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| Logo  Description automatically generated | Institutional Review Board  **PROTOCOL DEVIATION**  **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 protocol deviations. A "protocol deviation" is any alteration and/or modification to an IRB-approved protocol, including the detailed protocol, protocol summary, consent form, recruitment materials, questionnaires, and any other information relating to the research study. A major violation impacts subject safety, study data integrity, and/or a subject's willingness to participate in the study. 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 Deviation:** Click here to enter a date.

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

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

Click here to enter text.

1. **How many participants were affected?**

Click here to enter text.

1. **Did this deviation increase risk to the participants?**

No

Yes – *describe*: Click here to enter text.

1. **Did this deviation affect the integrity of the study data?**

No

Yes – *describe*: Click here to enter text.

1. **What corrective actions have been taken to ensure that similar problems do not occur in the future?**

Click here to enter text.

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

Investigational device

Investigational new drug

Approved and marketed drug or device

Other: Click here to enter text.

1. **Study status:**

Actively enrolling

Enrollment closed

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

Yes

No

N/A

1. **Has this protocol deviation been reported to the study or device sponsor?**

Yes, reported: Click here to enter a date.

No

N/A



**Signature Page**

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

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| --- | --- | --- | --- |
| **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**