St. Mary's University
Institutional Review Board – Human Subjects
Request for IRB Proposal Review

A. Investigator(s)
Provide the names and department or institutional affiliations of all **research investigators** associated with this research project.

Principal Investigator:

Name _____ Dept/Instit _____

Secondary Investigators:

Name _____ Dept/Instit _____

Name _____ Dept/Instit _____

Additional Investigators:

Faculty Adviser, required if Principal Investigator is a student:

Name _____ Dept/Instit _____

Please provide a copy of the IRB Training Certificate for each Investigator and Adviser; attach at the IRB Blackboard Portal.

Subject Matter Expert, if required

Name _____ Dept/Instit _____
Please attach Vitae and Subject Matter Review

B. Title of Project

_____

C. Submission Review signatures
(*Please use PDF electronically validated signatures*)

_____ _____
Principal Investigator signature Date

_____ _____
Faculty Sponsor signature Date

The faculty sponsor certifies that the protocol has been checked for content and that research is conducted according to human participant guidelines (StMU IRB Policies and Procedures).

_____ _____
Department Chair or Designee signature Date

The Department Chair, by signing the application, indicates that he/she is aware of the research being done by individuals in the department (faculty, students or employees). Thus, Department Chairs should critically evaluate applications before signing them. The college or department may set up any internal screening procedures that are determined to be necessary to assure adequate internal review. (StMU IRB Policies and Procedures).

No individual involved in the conduct and/or supervision of a specific project shall participate in IRB-HS review, except to provide information. (StMU IRB Policies and Procedures). Therefore, Dept. Chairs who are a Principal Investigator or Faculty Adviser should seek review from their dean, a graduate program advisor or another chair.

All attachments should be submitted through the appropriate item of the IRB Blackboard Portal.

D. Proposed start date (mm/dd/yyyy): _____
(human subjects data collection cannot begin prior to IRB-HS written approval.)

Proposed end date (mm/dd/yyyy): _____

E. Funding Source, if any: ☐ Not Applicable

Please attach copy of grant proposal or contract related to this research at the IRB Portal.

F. Type of Submission:

☐ **New** ☐ **Revision of Initial Proposal**	☐ **Renewal** **Project Title: _____** **Approval Date: _____**
☐ **Modification of Previously Approved Project** **Project Title: _____** **Approval Date: _____**	

If this is a Modification of a Previously Approved Project, please attach prior IRB approval at the IRB Portal.

G. Brief Description of Study:

Briefly summarize the study purpose, the research method, the variables, data collection strategy (instruments; interview protocol; observational procedures), any experimental manipulation or non-experimental comparisons, and the participants. No more than 300 words.

H. Research Problem/Rationale

Summarize the research problem found in the review of the literature and how this study design will address that problem. If this is Research of Limited Scope, please indicate how this study design will lead to needs assessment, program evaluation, or quality improvement. If this is a class project, please indicate how this fulfills the student learning objectives. No more than 150 words.

I. Intended type of research:

Is this research intended to be:

- ☐ Generalizable research intended for publication or presentation
- ☐ Program evaluation research intended for a specific organization
- ☐ Quality improvement research intended for a specific organization
- ☐ A class project intended for student learning

Please check all that apply.

J. Location, laboratories, facilities to be used

_____

If research is conducted in facilities other than St. Mary's campus, IRB-HS approval may be required from that institution or organization.

The St. Mary's University IRB-HS requires school district approval for any research being conducted in that setting. This approval must come from the superintendent or a properly appointed designate. Approval from a classroom teacher or a principal (unless the district has given authority to the principal) is not sufficient. Some school districts have more complicated application and review processes than others.
The St. Mary's University IRB-HS requires approval from cooperating institutions, organizations, companies, and/or an IRB-HS. If the cooperating organization is an institution of higher education, approval must be from the appropriate human participants institutional review board.

If the other institution requires St. Mary's University IRB approval, a letter of support from a representative of that institution will suffice.
Please attach permission or support documentation at the IRB Portal.

K. Subjects

Describe the participants/ populations to be studied and the means of sampling/ selecting/ or soliciting participants.

