Boston Children's Hospital

Date: Sunday, March 23, 2025 2:10:50 PM Print Close

**IRB-R00050051-1** UAP - Description

**Title: Reportable Event 1 : Test removal of device question**

## Reportable Events - Description

The following events require reporting to the IRB within 72 hours of the occurrence of the event or notification to the PI or research team of the event;

- DEATH of research subject thought to be either related to research study or possibly related to research study.
- UNANTICIPATED ADVERSE DEVICE EFFECT (UADE) that result in the death of a research subject.
- Termination or suspension of the study by the sponsor, DSMB or federal agency overseeing the research due to a safety issue.

All other events require reporting to the IRB within 5 business days of the occurrence of the event or notification to the PI or research team of the event, When BCH serves as the sIRB/reviewing IRB for external institutions reportable events occurring at internal institutions must be reported in compliance with this policy.
Events from protocols that are not conducted at Children's but involve the same drugs/devices do not need to be reported unless there is a clear rationale why the report meets the BCH criteria for reporting AND is pertinent to the protocol approved at BCH. The reason it is being submitted must be clearly explained at the beginning of the summary.

**1** * **Check the category that applies to the event being reported (check all that apply).**

**1.1** ☐ **DEATH** of a Children's Hospital research subject thought to be

**1.1.1 Please select:**

○ Related to research study

○ Possibly related to research study

**1.2** ☑ **ADVERSE EVENT** - Both must apply and be checked in order to be reportable.

**1.2.1** ☑ Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and the characteristics of the subject population being studied.

**1.2.2** ☑ Related or possibly related to a subject's participation in the research.

**1.3** ☐ **UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)** - any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

**1.4** ☐ **MEDICATION OR LABORATORY ERRORS** that have or could have caused risk to subjects or others.

**1.5** ☐ **BREACH OF CONFIDENTIALITY/HIPAA VIOLATION** – Resulting from disclosure of confidential information or identifiable private information or loss/stolen confidential information (lost laptop, inadvertent email distribution).

**1.6** ☐ **NON-COMPLIANCE/PROTOCOL DEVIATION** – Any violation of any human subject research regulation, institutional policy or any conditions imposed by the IRB, or a deviation/departure from an IRB-approved protocol that has or had the potential to (check all that apply

**1.6.1** ☐ Impact subject rights, welfare or safety of present, past or future subject(s)

**1.6.2** ☐ Increase the risks and/or decrease the benefit for research subjects(s)

**1.6.3** ☐ Compromise the integrity of the study data

**1.6.4** ☐ Affect the subjects willingness to participate in the study

**1.7** ☐ **COMPLAINT** - A research-related complaint by a research subject or another person.

**1.8** ☐ **INTENTIONAL CHANGE TO PROTOCOL WITHOUT IRB APPROVAL** to eliminate apparent immediate hazard to research subject(s).

**1.9** ☐ **INTERIM FINDINGS, PUBLICATION OR SAFETY REPORT** - An interim safety report (including a Data and Safety Monitoring report), publication in the literature, report of interim results, or another finding that indicates an unexpected adverse change to the risks or potential benefits of the research.

**1.10** ☐ **ENFORCEMENT ACTION** – E.g., an unfavorable audit report; suspension or disqualification of an investigator; FDA Form 483 or Warning Letter.

**1.11** ☐ **INCARCERATION OF A RESEARCH SUBJECT** during participation in the study (this is required for regulatory purposes, so that additional mandated IRB review can be accomplished in order for the participant to remain in the trial).

**1.12** ☐ **REQUIRED PROMPT REPORTING** - An event that required prompt reporting to the sponsor or IRB in accordance with the protocol.

**1.13** ☐ **OTHER** – Any other event that the PI thinks (or is unsure if it) may represent an unanticipated problem involving risk to subjects or others, or serious or continuing non-compliance.

*If OTHER:*
**1.13.1 Explain:**

**STUDY PERSONNEL MISCONDUCT : For reporting allegations of research misconduct, contact the Research Integrity Officer for Boston Children's:** rio@childrens.harvard.edu **or call the anonymous Compliance Department Hotline: 888-801-2805**

**2 If Children's Hospital subject/patient**

| Patient Name | Medical Record Number | Date Of Event | Time Of Event | Date Investigator Aware of Event |
|---|---|---|---|---|

There are no items to display

**3 If non-Children's Hospital subject/patient**

| Patient Identifier and/or Subject Number | Manufacturer Report # and/or Adverse Event Report # | Date Investigator Aware of Event |
|---|---|---|

There are no items to display

**4 *Provide a detailed description of the event.**
test

**5 If this is a report of noncompliance, a significant deviation, medication error or breach of confidentiality include an explanation of why the event occurred.**
test

