Suspensions, Terminations, Administrative Closures, Investigator–Initiated Voluntary Suspension or Termination

Policy

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

- The CCI 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.

Purpose

To outline 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 CCI staff close a research protocol if an investigator does not submit the required continuing review materials. Administrative closures occur after the CCI 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

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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 CCI 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 noncompliance. In these situations the appropriate policies will be followed.

Procedures

Authority to Suspend or Terminate Approval of Research Protocols

The CCI may suspend or terminate some or all of the research conducted by a principal investigator (PI) as a result of the following:

- Serious or continuing noncompliance with the research
- There are unanticipated problems that may involve risks to subjects or others.

In addition the IRB Chair or the Institutional Official may suspend a protocol on an urgent basis in between IRB meeting. Suspensions are to be used when the evidence is sufficiently clear that the CCI 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 CCI's determination that termination is the appropriate step to take to protect human subjects.

Reporting Suspensions, Terminations,

- The CCI Chair, the Director of Clinical Research Compliance, or the Institutional Official are to directly notify the PI the CCI has suspended or terminated the research. If the PI is unavailable, the CCI Chair, the Director of Clinical Research Compliance, or the Institutional Official are to directly notify the PI's Department Chair or other appropriate supervisor of the action taken.
- The 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.
- Any suspension or termination made by the CCI, Director of Clinical Research Compliance of the Institutional official will be reported to the IRB at the next scheduled meeting
- If there is a suspension or termination of a research protocol the Reporting Policy will be followed.

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Subject Protection after Suspension, Termination olds

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

- Notification to 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
- Notification to the subjects' health care providers
- In special circumstances, the gradual withdrawal of subjects from a protocol if abrupt discontinuation may put them at risk
- Follow-up assessments and referrals, as required
- Required PI submission of follow-up information regarding the welfare of the research subjects.
- Temporary or permanent transfer of the responsibility of the research to another principle investigator
- 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. This should be reported to the CCI 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 non-compliance.

When an investigator voluntarily suspends or terminates a protocol, the CCI will be notified about the reason for the investigator initiated voluntary suspension or termination. The CCI may request any additional information required in order to make their own findings and determinations.

Records

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

Administrative Closure of Protocols

When required by CCI policy, the CCI staff will administratively close a research protocol if an investigator does not submit the required continuing review materials. Administrative closures occur after the CCI approval period expires. This action is taken to ensure that investigators do not mistakenly assume that their protocols remain active.

When the CCI staff administratively closes a research protocol, the investigator is sent written notification of this action, and no further work may continue on the protocol. The database is updated to note the administrative closure.

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A copy of the closure notification is sent to the Investigator. 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 the “Reporting” Policy.

Related Content

None Identified.

Document Attributes

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