Please attach any oral and/or printed solicitation that you will use to solicit participants at the IRB Portal.

If subjects are to receive compensation for participating, describe the conditions for payment, the amount of payment, and the investigator's evaluation of whether the compensation is of such magnitude that the subject might not weigh appropriately the risks of participation:

Does the study include a vulnerable population, as defined by 45 CFR Subpart B, C, or D:
☐ *Children* ☐ *Pregnant Women* ☐ *Prisoners* ☐ *No vulnerable population*

L. Purpose, Methods, Procedures

Describe in detail the purpose, research methods, variables, research questions, and procedures. Describe in detail data collection strategies, including how you operationalize each variable, measurement validity of the data collection methods. No greater than 500 words.
Attach relevant portions of an associated grant or contract proposal at the IRB Portal.

M. Risk Determination

Describe the potential risks of the research to the subject (physical, psychological, social, legal, ethical, moral). Assess the likelihood and seriousness of those risks. Describe procedures for minimizing risks.
If the methods of research create potential risks, describe other methods, if any, that were considered and why they were not chosen.

If you encounter unanticipated problems or adverse events, you will need to suspend the data collection activity and contact IRB representative. See IRB Policies and Procedures.

*Unanticipated problems, in general, include any incident, experience, or outcome that meets **all** of the following criteria:*

(1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

(2) related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Events are defined as: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding, extreme anxiety), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Medical Emergency: Manage according to University emergency procedures; if on-campus, notify campus police, if off-campus, call 911.

Non Emergency: Communicate the nature of the problem to the IRB-HS Chair or Area Representative within 72 hours of knowledge of the problem.

N. Costs to Subjects

Justify any costs (monetary or otherwise) to the participant. For example, time, laboratory fees, travel, increase in hospitalization, etc. Include this information on the consent form.

O. Benefits of Research

Describe the anticipated benefits of the research to the individual subjects, to the particular group or class from which the subject sample is drawn, and/or to society.

P. Consent by Subjects

Describe the method of obtaining the subjects' consent. Describe any special requirements for ensuring participants are informed (language, educational level, interpreter, etc.) .Indicate who will be responsible for obtaining consent. Indicate where the forms will be stored and who will have access to them. Include the IRB contact information on the Informed Consent document:

If you have any questions about your rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary's University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu. ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT ST. MARY'S UNIVERSITY ARE GOVERNED BY THE REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT.

IRB regulations **45 CFR 46.117(c)** *require original signatures on informed consent documents, but allow the IRB to waive the signature requirement if:*

- *The study poses no more than minimal risk.*
- *The signed informed consent is the only link to subject identity.*
- *The principal risk is breach of confidentiality.*
- *No procedure for which consent is required outside the research context.*

☐ **Yes** ☐ **No** *The researcher is requesting a waiver of documentation. Explain below:*

IRB regulations **45 CFR 46.117(d)** *allow the researcher to alter or omit some elements of the informed consent requirements if:*

- *The study poses no more than minimal risk.*
- *It is not practicable to conduct the research without altering some necessary elements of consent.*
- *Altering consent will not adversely affect subjects' rights.*
- *Full information will be provided orally or in writing to subjects later.*

☐ **Yes** ☐ **No** *The researcher is requesting an alteration of consent requirements. Explain below:*

Attach examples of consent forms to be used at the IRB Portal. You should carefully ***edit*** *Consent Forms presented for Proposal Review. Once approved, the consent forms cannot be altered or modified without resubmitting the proposal. In approved research proposals, the IRB will provide an approval stamp that must appear on all Informed Consent forms.*

Informed Consent Checklist **[45 CFR 46.116]**

PI to complete	**Description of Criteria**	
☐ **Yes** ☐ **No**	*Statement that the study involves research*	
☐ **Yes** ☐ **No**	*Explanation of the purpose, duration & procedures of the research*	
☐ **Yes** ☐ **No**	*Description of risks and benefits*	
☐ **Yes** ☐ **No**	*Extent to which confidentiality is maintained*	
☐ **Yes** ☐ **No**	*If more than minimal risk, compensation, mental health or medical treatment*	
☐ **Yes** ☐ **No**	*Participation is voluntary*	
☐ **Yes** ☐ **No**	*Whom to contact (Principal Investigator and contact number)*	
☐ **Yes** ☐ **No**	*IRB Contact Information*	

Q. Confidentiality and Records Management

Describe the types of records this project will require (audio, video, paper, etc.). Describe the methods for ensuring confidentiality of participant information.

