|  |  |
| --- | --- |
| Logo  Description automatically generated | Institutional Review Board  **INITIAL SUBMISSION**  **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 the initial submission of a new study. Application must be typed and complete. Please reference the INITIAL SUBMISSION REQUIREMENTS document for more information about what to submit for a new study. 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.

**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.*

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

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

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.*

Previously approved activity that does not classify as research.

Research on drugs for which an investigational new drug application is not required.

Research on medical devices for which an investigational device exemption application is not required or the medical device is being used in accordance with its cleared or approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. (For healthy, non-pregnant adults that weigh 110 pounds or more, no more than 550 ml may be drawn in an 8-week period and no more frequently than twice a week.) (For other adults and children, the age, weight, and health, collection procedure, the amount of blood, and the frequency must be considered. The amount drawn may not exceed the lesser of 50ml or 3ml per kg in an eight-week period and may not occur more than twice in one week.).

Prospective collection of biological specimens for research purposes by noninvasive means.

Collection of data through noninvasive procedures routinely used in clinical practice, excluding x-rays or procedures using microwaves.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.

Collection of data from voice, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior or research employing survey, interview, oral history, program evaluation, human factors evaluation, or quality assurance methods.

1. **Financial Information:**

*Please check one category:*

This study is being financially supported

This study is not being financially supported – *skip to section 3*

1. **Name of sponsor:** [Category]
2. **Type of sponsor:** Choose an item.
3. **Sponsor contact information:**

Name:Click here to enter text.

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

1. **Has this study been certified as a Medicare-qualifying clinical trial?**

Yes

No

Not Applicable

1. **Does this study involve procedures, equipment, drugs or other items that will be paid for by the study sponsor?**

Yes *– provide a list of items, frequency of use/occurrence, and how hospital will bill study sponsor*

Click here to enter text.

No

1. **Study Team** 
   1. **Principal Investigator***Please provide information about the person legally responsible for the conduct of the research. The IRB and hospital must be assured that the investigator can personally oversee the conduct of the research and the protection of human research participants. [21 CFR 56.102(h)]*

1. **Contact information:**

**Name**: [Subject]

|  |  |  |  |
| --- | --- | --- | --- |
| **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. | | |

1. **Position:**

Member of medical staff

Hospital employee

Contracted hospital employee

Not affiliated with hospital – *describe relationship with hospital and provide name/telephone number of any hospital employee affiliated with this research study*

Click here to enter text.

* 1. **If a member of the medical staff:**

Active staff

Courtesy staff

Affiliate staff

Medical associate staff

Honorary staff

* + 1. **Has he/she received a recommendation for a reappointment period of less than two years?**

Yes – *please provide explanation:* Click here to enter text.

No

* 1. **Additional Team Members**

*Please list all team members who will be involved in the study. Add sections as needed.*

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

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

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

*or copy and paste this section*

1. **Study Information**
2. **In non-technical language, briefly summarize the study.**

*Please limit your summary to less than a page. 'See protocol' will not be accepted. Include the following:*

* *The objective of the study*
* *Brief description of the desired protocol study outcome*
* *Study design and all procedures*
* *Potential risks*
* *Measures to minimize these risks*
* *Potential benefits to the patient and/or the community*
* *Alternative treatments available*
* *Subject inclusion/exclusion criteria*

Click here to enter text.

1. **This research involves:**

*Mark all that apply*

Investigational device

Device name: Click here to enter text.

Investigational new drug

Investigational new drug (IND) number assigned by the FDA: Click here to enter text.

Approved and marketed drug or device

Drug or device name: Click here to enter text.

Behavioral research

Survey research

Retrospective medical record audit research

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

1. **Data safety monitor contact information:**

*Required only for Biologic Devices or Investigational New Drugs, otherwise, skip to section D.*

**Name:** 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. | | |

1. **Have there been recent events in our community (deaths or serious injuries) related to this research or device?**

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

No

1. **Does the principal investigator have an obligation to use another Institutional Review Board for any site in this study?**

Yes – *attach a written statement from the other Institutional Review Board acknowledging its review decision*

No

1. **Has this research study been disapproved or terminated by another Institutional Review Board prior to submission to Saint Alphonsus Institutional Review Board?**

Yes – *attach a written statement from the other Institutional Review Board acknowledging its review decision*

No

1. **Is equipment available at this research location to treat life-threatening adverse reactions?**

Yes

No

Not Applicable

1. **Explain how the confidentiality of any direct or indirect patient identifiers will be maintained:**

Click here to enter text.

