**Institutional Review Board**

**Southwestern Assemblies of God University**

**Request for Renewal of IRB Approval of**

**Research Involving Human Subjects:**

**Faculty-Staff Researcher as Principal Investigator**



# Directions

Double click on the shaded boxes (fields) to add the requested information. Return the completed renewal application as an attachment to: irb@sagu.edu, or mail it to:

IRB Co-chair

Harrison Graduate School

1200 Sycamore St.

Waxahachie, TX 75165

Note 1: The training certificate for the Protecting Human Research Participants course offered by the National Institute of Health must be current.

Note 2: Required attachments that are not available electronically must be mailed or delivered to the designated IRB Co-chair.

Note 3: This Renewal Application should be submitted prior to the one-year expiration of the original Application for IRB Approval.

# Section 1: Preliminary Information

Date of Submission: add date

Submitted by: state the name of faculty or staff applicant

Principal Investigator’s: phone: phone number email: email

Department/school or campus[[1]](#footnote-1): department school or campus

Title of Project: state project title

Date of original application: add date Protocol number: add the protocol number

## Principal Investigator’s Endorsement

I agree to continue to use procedures that safeguard the human subjects contributing to this research. As affirmed in the original application, 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.

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

Principal Investigator’s Signature Date

# Section 2: Explanation for Needed Extension of IRB Approval

**What is the current status of the study?** (Click the one box that best describes the study’s status.)

[ ] Subject recruitment is still in progress; data collection has not begun

[ ] Subject recruitment is still in progress; data collection is in process

[ ] Subject involvement is complete; data collection is still in process

[ ] Subject involvement is complete; data analysis with identifiable information is still in process
[ ] The study has not started. add explanation

1. Summarize briefly the study’s research procedures. What do subjects do, or what is done to them? What information is gathered?(Use additional pages if necessary.)

add summary

1. Summarize briefly the study’s progress to date.(Use additional pages if necessary.)

add summary

1. How many subjects have completed participation in the study? number

How many are currently participating? number

How many have withdrawn? number

Provide the reason for withdrawal. add explanation

How many have yet to be recruited? number

1. Have procedures described in the original IRB application changed? [ ]  Yes [ ]  No (tick one)

If Yes, what has changed?[[2]](#footnote-2) add summary or explanation

1. Identify all project assistants who have left the study since the last review. List any new assistants or other investigators being added, AND their roles and qualifications.

add explanation, as may be relevant

1. Since the last IRB review, has the principal investigator generated any interim findings? If so, please attach a summary of the interim findings.

add summary, as may be relevant

1. Describe any unanticipated risks that have arisen during the course of the research. What precautions has the principal investigator taken to minimize the risk to subjects?

add explanation, as may be relevant

1. Describe any harm (physical, psychological, legal, or social) suffered by subjects in this study thus far, and any complaints received. What happened? Has the problem been resolved? If not explain why. What measures has the principal investigator taken to guard against similar occurrences?

add explanation, as may be relevant

1. Since the last IRB review of the research protocol, has the principal investigator changed his or her assessment of the risk-potential benefit profile of the study, based on results to date or updates to the methodological literature? [ ]  Yes [ ]  No

If Yes, please explain. add summary or explanation

1. Please attach to this application the current Informed Consent template(s) (or script(s) for informing subjects about the study).
1. For example, SAGU-AIC. [↑](#footnote-ref-1)
2. Append copies of any new instructions, tests or questionnaires. List new sites or data sets being added. [↑](#footnote-ref-2)