**Institutional Review Board**

**Southwestern Assemblies of God University**

**Application for Approval of**

**Research Involving Human Subjects:**

**Faculty-Staff as Principal Investigator**



# Section 1: Preliminary Information

## Principal Investigator’s Details

Date of Submission: double click, add date Submitted by: double click, add name of Principal Investigator

Title of Project: double click, add title

Directions: Submit the completed application either electronically or in hardcopy to the SAGU Institutional Review Board (IRB).[[1]](#footnote-1) Ensure that all research-related documents are attached. The IRB will review only *complete* applications; failure to complete fully this application or provide essential supplemental documents will delay the IRB review.

Double click each shaded field or tick the appropriate boxes (where relevant) to enter the requested information.

PI’s telephone: phone number email: email

Department/school or campus[[2]](#footnote-2): department school or campus

Institution (if not SAGU): institution

Location (if other than SAGU-Waxahachie or other SAGU campus): city, ST

Multi-year project by design (tick only one option): [ ]  Yes [ ]  No

Project period (anticipated): number [ ]  days *or* [ ]  weeks *or* [ ]  months (tick only one box)

## Principal Investigator’s Assurance

I agree to use procedures that safeguard the human subjects contributing to this research. If significant changes in the project’s procedures involving the participants are warranted, I shall seek prior IRB approval for such changes and I agree to follow its instructions. I further agree to report to the IRB unanticipated complications or untoward incidents involving human subjects as soon as such incidents occur.

I also agree to hold in confidence all information obtained from human subjects during and after the data-collection phase of the study, in agreement with the informed consent document(s) used during this study.
I agree to store securely for a minimum of three years all physical documents generated by this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ date of signature

Principal Investigator’s Signature Date

# Section 2: Description of Human Subjects and the Research Design

This section requires the description of the human subjects who will contribute data to the proposed study. It also requires a summary of the planned research design.

## Population Demographics:

|  |
| --- |
| The human subjects contributing to this study are best described as: (tick all that apply) |
| General population (no protected group)  | [ ]  | Immigrants/aliens  | [ ]  |
| Children (younger than 18 years)  | [ ]  | Students  | [ ]  |
| Seniors (older than 65 years)  | [ ]  | Racial minorities  | [ ]  |
| Pregnant  | [ ]  | Hospital inpatients  | [ ]  |
| Prisoners  | [ ]  | Hospital outpatients  | [ ]  |
| Intellectually disabled  | [ ]  | Non-English speaking  | [ ]  |
| Adults with life-controlling vulnerabilities | [ ]  | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  |
| At-risk children[[3]](#footnote-3)  | [ ]  |  |  |

(For each group selected above, include in Section 3 a detailed justification for that group’s participation.)

## Additional Information about the Human Subjects:

* Gender: [ ]  male [ ]  female [ ]  both [ ]  gender is not a research variable
* Age range: lowest age to highest age [ ]  age range does not apply
* Estimated number of human subjects: number
* Duration of each participant’s direct involvement: number of hours, days, weeks, months

## The Proposed Study’s Research Design:

* Type of research: [ ]  qualitative [ ]  quantitative [ ]  experimental (or quasi-experimental) [ ]  mixed-methods
* Incentives-compensation:
* Will the human subjects receive an incentive or compensation to participate? [ ]  Yes [ ]  No

If “Yes,” state the type and amount of incentive-compensation to be offered: enter details

* Will incentives be prorated for those who withdraw from participation? [ ]  Yes [ ]  No

# Section 3: Project Summary

Using the outline below, summarize the project.

**Title of the Study**

Restate the title (from Section 1).

**Purpose**

State the purpose of the research (in one sentence), then summarize in one paragraph each of the following: (1) the research objectives, and (2) the expected outcomes. (Bullet points may be used.)

**Proposed Start Date and End Date for the Data-Collection Phase**

State the proposed beginning and ending time frame for the study. If an extensive period of data collection is essential, explain why.

**Background**

In a maximum of 200 words, summarize the precedent literature most relevant to the study’s purpose.

**Recruitment of Human Subjects**

Specify the criteria that will be applied to subjects’ inclusion/exclusion in the study.

Specify how the subjects will be contacted and recruited.

Describe the use (if any) of incentives for subjects’ participation.

**Protection of Vulnerable Human Subjects** (see Population Demographics in Section 2)

Explain how vulnerable human subjects recruited to participate in the study will be protected during and after data collection.

**Deception and Debriefing**

If deception, misdirection, or withholding of information is planned during data collection, describe the nature of such actions. State the rationale for this methodology, and why it does not violate basic principles of Christian ethics.

Detail the comprehensive plan to (1) debrief the study’s human subjects, (2) share the research results with them, and (3) respond to their questions, concerns, or objections.

**Research Materials and Procedures**

Briefly describe the procedures that will be used in the project: specific methods, measurement tools, and data-collection activities.

For any measurement tool not available in the public domain, specify how permission to use it was obtained. (Document such permission in an appendix to this application.)

**Procedures for Maintaining Confidentiality, Storing Data, and Eventually Destroying Data**

Describe how human subjects will be assured of confidentiality, with reference to information they provide.

Describe the procedures to be used in storing, disseminating, and disposing of all data collected during the study. If subject identifiers are collected, explain why those identifiers are essential and how they will be protected/secured.

**Potential Risks**

Identify all potential risks to the human subjects and assess the magnitude of each risk (physical, psychological, social-relational, financial, and privacy).

**Potential Benefits**

Project how the outcomes of this study will contribute to the body of knowledge in this research field, and to human welfare in general.

# Section 4: Required Appendices

Attach all relevant supportive documents, including the following (as may be relevant):

* CITI Certificate of appropriate course completion or NIH Certificate of course completion for the Protection of Human Research Participants course
* All data-collection instruments to be used in the study
* Assurance(s) of institutional access to required data sources: human subjects, data stored in database(s), essential documents, records, and test scores
* All recruitment flyers, letters of invitation to participate in the study, and similar documents.
* Informed consent template(s)[[4]](#footnote-4)
* Confidentiality agreement(s) if external researcher or technician will be involved in data collection or analysis
1. Submit electronically: irb@sagu.edu; submit by mail: Institutional Review Board, c/o Harrison Graduate School, 1200 Sycamore, Waxahachie, TX 75165. [↑](#footnote-ref-1)
2. For example, SAGU-AIC. [↑](#footnote-ref-2)
3. For example, human fetuses or wards of the state (younger than 18 years) in foster care. [↑](#footnote-ref-3)
4. Available at the IRB web page: https://www.sagu.edu/academics-home/institutional-review-board [↑](#footnote-ref-4)