

Institutional Review Board (IRB) Arizona College of Nursing 2510 W Dunlap Ave, Suite 290 Phoenix, AZ 85021

Request for Renewal Form

PI Name:

Reviewer Name:

Protocol Number:

Date:

Project Title:

Initial Review Level:
□ Full □ Expedited

Form Submission

This form should be completed and submitted with any supporting documentation to <u>irb@arizonacollege.edu</u> to request a renewal of an existing IRB approved protocol that is set to expire.

IRB Approval Status

□ IRB Approval is current

□ IRB approval is expired or will expire prior review of Request for Renewal can reasonably be processed (within 15 business days of submission)

Note: Without a current approval all research activities must suspended until the renewal request is approved

Research Personnel

Are there changes to the research personnel included in the initial protocol submission? \Box Yes \Box No

If yes, submit a revised Co-Investigators and Research Personnel form

Amendments

Is there an amendment describing changes to the protocol or supporting materials included with this renewal request?

 $\Box Yes \ \Box No$

Provide a summary of the specific aims/goals of the research study and method

Provide a summary of research progress to date (Include completion status of participant recruitment and enrollment, approved research activities, and study procedures)

The research study is in the data analysis phase only \Box Yes \Box No

Informed Consent

Are there plans to recruit and enroll additional participants into the research study? \Box Yes \Box No

If yes, all recruitment and consent documents must be submitted with this form

| Provide a summary of the total number and demographic breakdown of participants in the study to date | | | | |
|--|--|--|--|--|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Have participants declined to participate in the research since initial or last approval? | | | | |
| \Box Yes \Box No | | | | |
| | | | | |
| Provide a summary of the number of participants declining and cited reasons since initial or last approval | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Have any participants withdrawn from the research study after initial enrollment? \Box Yes \Box No | | | | |
| | | | | |
| Provide a summary of the number of participants that have withdrawn from the research study | | | | |
| and the reasons, if applicable. | | | | |
| | | | | |
| | | | | |
| Created 10/17/22 | | | | |

Have participants been withdrawn from the research study by the principal investigator since initial or last approval?

 \Box Yes \Box No

Provide a summary of the number of participants the principal investigator has withdrawn and the reasons, if applicable.

Participant Complaints

Have participants reported any complaints related to the research since initial or last approval? \Box Yes \Box No

If yes, provide a summary of the complaints and resolution.

Preliminary Findings or Results

Are there preliminary findings or results? \Box Yes \Box No

Do the findings suggest a change to the risk/benefit ratio for participants or that other alternatives are now available? \Box Yes \Box No \Box N/A

Provide a summary of preliminary findings or results and how participants may be impacted, if applicable.

Describe how significant findings will be communicated to participants, if applicable.

Describe revised plans to minimize risk to participants, if applicable.

Unanticipated Problems or Adverse Events

Have there been any unanticipated problems involving increased risk to participants or adverse events since initial or last approval?

 \Box Yes \Box No

| Date of Event | Event or Problem Description | Event or Problem Related to Research | Date Reported to IRB | Outcome |
|---------------|---------------------------------|--|----------------------|---------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Plan for Data Disposition

Select all that apply regarding the status of collected data for this research study.

- □ Data has and will continue to be collected anonymously
- □ Identifiers have or will be removed and key code destroyed
- □ Data containing identifiers will be secured as described in the approved protocol and no additional research using this data is planned at this time
- De-identified data will be maintained permanently by the PI
- \Box Data will be destroyed by the PI
- Other, describe: Click or tap here to enter text.

I certify that the information provided in this Request for Renewal form is complete and accurate to the best of my ability. By signing this form, I agree to conduct research in accordance with Arizona College of Nursing policies and procedures related to human subjects research and federal, state, and local laws. I affirm the following:

- i. Research procedures has and/or will continue to be performed by trained personnel listed in the approved protocol
- ii. Informed consent was obtained for all participants and will continue unless IRB approved waiver
- iii. Any adverse events or participant complaints have and will continue to be reported within 72 hours.

Principal Investigator's Signature:

Date_____