**6 Select all that apply.**

**6.1 *Study type**

○ Sponsored study

● **Investigator-initiated study**

**6.2 *Report type**

- (●) **Initial report**
- ( ) Follow up report

**6.2.1 If follow up report, please specify date of initial report.**

**6.3 *Event type**

- (●) **Internal event (occurred at Children's Hospital)**
- ( ) External event (occurred at site external to Children's Hospital. This includes sites relying on the BCH IRB)

**7 *What is the status of study and recruitment?**

- (●) **Open to accrual**
- ( ) Closed to accrual, but subjects are still receiving a required research intervention (drug, device, or biologic).
- ( ) Closed to accrual and no subjects receiving required research intervention (drug, device, or biologic), but subjects are still undergoing follow-up.
- ( ) Closed to accrual and no subjects receiving required research intervention (drug, device, or biologic) or follow-up; data analysis is ongoing.
- ( ) Other

*If OTHER:*

**7.1 Explain:**

**IRB-R00050051-1** UAP - Additional Information

**Title: Reportable Event 1 : Test removal of device question**

## Unanticipated Problems - Additional Information

1 * **Does the event involve a drug or biologic?**
○ Yes ● **No**

*If YES:*

**1.1 Name of Study Drug/Biologic.**

**1.2 Date the subject started taking/received first dose of study drug.**

**1.3 Date the subject took/received the last dose of study drug prior to event.**

**1.4 Dose/dosing regimen.**

2 * **Does the event involve a device?**
○ Yes ● **No**

*If YES:*

**2.1 Name of the Device.**

**2.2 Date device used/implanted.**

3 * **Does the event involve other research interventions?**
● **Yes** ○ No

*If YES:*

**3.1 Describe the research intervention.**
other

**3.2 Date intervention performed.**
3/10/2025

4 **Provide other pertinent information, as applicable.**
test

5 * **Has this been reported to an institutional official, the sponsor or any federal officials?**
● **Yes** ○ No

*If YES:*

**5.1 Indicate to whom and when.**
test

**5.2 Attach a copy of any relevant report or FDA Medwatch form.**

| Name | Date Last Modified | Version Number | Owner |
|---|---|---|---|
| CONTRAST Pregnant ICF 1.10.docx(0.01) | 3/23/2025 2:10 PM | 0.01 | Lisa Prock |

6 * **In the opinion of the Principal Investigator, as a result of the event, participants or other individuals are either placed or are likely to be placed at physical, psychological, social, or emotional harm that has increased since the time the research was approved by the IRB.**

● **Yes** ○ No

*If YES:*

**6.1 Please explain why.**
Risk

**7 * Does this event/problem increase the likely risk or decrease the likely benefit of the study?**
● **Yes** ○ No

*If YES:*

**7.1 Please explain.**
Increase risk

**8 * Is there an independent Data Safety Monitoring Board (DSMB/DSMC), Data Safety Monitor (DSM) or equivalent for this study?**
○ Yes ● **No**

*If YES:*

**8.1 Choose one:**

○ A copy of the last DSMB/DSMC/DSM deliberation is attached.

○ The DSMB/DSMC/DSM has not yet met, but the meeting is scheduled.

○ The event does not require reporting under the Data Safety Monitoring Plan.

○ Other

**8.2 If meeting is scheduled, please specify the date.**

**8.3 If event does not require reporting under the DSMP or Other is selected, please explain.**

**9 * Is Children's Hospital the coordinating center?**
○ Yes ● **No**

*If YES:*

**9.1 Is it necessary to inform other centers?**
○ Yes ○ No

*If NO:*

**9.1.1 Please explain.**

**10 * What actions were taken to address/correct/resolve the event?**
Test

**11 * What actions are being implemented to minimize the likelihood of recurrence of the event in the future?**
Test

**12 * Are any protocol revisions required?**
● **Yes** ○ No

*If YES:*

**12.1 Provide a detailed description of the change(s).**
Test

**If protocol information requires revision, please submit an amendment.**

**13** * **Should the consent/assent form be modified?**

● **Yes** ○ No

**If consent/assent form needs to be modified, please submit an amendment.**

*If NO:*

**13.1 Please explain why.**

**14** * **Is it necessary to inform currently enrolled subjects of this serious and/or unexpected event or unanticipated problem so they may consider their willingness to continue to participate?**

● **Yes** ○ No

*If YES:*

**14.1 Explain how this will be accomplished.**

Test

**14.2 Attach additional pages as needed.**

| Name | Date Last Modified | Version Number | Owner |
|---|---|---|---|

There are no items to display

*If NO:*

**14.3 Please explain why.**

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Addtional Documents

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## Additional Documents

**1 Please upload any additional documents if it is necessary.**

| Name | Date Last Modified | Version Number | Owner |
|---|---|---|---|

There are no items to display

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