Describe the methods for managing data records once the project is completed.

For audit purposes, the University requires that all copies of consents must be kept for five (5) years after the project is completed or the final report is accepted. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records (StMU IRB Policies and Procedures).

FOR IRB USE ONLY:

INITIAL REVIEW

Is the PI and Faculty Adviser's training certificates on file?	☐ **Yes** ☐ **No** ☒ **UD**
1) Is it systematic research intended for generalizable results? **NO:** Research of limited scope, Administrative evaluation, Classroom learning activity	☐ **Yes** ☐ **No** ☐ **UD**
2) Is there identifiable, private information about a living person?	☒ **Yes** ☐ **No** ☐ **UD**
IF YES: Is there adequate privacy protection?	☐ **Yes** ☐ **No** ☐ **NA**
Is there adequate informed consent?	☐ **Yes** ☐ **No** ☐ **NA**
3) Is it more than minimal risk?	☐ **Yes** ☐ **No** ☐ **UD**

CRITERIA GUIDE:
If UD on any: Unable to Determine, return to applicant for revision
N, N, NA, NA, N: Does not meet criteria of 45 CFR 46; no review needed
Y, N, NA, NA, N: Does not meet criteria of 45 CFR 46; no review needed
Y, Y, Y/N, Y/N, N: Needs IRB review; evaluate if Exempt or Expedited
Y, Y, Y/N, Y/N, Y: Needs full review

4) Recommended Review

☐ Unable to Determine; return for revision
Please note reasons below:
open field for notes:

☐ Research of Limited Scope (N, N, N)
- ☐ Not greater than minimal risk; AND one of the following:
  - ☐ Program Evaluation
  - ☐ Quality assurance/ improvement
  - ☐ Customer Satisfaction
  - ☐ Student learning activity (class project)

☐ Exempt from annual review
- ☐ No more than minimal risk AND one of the following:
  - ☐ Normal educational practices
  - ☐ Survey, interview procedures
  - ☐ Observations of public behavior
  - ☐ Existing data, documents, records or specimens
  - ☐ Taste and food quality

☐ Expedited Research
- ☐ Survey, interview, program evaluation, quality improvement AND more than minimal risk
- ☐ Collection of data through non-invasive means
- ☐ Existing data, greater than minimal risk, collected for non-research purposes
- ☐ Voice, video, digital or image recordings for research
- ☐ Drug or medical studies for which application not required
- ☐ Blood samples by finger stick or equivalent
- ☐ Collection of biological specimen by noninvasive means
- ☐ Continuing review of previously approved study
- ☐ Approved by another IRB: _____

☐ Full Review
- ☐ Vulnerable population
- ☐ Greater than minimal risk
- ☐ Other: *open response field*

IRB Reviewer:

Signature

If Initial Review Determination is Exempt, Expedited, or Full Review, the assigned Area Representative will complete the remaining criteria.

INFORMED CONSENT CHECKLIST [45 CFR 46.116]

	Description of Criteria	**for IRB use only:**
	Statement that the study involves research	☐ **Yes** ☐ **No**
	Explanation of the purpose, duration & procedures of the research	☐ **Yes** ☐ **No**
	Description of risks and benefits	☐ **Yes** ☐ **No**
	Extent to which confidentiality is maintained	☐ **Yes** ☐ **No**
	If more than minimal risk, compensation, mental health or medical treatment	☐ **Yes** ☐ **No** ☐ **NA**
	Participation is voluntary	☐ **Yes** ☐ **No**
	Whom to contact (Principal Investigator and contact number)	☐ **Yes** ☐ **No**
	IRB Contact Information	☐ **Yes** ☐ **No**

Include the IRB contact information on the Informed Consent document:
If you have any questions about your rights as a research subject or concerns about this research study please contact the Chair, Institutional Review Board, St. Mary's University at 210-436-3736 or email at IRBCommitteeChair@stmarytx.edu.

