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**Boston
Children's
Hospital**

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

Suspensions, Terminations, Administrative Closures, and Investigator-Initiated Voluntary Suspension or Termination Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

The policy outlines the procedures to be followed to suspend or terminate some or all of an approved research protocol.

Definitions

Suspension: Some or all activities on a protocol are stopped while a full investigation is completed, based on a determination that there is substantial reason to believe serious or continuing noncompliance or unanticipated problems involving risks may have occurred, and that suspension in whole or part is appropriate in order to protect human subjects pending completion of the investigation. Once the investigation is complete, a determination is made as to whether the suspension may be revoked, and protocol activities resume.

Termination: Some or all activities on a protocol are permanently discontinued. There has been a determination that serious or continuing noncompliance or unanticipated problems involving risks have occurred and no further work on the protocol may continue.

Administrative Closure: The process by which the Institutional Review Board (IRB) administrative staff close a research protocol if an investigator does not submit the required continuing review materials.

Administrative closures occur after the IRB approval period expires. This action is taken to ensure that investigators do not mistakenly assume that their protocols remain active. Administrative closures are not reportable events since the protocol approval is already expired and there is no withdrawal of IRB approval.

Investigator–Initiated Voluntary Suspension or Termination: An investigator may choose to voluntarily suspend or terminate some or all activities of an approved protocol. This should be reported to the IRB and is not considered to be a reportable event unless the IRB independently determines that suspension or termination has occurred because there was an unanticipated problem involving risks to subjects or others or an incident of serious and continuing

Policy Statements

It is the policy of Boston Children's Hospital to comply with all applicable local, state, and federal regulations in the conduct of human subject research.

The IRB may suspend or terminate some or all of a research protocol as a result of the following:

- There is serious or continuing noncompliance.
- There are unanticipated problems that may involve risks to subjects or others.

In addition, the IRB Chair/Vice Chairs or the Institutional Official may suspend a protocol on an urgent basis in between IRB meetings.

- Suspensions are to be used when the evidence is sufficiently clear that the IRB determines that a suspension is warranted based upon the need to protect human subjects, and the significant likelihood, based on the evidence, that one or both of those criteria have been met.
- Terminations are based upon a completed investigation substantiating one or both of those criteria, and the IRB's determination that termination is the appropriate step to take to protect human subjects.

Procedures

Reporting Suspensions and Terminations

1. The IRB Chair/Vice Chairs(), the Senior Director of Clinical Research Compliance, or the Institutional Official is to directly notify the Principal Investigator (PI) that the IRB/Chair/Vice Chair(s) has suspended or terminated the research.
 - a. If the PI is unavailable, the IRB Chair/Vice Chairs, the Senior Director of Clinical Research Compliance, or the Institutional Official is to directly notify the PI's Department Chair/ Chief or other appropriate supervisor of the action taken.
2. The Senior Director of Clinical Research Compliance is to send the PI and Department Chair/ Chief written notification of the suspension or termination of the research. The reasons for the action are to be included in the notification.
3. Any suspension made by the IRB Chair/Vice Chair(s) or the Institutional Official will be reported to the IRB at the next scheduled convened IRB meeting.

4. If there is a suspension or termination of a research protocol the *Internal and External Reporting Policy* will be followed.

Subject Protection after Suspension, Termination

Suspension and termination do not preclude other remedies, to be considered as appropriate in order to protect human subjects, such as:

1. The notification of subjects (via phone, mail) of the protocol's suspension or termination that includes the reasons for the suspension or termination and any course of action necessary.
2. The notification of the subjects' health care providers.
3. In special circumstances, the gradual withdrawal of subjects from a protocol if abrupt discontinuation may put subjects at risk.
4. Follow-up assessments and referrals, as required.
5. Required PI submission of follow-up information regarding the welfare of the research subjects.
6. Temporary or permanent transfer of the responsibility of the research to another principle investigator
7. Any adverse events or outcomes are reported to the IRB.

Investigator-Initiated Voluntary Suspension or Termination

An investigator may choose to voluntarily suspend or terminate some or all activities of an approved protocol.

1. Voluntary suspension or termination should be reported to the IRB and is not considered to be a reportable event, unless the IRB independently determines that suspension or termination has occurred because there was an unanticipated problem involving risks to subjects or others or there was a incident of serious or continuing noncompliance.
2. When an investigator voluntarily suspends or terminates a protocol, the IRB will be notified about the reason for the investigator initiated voluntary suspension or termination.
 - a. The IRB may request any additional information required in order to make its own findings and determinations.

Records

1. All correspondence associated with the suspension or termination is to be maintained in the protocol record.
2. The date that research is suspended, terminated, voluntarily suspended, or terminated by the investigator is to be indicated in the protocol records.

Administrative Closure of Protocols

When required by *Continuing Review and Administrative Update* policy, the IRB administrative staff will administratively close a research protocol if an investigator does not submit the required continuing review materials.

1. Administrative closures occur after the IRB approval period expires. This action is taken to ensure that investigators do not mistakenly assume that their protocols remain active.
 - a. When the IRB staff administratively closes a research protocol, the investigator is sent written notification of this action, and no further work may continue on the protocol.
 - b. The database is updated to note the administrative closure.
2. A copy of the closure notification is sent to the PI.
3. Administrative closures that occur as a result of an investigator's failure to submit the required continuing review materials are not reportable in accordance with *Reportable Events: Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events*.

Related Content

- IRB Policies
 - Continuing Review and Administrative Update
 - Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures