Boston Children's Hospital

Date: Wednesday, April 29, 2020 2:04:50 PM Print Close

Title: Reportable Event 1 : Sample New Research Activity

Exception Description

A protocol exception is a one-time, intentional action or process that departs from the IRB approved study protocol, and anticipated or known prior to the event occurring. In compliance with federal regulations and CH policy, protocol exceptions must be reported and reviewed by the IRB. The Principal Investigator should document all protocol exceptions, file them in study records, and submit copies to the IRB with the next continuing renewal.

Only if the exception is deemed 'Significant' must the PI also complete this form. Significant protocol exceptions must be submitted to the IRB and receive approval prior to implementation of action or process.

Please note, if this is an urgent request for an exception that is planned within the next few days, please call the CCI Office at (617) 355-7052 and/or email your IRB Analyst to ensure prompt attention to the request.

1 Date Exception anticipated.
4/29/2020

2 Protocol Exception Request

2.1 *Describe the anticipated exception below (include reason and justification for request).
Description of the anticipated exception, including reason and justification for request.

2.2 *Check all that apply.

- [x] **Action may increase risk of subject(s)**
- [x] **Action may impact the study progress**
- [ ] Action may impact the integrity of study design and results

3 Additional Actions

3.1 *Describe any additional action(s) already taken or planned in anticipation of this protocol exception. (e.g. DSMB reporting, report to or approval from sponsor, informing subjects).
Any additional action(s) already taken or planned in anticipation of this protocol exception.

3.2 *Describe why this departure from the approved protocol will only be a one-time occurrence, rather than a permanent change requiring an amendment request.
Why this departure from the approved protocol will only be a one-time occurrence.

3.3 *Is there any information in this modification that should be provided to participants because such information might relate to their willingness to continue to take part in the research?

○ Yes ● **No**

If YES:

3.3.1 Explain:

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Additional Documents

1 Please upload any additional documents if it is necessary.

Name	Date Last Modified	Version	Owner
There are no items to display			