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

Protocol Exception Request Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy outlines the procedures for documenting and requesting exceptions from the Institutional Review Board (IRB).

Definitions

Amendment: An on-going permanent revision or clarification to an IRB-approved protocol. IRB-approval is obtained prior to implementation.

Minor Exception: The Investigator deems a protocol exception non-significant. IRB-approval is not required prior to implementation, but summary of all minor exceptions should be submitted at the time of the continuing review/administrative update.

Protocol Exception: A one-time, intentional temporary action or process that departs from the IRB-approved protocol, intended for one occurrence.

Significant Exception: A protocol exception which will or may have the potential for at least one of the following:

1. impact subject rights, welfare or safety of present, past or future subject(s)
2. increase the risks and/or decrease the benefit for research subjects(s)
3. compromise the integrity of the study data, or

4. affect a subject's willingness to participate in the study

IRB-approval is obtained prior to implementation.

Policy Statements

Federal regulations require that all protocol modifications (**any** change from the approved protocol) must be submitted to the IRB for review and receive approval prior to implementation unless the change is to eliminate an immediate harm to a research subject.

When a PI anticipates a **one-time, intentional** action or process that departs from the approved protocol and which the PI deems significant, they must request a **protocol exception** be granted by the IRB **prior** to implementation.

Minor exceptions do not require prior IRB approval, but a summary or list of minor exceptions implemented should be submitted at the time of continuing review.

A **significant exception** requires prior IRB-approval. If a significant exception is implemented without prior IRB-approval, the event must be reported to the IRB as a Significant Protocol Deviation/Non-compliance within 72 hours of being known, using the Reportable Event SmartForm.

If a change is implemented prior to IRB-approval to eliminate an immediate harm to a research subject, then the event must be reported to the IRB within 72 hours of being known, using the Reportable Event SmartForm.

Whether significant or minor, protocol exceptions are intended to be one-time requests without the intention of amending the protocol permanently. If the same exception is requested more than once, the IRB may not grant the exception and request the investigator to submit a protocol amendment.

Procedures

Significant or Minor Exception Determination and Documentation

When a protocol exception is anticipated, the Principal Investigator (PI) should promptly assess the potential impact the exception may have on the rights, safety, and welfare of subjects, as well as the integrity of resultant study data.

It is the responsibility of the PI to make an independent determination as to whether an exception should be classified as significant or minor.

1. The PI may contact the IRB administrative office for assistance with making this determination.
2. It is up to the PI and research staff to determine a suitable method of documentation, such as a summary log or a note to file in the investigator's study records. Whatever method is determined, it should include the following information:
    a. Date or time frame the exception will be applied

b. Description of Protocol Exception
c. Reason and rationale for Exception
d. Explanation why the action will be one-time, rather than permanent
e. PI assessment whether action is significant or minor, and reason for choice
f. PI signature and date

Significant Exceptions

When a protocol exception is deemed significant, the PI is required to submit a formal request to the IRB using the Reportable Event SmartForm and receive approval prior to implementation.

If there is an outside study sponsor applicable, then the PI should obtain approval for the exception request prior to IRB submission. The PI should maintain a copy of IRB approval with the corresponding request documentation as part of their study records.

Related Content

- IRB SmartForm: Reportable Event

Approval Signatures

Step Description	Approver	Date