1. **Describe how the study team will notify the hospital (including registration and/or billing) of patients entering studies and how these participants will be identified:**

Click here to enter text.

1. **List clinical areas within the hospital where the patient may receive study-related care:**

Click here to enter text.

1. **Recruitment, Consent & Participant Information**
2. **Check which of the following recruitment materials will be used:**

*Please attach a copy of each.*

Brochure

Newspaper

Television – *attach script or tape*

Web Site – *include a hard copy of the recruitment section*

Public Service Announcement – *attach script or tape*

Radio – *attach script or tape*

Posting

Other – *specify*: Click here to enter text.

1. **Will participants receive any form of payment for being in this study?**

Yes – *participants will be paid as follows:* Click here to enter text.

No

1. **Identify target enrollment dates and numbers:**

*These dates and numbers can be approximate. Indicate 'N/A' if not applicable.*

1. Anticipated national enrollment start date: Click here to enter a date.
2. Anticipated national enrollment completion date: Click here to enter a date.
3. Anticipated local enrollment start date: Click here to enter a date.
4. Anticipated local enrollment completion date: Click here to enter a date.
5. Local enrollment target number: Click here to enter text.
6. National enrollment target number: Click here to enter text.
7. Length of time (approximate) participants will be in follow-up: Click here to enter text.
8. **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 E*

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, list any new risks reported that might affect pregnant women or their fetuses:**

Click here to enter text.

1. **Will informed consent be required?**

Yes

No – *explain how waiver criteria are met per 45 CFR 46 116(d):* Click here to enter text.

1. **The following will be conducting the consent discussion:**

*Mark all that apply*

Principal Investigator

Sub-Investigator

Research Coordinator

Other Site Staff

1. **Will an interpreter will be available for the consent discussion?**

Yes – *provide name(s) of interpreters and/or method of interpretation:*

Click here to enter text.

No

Not Applicable



**Additional Documents**

*Incomplete or inaccurately completed applications will not receive IRB review.*

*Please submit the following required documents:*

Protocol

Informed consent form – *please use the St. Alphonsus Regional Medical Center format*

Financial interest disclosure(s)

Case report forms, surveys, or data collection sheets that will be used to record data

Medical/professional license(s) – *for each study member*

Curriculum vitae – *for each study member*

Certificate of human research ethics training – *for each study member*

*Please submit the following documents as applicable:*

Financial contract, grant or award

Sponsor site agreement and/or data use agreement

Documentation of any criminal or medical organization proceeding against the principal investigator

Documentation of recommendation for approval of the principal investigator for less than two years

For investigational new drug trials – Investigational New Drug information, including:

Investigator's drug brochure, applicable package insert(s), or background information

U.S. Federal Drug Administration form 1572

For investigational device trials – Investigational Device Exemption information, including:

Product labeling, package inserts, and/or bio-safety recommendations

Letters and supporting documentation from the device sponsor/manufacturer's application to the FDA for IDE status or

FDA letter granting IDE use or

Documentation for why the device is exempt from IDE requirements or

Letter from sponsor stating that this a non-significant risk device

For approved drug or device trials:

Investigator's drug or device brochure, package inserts, product labeling, or background information

Other Institutional Review Board approval or disapproval, with explanation

St. Alphonsus Institutional Review Board prior disapproval or termination letter, with explanation

Any advertisement and recruitment materials

**Submission Fees:**

*Submission fees for funded studies (subject to change):*

$3,000 – Initial Full Board Review

$2,000 – Initial Expedited Review

$2,500 – Administrative Start-Up Fees

$2,000 – Legal Star-Up Fees

$1,500 – Pharmacy Start-Up Fees

$1,500 – Annual Review

$1,000 – Amendments



**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**