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| Logo  Description automatically generated | Institutional Review Board**ANNUAL REVIEW****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 |

***Instructions:***

*This application is for the annual review of a previously approved study. Application must be typed and complete. For any study team member changes, a STUDY TEAM CHANGE APPLICATION must be completed and submitted with this application. For any other changes to the study design or study documents, an AMENDMENT APPLICATION must be completed and submitted with this application. If the study has ended or been terminated, fill out the STUDY CLOSURE APPLICATION instead* of *this application. For these forms 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.

**Annual Review Due Date:** 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, the study 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 study 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 study meet at least one of the following criteria?**

*Please check all that apply*.

[ ] The study has been previously reviewed and approved by the IRB using expedited procedure.

[ ] The research conditions/protocol has not changed such that the research continues to be eligible for expedited review.

[ ] The study is permanently closed to enrollment of new subjects, all subjects have completed all research-related interventions, AND the research remains active only for long-term follow-up of subjects.

[ ] No subjects have been enrolled and no additional risks have been identified.

[ ] The remaining research activities are limited to data analysis.

[ ] The research is not conducted under an investigational new drug application or investigational device exemption and does not meet any of the above criteria, but the IRB has determined and documented at a previous convened meeting that the research involves no greater than minimal risk AND no major protocol changes have been made or additional risks identified.

1. **Participants**

*Please check one category:*

[ ] No human research participants have been used – *skip to section 3*

[ ]  Human research participants are currently being used.

[ ]  Use of research participants was completed: Click here to enter a date.

[ ] Other: Click here to enter text.

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

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

1. **Enrollment of Participants:**

|  |  |  |
| --- | --- | --- |
|  | **Since last IRB review** | **Total** |
| **Number screened** | Click here to enter text. | Click here to enter text. |
| **Of those screened, number eligible** | Click here to enter text. | Click here to enter text. |
| **Of those eligible, number consented** | Click here to enter text. | Click here to enter text. |
| **Number who elected to withdraw** | Click here to enter text. | Click here to enter text. |
| **Number removed by investigator** | Click here to enter text. | Click here to enter text. |
| **Number who completed study activities** |  | Click here to enter text. |
| **Number currently enrolled** |  | Click here to enter text. |
| **Number in treatment phase** |  | Click here to enter text. |
| **Number in follow-up** |  | Click here to enter text. |
| **Number yet to be enrolled, if any** |  | Click here to enter text. |

1. **If subjects elected to withdraw or were removed from the study, please explain:**

Click here to enter text.

1. **Gender of Participants:**

|  |  |
| --- | --- |
| **Male:**  | Click here to enter text. |
| **Female:** | Click here to enter text. |

1. **Race of Participants:**

|  |  |
| --- | --- |
| **American Indian/Alaskan Native:** | Click here to enter text. |
| **Asian or Pacific Islander:** | Click here to enter text. |
| **Black/African American:** | Click here to enter text. |
| **White:** | Click here to enter text. |
| **Other:** | Click here to enter text. |

1. **Ethnicity of Participants:**

|  |  |
| --- | --- |
| **Hispanic** | Click here to enter text. |
| **Non-hispanic** | Click here to enter text. |

1. **Protocol and Consent**

*For any changes to the protocol or consent, an AMENDMENT FORM must be completed and submitted with this form.*

* 1. **Has a signed informed consent been obtained from each participant and kept on file?**

[ ]  Yes

[ ]  No

[ ] Not Applicable

* 1. **Will participants from any of the following vulnerable categories be enrolled in the study?**

[ ]  Yes – *check all the categories that apply below*

[ ]  No – *skip to section 4*

[ ]  Mentally ill [ ] Employees of research site

[ ]  Mentally disabled or impaired [ ] Employees of SARMC

[ ]  Chronically ill [ ] Students of PI or study staff

[ ] Terminally ill [ ] Military personnel

[ ]  Institutionalized [ ] Prisoners

[ ] Hospitalized [ ] Pregnant women**\***

[ ] Nursing home residents [ ] Fetuses

[ ] Limited or non-readers [ ] Children

[ ] Non-English speaking [ ] Poor/uninsured

[ ] Other: Click here to enter text.

**\*If this protocol includes pregnant women, please list any new risks reported that might**

 **affect pregnant women or their fetuses:**

Click here to enter text.

1. **Adverse Events**

**Since the last IRB review, have any Saint Alphonsus participants:**

* 1. **Experienced any unexpected complications related to this protocol?**

[ ] Yes

[ ]  No

[ ] N/A

* 1. **Died?**

[ ] Yes, and the IRB was notified on these dates: Click here to enter a date.

[ ] No

[ ] N/A

1. **Team Members**

*Please list all team members who are involved in the study. Add sections as needed. For any study team member changes, a STUDY TEAM MEMBER CHANGE FORM must be completed and submitted with this form.*

**Name:** Click here to enter text.

**Role:** Click here to choose an item. **If "Other", describe:** 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. |

*To list another team member, click the plus symbol*

*or copy and paste this section*

1. **Study Progress**
	1. **Since the last IRB review, have there been any publications related to this project?**

[ ] Yes – *include full reference*: Click here to enter text.

[ ] No

* 1. **Provide a brief summary of progress/results and attach a copy of the progress report (if applicable).**

Click here to enter text.

**Additional Documents**

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

[ ] Protocol

[ ] Informed consent form

[ ]  Financial interest disclosure(s)

[ ] Curriculum vitae – *for each study member, updated yearly*

**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**