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| Logo  Description automatically generated | Institutional Review Board  **EXEMPTION**  **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:***

*Research activities that involve no greater than minimal risk to human subjects may qualify for exemption from continued IRB review. The Director of Research and/or IRB Chairperson will make an initial determination of the exemption status. Once exempt status is determined, the research is not subject to further review unless the protocol is modified in such a way that it no longer meets the criteria for exemption. 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 Application:** Click here to enter a date.

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

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

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

1. **Study Team**
   1. **Principal Investigator**

*Please provide information about the person legally responsible for the conduct of the research. The Office of Medical Affairs must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. {21 CFR 56.102(h)}*

**Name:** [Subject]

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* 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.

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

*or copy and paste this section*

1. **Financial Information:**

*Please check on 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.

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1. **Criteria for Exemption**

*In order to qualify for exempt status, the project must meet the criteria of both sections A and B.*

1. **Is the study 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 exemption, stop filling out this form and apply for full IRB review*

1. **Does the study only involve procedures listed in one or more of the following categories**

*Check all that apply*

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as;

1. Research on regular instruction or training strategies, or
2. Research on the effectiveness of, or the comparison among, instructional or training procedures, content, or management methods.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures\*, interview procedures, or observation of public behavior, **unless**:

1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers (e.g., social security numbers); and
2. Any disclosure of the subjects' responses could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial status or reputation.

***\*Please note that survey research involving children (minors) is not exempt.\****

Research involving the collection or study of existing data, documents, records/medical charts, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers.

Research and demonstration projects which are conducted by or subject to the approval of SARMC administration, and which are designed to study, evaluate or otherwise examine:

1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under those programs;
3. Possible changes in or alternatives to those programs or procedures, or
4. Possible changes in methods or levels of payment for benefits or services under those programs.

Taste and food quality evaluation and consumer acceptance studies, if:

1. Wholesome foods without additives are consumed, or
2. All food ingredients, agricultural chemicals or environmental contaminants consumed are at or below safe levels, as determined by governmental regulating agencies.



**Additional Documents**

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

Protocol

Informed consent form (if applicable) – *please use the St. Alphonsus Regional Medical Center format*

A waiver of informed consent (if applicable)

Case report forms, surveys, questionnaires, 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*



**Signature Page**

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

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**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 SignatureDate**