutional policy for human subjects research violation of any conditions imposed by the IRB on the approval of the study or conduct of the research, or deviation or departure from an IRB-approved protocol.

Serious Noncompliance: A noncompliant event that has or had the potential to impact rights, welfare or safety of present, past or future subject(s), increase the risks and/or decrease the benefit for research subjects(s), compromise the integrity of the study data, or affect a subject's willingness to participate in the study.

Continuing Noncompliance: A series of more than one noncompliant event, in reasonably close proximity that indicates the need for evaluation of the methods and systems used to protect human subjects. Continuing noncompliance need not involve a sequence of similar events if the events, taken as a whole, indicate that examination of the methods and systems used is warranted.

Policy Statements

The purpose of this policy is to outline the procedure for reporting and investigating suspected incidents of noncompliance with human research protection requirements.

It is the policy of Boston Children's Hospital (BCH) to comply with all applicable federal, state, and local regulations in the conduct of clinical research studies.

Any allegation regarding a noncompliant event or any concern about human subject protections will be fully investigated. If at any time during an inquiry or investigation there are concerns regarding scientific misconduct, it will immediately be referred to the Vice President of Research Administration, who also serves as the Institutional Official.

Principal Investigators (PIs) and Department/Division Chiefs or any staff member are:

1. Required to report suspected regulatory **noncompliance** to either the Institutional Review Board (IRB) Chair, the Senior Director of Clinical Research Compliance, or to the Vice President of Research Administration (Institutional Official)
2. To participate in institutional efforts to address and resolve noncompliance.

The IRB, IRB Chair, Senior Director of Clinical Research Compliance, and Institutional Official are responsible for investigating and assessing noncompliance, reporting to the IRB, and requesting further remedies from the IRB itself. The IRB will make the final determination if there was **noncompliance**, **serious noncompliance**, or **continuing noncompliance**.

Procedures

Initial Reporting

1. Principal Investigators (PIs) or any other individual employed by, on staff at, or otherwise affiliated with BCH who observes or otherwise becomes aware of suspected incidents of noncompliance that could potentially be considered serious or continuing are responsible for promptly reporting the suspected noncompliance as soon as possible, but in no later than 5 business days of being known.
 - a. If the PI has any question whether a non-compliant event/deviation should be reported, they should contact the IRB.
 - b. Initial notification of suspected noncompliance can be verbal, in person, or via email, but must follow-up with a written report using the Reportable Event form.
 - c. Deviations or departures from the IRB-approved protocol that do not have the potential for being considered serious or continuing noncompliance must still be documented by the investigator as part of their own study records and a summary of these events should be submitted to the IRB at the time of continuing review.
2. PIs or any other individual employed by, on staff at, or otherwise affiliated with BCH who observes or otherwise becomes aware of suspected incidents of noncompliance that could potentially be considered serious or continuing may make an initial report via email, in person, or verbally, but must follow up with a written report using the *Reportable Event* form.

- a. If the report is made outside of CHeRP, then the report should be sent to the IRB Chair, the Senior Director of Clinical Research Compliance, or the Institutional Official.

Deviations that are possibly noncompliant

Deviations or departures from IRB approved protocols that could potentially be considered serious or continuing noncompliance are submitted using the IRB form: *Reportable Event*.

1. The Senior Director of Clinical Research Compliance is responsible for screening the event and obtaining any additional information that may be required for initial consideration of the event.
2. The event is then reviewed by the IRB Chair.
 - a. The IRB chair may request additional information as required and will make a determination as to whether the report should be submitted to the full IRB for a final determination on whether the event meets criteria for serious or continuing noncompliance.
 - b. Issues such as whether the event was under the control of the investigator will be considered in making this determination.
 - c. If the event is determined to be serious or continuing noncompliance, the *Reportable Events* policy will be followed.

Responsibilities: IRB, PI, and Institutional Official

Senior Director of Clinical Research and IRB Chair Responsibilities

The Senior Director of Clinical Research Compliance is responsible for screening the event and obtaining any additional information that may be required for initial consideration of the event. The IRB Chair and the Senior Director will then discuss the following:

1. The incident and the facts presented to date.
2. Identification of those individuals involved in the incident or likely to be involved in the investigation and resolution of the incident.
3. If necessary, a meeting will be scheduled as soon as possible after the incident is reported to begin to discuss and resolve the incident.
 - a. Attendees may include the investigator(s), the investigator's Department/Division Chief, the IRB Chair, the Senior Director of Clinical Research Compliance, General Counsel, the Institutional Official, and any other staff member thought to be involved in the noncompliant incident and required resolution.
4. Whether there are sufficient facts to demonstrate serious or continuing noncompliance that is reportable in accordance with the *Reportable Events* policy.
 - a. If so this will be immediately reported to the IRB who, based on a completed investigation, will make a final determination.
 - i. If the IRB determines it is serious or continuing noncompliance the *Reportable Events* policy will be followed.
 - ii. In most cases, more information will be required before a determination is

made that the event is either serious or continuing noncompliance

The IRB Chair may also:

1. Determine that the incident does not meet potential criteria for serious or continuing noncompliance and require either no further action or compliance with a corrective action plan that is acceptable to the Chair and agreed upon by the investigator.
2. Require that preliminary steps be immediately taken to further investigate and begin to correct the noncompliant incident and report to the IRB.
3. Determine the incident to represent serious or continuing noncompliance and recommend to the IRB that the protocol be suspended or terminated in whole or in part. This step may be taken as a final measure or as an interim measure where investigatory conclusions, although incomplete, are conclusive enough in pertinent part to just IRB action.

Convened IRB Responsibilities

1. The IRB is responsible for making a final determination as to whether serious or continuing noncompliance has occurred.
2. The IRB is to receive notification of any instance where the IRB Chair has determined that a potential incident of serious or continuing noncompliance exists. This should occur at the earliest possible time which is usually the next scheduled meeting.
3. The IRB should be advised by the Senior Director of Clinical Research Compliance or the IRB Chair about the actions taken thus far, and determine further actions to be taken.
 - a. All members will be given information known to date of the incident and important supporting documents.
 - b. The IRB, directly or through a delegate, such as the Senior Director of Clinical Research Compliance or a subcommittee formed for the purpose, may request any documents it deems necessary to conduct the investigation.
4. As determined by the specifics of the situation, the IRB reserves the right to conduct any type of investigation deemed necessary in order to obtain the required information. Moreover, the IRB may delegate any component of the investigation to those individuals best suited to perform the functions of the investigation. At any time during the investigation, the IRB may take any one or more of the following actions:
 - a. Suspend or terminate the protocol.
 - b. Designate an individual or a subcommittee to review and investigate the incident and provide information and recommendations for resolution back to the IRB.
 - c. Require additional information.
 - d. Require modifications to the protocol and/or consent form.
 - e. Require that subjects currently or previously on protocol be notified of the non-compliance when such information might relate to their willingness to continue to take part in the research.
 - f. Require that subjects be reconsented.
 - g. Modify the continuing review schedule.

- h. Require remedial education.
 - i. Require oversight by a senior investigator.
 - j. Monitor the informed consent process.
 - k. Require immediate or periodic audits by the Education and Quality Improvement Program (EQulP).
 - l. Referring concerns or findings to areas of the organization that administer other policies, laws, and regulations implicated by the non-compliance
 - m. Any other action deemed necessary by the IRB
5. The IRB will be continually updated as information becomes available until final resolution.
- a. If it determined the incident represents serious or continuing noncompliance the *Reportable Events* policy will be followed.

In the case of noncompliance due to IRB administrative operations, the IRB chair will ensure that all IRB administrative operations staff is recused from IRB members' discussion and/or determinations made about serious or continuing noncompliance.

Investigator Responsibilities

1. Investigators are responsible for reporting noncompliance that could potentially be considered serious or continuing in their protocols.
2. Investigators may choose to voluntarily initiate a suspension or termination until the potential issue is investigated and/or resolved.
3. Investigators will also be informed in writing when allegations of noncompliance are made on their protocols.
4. Investigators are required to fully cooperate with any fact finding and subsequent investigation and maintaining all potentially useful records pending investigation, even if regulations or other policies would otherwise permit destruction of those records.
5. The investigator is responsible for responding promptly in writing, to all issues and questions raised.
 - a. This may include an explanation of the noncompliant event, answers to questions raised by the IRB, and a plan of action to ensure that similar incidents do not occur in the future.
6. Investigators are responsible for complying fully with all directives of the IRB, whether investigatory or remedial.
7. If the IRB has determined that subjects must be contacted with regards to the noncompliant incident, the investigator will be responsible for doing so if the IRB so directs.
8. For deviations or departures from approved protocols that do not have the potential for being considered serious or continuing noncompliance, investigators are still required to track these events and submit them with the next continuing review.

Institutional Official Responsibility

The Institutional Official is responsible for submitting a report as required by federal regulations on

behalf of the institution in accordance with the *Reportable Event* policy.

The Final Report

For incidents determined to be serious or continuing noncompliance, the *Reportable Event* policy will be followed. A file of the noncompliant incident, regardless of the ultimate determination, will be maintained in the IRB office.

Related Content

- IRB Policy: Reportable Events: Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events
- IRB Form: Reportable Event

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
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
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Applicability

Boston Children's Hospital- Policies & Procedures