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| --- | --- |
| Logo  Description automatically generated | Institutional Review Board  **ADVERSE EVENT**  **REPORT**  *Confidential pursuant to Idaho Code* |
| **Return to the Research Institute:**  1055 N. Curtis Road  Boise, ID 83706  (208) 367-8897  (208) 367-8386  [sahslocalirb@saintalphonsus.org](mailto:sahslocalirb@saintalphonsus.org) |



***Instructions:***

*This form is for the reporting of adverse events. Application must be typed and complete. For additional resources, visit the IRB website:*

<https://www.saintalphonsus.org/services/research-institute/institutional-review-board/forms-and-resources>

**Date of Report:** Click here to enter a date.

**Study Title:** Click here to enter text.

**IRB Number:** Click here to enter text.

**Date of Event:** Click here to enter a date.

**Type of Report:** Choose an item.

**Principal Investigator:** Click here to enter text.

1. **Event Information**
2. **Brief description of event:**

Click here to enter text.

1. **Adverse event appears to be:**

Related

Possibly related

Unlikely related

Not related

Unknown

1. **The event is/was:**

Expected *(event is listed in the informed consent form)*

Not expected

1. **Severity of adverse event:**

Mild

Moderate

Severe

Fatal

1. **Outcome of event:**

Death due to event

Death due to other causes

Hospitalization

Extended hospitalization

Congenital abnormality

Other: Click here to enter text.

1. **Recovery of participant:**

Complete

Moderate

Minimal

None

Unknown

Not yet resolved

1. **Study Information**
2. **Research involves:**

Investigational device

Investigational new drug

Approved and marketed drug or device

Other: Click here to enter text.

1. **Are changes required to the protocol?**

Yes

No

N/A

1. **Are changes required to the informed consent form?**

Yes

No

N/A

1. **Has this adverse event been reported to the study or device sponsor?**

Yes, reported: Click here to enter a date.

No

N/A

1. **Has this adverse event been reported to the Food & Drug Administration?**

Yes, reported: Click here to enter a date.

No

N/A



**Additional Documents**

*Please submit the following documents along with this form:*

The patient's signed consent form

Procedural, interventional and/or operative notes

Any available outcomes

Documentation of report to the sponsor and/or FDA, if applicable



**Signature Page**

**Document prepared by:** Click here to enter text.

|  |  |  |  |
| --- | --- | --- | --- |
| **Phone:** | Click here to enter text. | **Fax:** | Click here to enter text. |
| **Company:** | Click here to enter text. | **Address:** | Click here to enter text. |
| **Email:** | Click here to enter text. | | |

**Research Principal Investigator Statement of Integrity:**

**By signing this form, I certify that the information provided is both complete and accurate. As the principal investigator for this study, I understand that I have the ultimate responsibility to ensure protection of the rights and welfare of human subjects. I am aware that it is my responsibility to remain current of Saint Alphonsus Health System, state and federal research requirements. I agree to comply with Saint Alphonsus policy and procedure research requirements and those imposed by the Saint Alphonsus IRB, as well as any applicable Federal, State, and local laws pertaining to human research subjects.**

[Subject]

**Principal Investigator Name (Typed/Printed)**

**Principal Investigator's Signature Date**