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| Logo  Description automatically generated | Institutional Review Board  **AMENDMENT**  **APPLICATION**  *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 application is for any amendment to a previously approved study, including changes to any study documents or a change in Principle Investigator. The application must be typed and complete. If only study team member changes are needed, complete the STUDY TEAM CHANGE APPLICATION instead of this application. For this form and additional resources, visit the IRB website:*<https://www.saintalphonsus.org/services/research-institute/institutional-review-board/forms-and-resources>

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

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

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

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

**Sponsor and/or Granting Agency:** Click here to enter text.

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

1. **Expedited Review**

*In order to qualify for expedited review, this study amendment must meet the criteria of both sections A and B. If it does not, you must apply for full board review. If applying for full board review, skip to section 2.*

1. **Does this amendment meet the criteria for minimal risk?**

Yes – *continue to section B*

No – *this study does not qualify for expedited review, you must apply for full board review, skip to section 2*

1. **Does this amendment meet either of the following criteria?**

*Please check all that apply.*

Does not change the risk to human subjects.

Involves only minor change(s) in approved research during the period of approval.

1. **Study Progress**
   1. **Date Started:** Click here to enter a date.

**Anticipated Completion Date:** Click here to enter a date.

* 1. **Enrollment of Participants:**

|  |  |
| --- | --- |
| Total number to be enrolled at all sites: | Click here to enter text. |
| Total number to be enrolled at this institution: | Click here to enter text. |
| Number currently enrolled at this institution: | Click here to enter text. |
| Number in treatment phase: | Click here to enter text. |
| Number in follow-up: | Click here to enter text. |

1. **Amendment Information**
   1. **Type of amendment:**

Sponsor generated

PI generated

* 1. **Areas affected by this amendment:**

*Describe changes in the areas provided, or attach a separate list*

**Informed consent form**

Click here to enter text.

**Participant eligibility**

Click here to enter text.

**Study treatments**

Click here to enter text.

**Safety**

Click here to enter text.

**Study methodology**

Click here to enter text.

**Statistical analysis**

Click here to enter text.

**Data management**

Click here to enter text.

**Editorial changes**

Click here to enter text.

**Study team members**

Click here to enter text.

**Study instruments (surveys, interviews, etc)**

Click here to enter text.

**Other:**

Click here to enter text.

* 1. **Do participants need to be re-consented because of these changes?**

Yes

No



**Additional Documents:**

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

Red-line and clean versions of any documents that were changed as part of this amendment

Adverse event information – *if this amendment is pursuant to an adverse event*

Summary of changes – *if provided by sponsor*



**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 (Typed/Printed Name)**

**Principal Investigator's Signature Date**