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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 |

***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**