Boston Children's Hospital

Date: Wednesday, April 29, 2020 2:14:08 PM Print Close

Title: Reportable Event 2 : Sample New Research Activity

Reportable Events - Description

Note: For CH patients these events need to be reported within 72 hours. For external patients enrolled through other sites they should be reported within 7 days of the event being reported to the CH investigator. Events from protocols that are not conducted at Children's but involve the same drugs/devices do not need to be reported.

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 ☐ **STUDY PERSONNEL MISCONDUCT**

1.12 **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).

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

1.14 ☐ **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:
1.14.1 Explain:

2 If Children's Hospital subject/patient

Patient Name	Medical Record Number	Date Of Event	Time Of Event	Date Investigator Aware of Event
Name of Subject/Patient	MRN000001	4/22/2020		4/22/2020

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.
Detailed description of the event.

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.
Explanation of why the event occurred.

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)

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:

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Unanticipated Problems - Additional Information

1 * Does the event involve a drug or biologic?

● **Yes** ○ No

If YES:

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

1.2 Date the subject started taking/received first dose of study drug.
4/1/2020

1.3 Date the subject took/received the last dose of study drug prior to event.
4/21/2020

1.4 Dose/dosing regimen.
Dose/dosing regimen.

2 * Does the event involve a device?

● **Yes** ○ No

If YES:

2.1 Name of the Device.
Name of the Device.

2.2 Date device used/implanted.
4/1/2020

3 * Does the event involve other research interventions?

● **Yes** ○ No

If YES:

3.1 Describe the research intervention.
The research intervention.

3.2 Date intervention performed.
4/1/2020

4 Provide other pertinent information, as applicable.

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.
To whom was this reported, and when.

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

Name	Date Last Modified	Version	Owner

Name	Date Last Modified	Version	Owner
MedWatch Form.pdf	4/29/2020 2:10 PM	0.01	PI Test

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.

Why 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.

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.

How does this event/problem increase the likely risk or decrease the likely benefit of the study?

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.

5/7/2020

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?**

What actions were taken to address/correct/resolve the event.

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

future?
What actions are being implemented to minimize the likelihood of recurrence of the event in the future.

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

If YES:

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

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.
How this will be accomplished.

14.2 Attach additional pages as needed.

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

If NO:

14.3 Please explain why.

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Additional Documents

1 Please upload any additional documents if it is necessary.

Name	Date Last Modified	Version	Owner
SERS Report.pdf	4/29/2020 2:13 PM	0.01	PI Test