If unable to determine any elements of Informed Consent checklist, please note below:

IRB DETERMINATIONS
The assigned IRB Representative will evaluate the proposal according to the criteria of 45 CFR 46. Yes= meets the criteria; No= does not meet the criteria; UD (Unable to Determine)= insufficient, unclear or contradictory information. Please explain for each score of No or UD.

☐ **Yes** ☐ **No** ☐ **UD** **Risks to participants are minimized by using procedures consistent with sound research design.**
Please explain for each score of No or UD.

☐ **Yes** ☐ **No** ☐ **UD** **Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably be expected to result.**
Please explain for each score of No or UD:

☐ **Yes** ☐ **No** ☐ **UD** **Selection of participants is equitable considering the purposes of the research, the research context, and any special-groups participation.**
Please explain for each score of No or UD:

☐ **Yes** ☐ **No** ☐ **UD** **Informed consent will be obtained as required in 45 CFR 46.116.**
See Informed Consent Checklist above

IRB regulations **45 CFR 46.117(d)** *allow the researcher to alter or omit some elements of the informed consent requirements if:*

- ☐ *The study poses no more than minimal risk.*
- ☐ *It is not practicable to conduct the research without altering some necessary elements of consent.*
- ☐ *Altering consent will not adversely affect subjects' rights.*
- ☐ *Full information will be provided orally or in writing to subjects later.*

Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD Informed consent is appropriately documented as required in 45 CFR 46.117.**

IRB regulations **45 CFR 46.117(c)** *require original signatures on informed consent documents, but allow the IRB to waive the signature requirement if:*

- ☐ *The study poses no more than minimal risk.*
- ☐ *The signed informed consent is the only link to subject identity.*
- ☐ *The principal risk is breach of confidentiality.*
- ☐ *No procedure for which consent is required outside the research context.*

Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD An adequate research plan is provided for monitoring data collection.**
Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD A clear process to protect the privacy of participants and the confidentiality of data is provided.**
Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD Adequate safeguards are in place to protect the rights and welfare of vulnerable populations included in this research.**
☐ **No vulnerable population**
Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD The researcher is competent in the planned area of research.**
Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD The researcher does not have dual roles that might produce a conflict of interest.**
Please explain for each score of No or UD:

☐**Yes** ☐**No** ☐ **UD The intent of the proposed research is to yield useful data that will benefit the research participants and/or similar groups in the future.**
Please explain for each score of No or UD:

IRB DETERMINATIONS

ASSESSMENT OF RISKS AND BENEFITS

☐**Yes** ☐**No** ☐ **UD This research is determined to place participants at minimal risk (as defined in 45 CFR 46.102), and risks are not unreasonable in relation to the anticipated benefits. Minimal risks: not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine… psychological examination (45 CFR 46.102)**

☐**Yes** ☐**No** ☐**UD This research is determined to place participants at greater than minimal risk and must provide precautions, safeguards, or alternative approaches to protocols to reduce the probability of harm or to limit its severity or duration.**

IRB REVIEW STATUS

☐**Yes The proposed project is EXEMPT from IRB review because it meets the requirements in one of the six exempt categories as determined by Federal regulations (45 CFR 46.101).**

☐**Yes The proposed research or change in approved research qualifies for EXPEDITED REVIEW as defined in university policies and Federal regulations.**

☐**Yes Another certified IRB-HS has approved this protocol.**

IRB name _____

Date of approval _____ (see approval form attached in § I above.)

__ Yes The proposed research or change in approved research must have A FULL BOARD REVIEW and must receive approval by a majority of the voting members of the IRB board.

Date of FULL BOARD REVIEW:_____

Vote: _____FOR _____AGAINST _____ABSTAIN

☐**UNABLE TO DETERMINE**

Please explain for each score of No or UD:

IRB Reviewer: _____

Signature: **_____**

IRB Chair: _____

Signature: **_____**