Title: SARMC Institutional Review Board: Exempt Review

Policy Statement: Research activities that involve no greater than minimal risk may qualify for exemption from further IRB review. The IRB Chairperson or designee will make a determination of the exemption status. Once an exempt status is determined, the research is not subject to further reviews. A letter from the IRB stating the exemption status will be sent to the primary investigator.

Procedure:

I. The proposal may be considered exempt if it involves minimal risk to human subjects and involves research in one or more of the following categories:

A. 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.

B. 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.

C. 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.
   1. A data use agreement may be required, as determined by Saint Alphonsus policy.

D. 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
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.

E. 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.

II. The IRB has the authority to approve, ask for clarifications to render a determination, or disapprove the request for exemption. If the exemption is rejected, the proposal will be eligible for expedited or full board review. The reviewer will provide a reason for the disapproval of exempt status to the researcher.

---

**Related Policies:** Research Studies; HIPPAA-De-Identification, Re-identification, and the Creation of Limited Data Sets of Protected Health Information (PHI)

**Related Forms:** Exception of Authorization for the Use of Protected Health Information; Application for Waiver of Authorization

[http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources)

**References:**
