Institutional Review Board Standard Operating Procedures Manual

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Institutional Review Board Standard Operating Procedures Subject to the Revised Common Rule

Purpose/ Description of Process or Policy:
This Standard Operating Procedure (SOP) describes the requirements and procedures that Arizona College of Nursing Institutional Review Board (IRB) shall adhere to for research subject to the guidelines set forth in the revised Common Rule conducted on or after January 1, 2023.

Effective Date:
Effective: January 1, 2023
Expires: N/A

Document Definitions [§46.102, §46.303, §46.402]**:**

Assent: A child's affirmative agreement to voluntarily participate in research.

Children: persons who have not reached the legal age to provide consent to the treatments or procedures involved in research under the applicable jurisdiction laws in which the research is conducted.

Federal Department or Agency: A federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Institution: Any public or private entity, or department or agency (including federal, state, and other agencies).

Institutional Review Board (IRB): An institutional review board established in accord with and for the purposes expressed in this policy.

Intervention: Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally Authorized Representative: an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by

institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Prisoner: an individual involuntarily confined or detained in a penal institution under criminal or civil statute.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(i) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

1.1 Mandate

The IRB at Arizona College of Nursing established on January 1, 2023, complies with all regulations of the United States Department of Health and Human Services (45 CFR 46). As a federally registered IRB, the board adheres to all federal and state regulations governing human subjects research and the ethical principles of conducting research as outlined in The Belmont Report. In accordance with established regulations the IRB reviews all research activities that involve human subjects to ensure:

1. Benefits and/ or importance of knowledge gained outweighs risks posed to participants in research
2. Risk posed to participants are minimized
3. Rights and welfare of participants are sufficiently protected
4. Participant selection is fair and equitable
5. Research protocols contain sufficient plans to protect privacy and safety of participants and confidentiality of data
6. Participants are fully aware of rights, risks, benefits, and research procedures as part of the informed consent process

1.2 Composition and Membership of the IRB

The IRB at Arizona College of Nursing maintains a diverse membership roster consisting of a Chair, Co-Chair, 6-10 additional voting members, an IRB Administrator, and 2 alternates. All members are qualified through professional experience and research expertise to review research protocols in accordance with safeguarding the rights and welfare of human subjects. Alternate members are appointed to serve in an advisory non-voting role, unless elevated to a voting member by the Chair or Co-Chair to establish quorum.

In accordance with the regulations set forth in the Revised Common Rule, the IRB maintains at least one member with research expertise in a scientific area, and one with a primary research focus in nonscientific areas. In addition to these distinctions, at least one member is not otherwise affiliated with the institution. The IRB may elect to invite a non-voting consultant to assist the IRB in reviewing a research protocol that requires expertise beyond the available members serving on the board.

All IRB members are appointed by the provost. To ensure sustainability of IRB operations, the initial terms of the inaugural board will be staggered so that no more than half of the members are up for renewal in a given year. All subsequent appointments made by the provost will be for a 2-year renewable term. As such, the initial appointment terms will be as follows:

1. IRB Chair: 2-year appointment
2. IRB Co-Chair: 1-year appointment
3. IRB voting members (non-science): one member with a 1-year appointment, one member with a 2-year appointment
4. IRB voting members: two members with a 1-year appointment, two members with a 2-year appointment
5. IRB Administrator: 2-year appointment
6. IRB Non affiliate member: 2-year appointment
7. IRB Alternate Members: one member with a 1-year appointment, one member with a 2-year appointment

The provost serves as the Signatory Official for the Institution and is ultimately responsible for all IRB activities. The provost may remove a board member at any time for failure to fulfill responsibilities of membership.

Table 1.2a
Responsibilities of IRB Members

Member	Responsibilities
Chair/Co-Chair	• Holds an earned doctorate degree • Ensures sufficient level of review of research protocols to maintain human research protections • Effectively conducts IRB full board and ad hoc meetings to make determinations of approval or disapproval on new and ongoing research • Responds to concerns presented by IRB members • Completes required training and continuing education to remain up to date on federal regulations governing human research protections • Partners with IRB Administrator to ensure accuracy and maintenance of all IRB records
Voting Member	• Holds an earned graduate degree • Completes required training and continuing education to remain up to date on federal regulations governing human research protections • Actively participates in research protocol review leveraging the ethical principles of the Belmont Report and federal regulations governing human research protections

	• Consistently attends full board and ad hoc meetings
Alternate Member	• Holds an earned graduate degree • Completes required training and continuing education to remain up to date on federal regulations governing human research protections • Actively participates in research protocol review when elevated to a voting member leveraging the ethical principles of the Belmont Report and federal regulations governing human research protections • Consistently attends full board meetings
IRB Administrator	• Completes required training and continuing education to remain up to date on federal regulations governing human research protections • Maintains records of all research protocols, correspondence, meeting minutes, and other pertinent information • Prepares and submits annual report of IRB activities to the IRB Chair and Provost • Serves as a liaison between federal agencies and investigators regarding issues maintaining human subjects protections

All voting and alternate members must have a research background, hold a graduate degree, and show proof of completing CITI Human Subjects research and Office of Human Research Protections (OHRP) Human Research Protection Foundational Training courses to be eligible to serve on the board. The IRB Chair and Co-Chair must meet the requirements of voting members, complete the IRB Chair CITI training course, and have an earned doctorate degree. The IRB Administrator shall meet all the requirements of voting members except holding a graduate degree and must complete the IRB Administration CITI training course.

Certificates for completed trainings will be audited monthly by the IRB Administrator to ensure compliance with IRB training requirement policies. The administrator will notify board members in writing 30 days prior to scheduled expiration date of training. In instances where the board member fails to complete required training by the deadline, the Administrator will notify the Chair of the IRB who will send notification to the provost within 1 business day. The provost may take the following actions upon notification:

1. Suspend the board member for a 2-week period until trainings are complete
2. Remove the board member permanently.

All Arizona College colleagues that meet eligibility requirements may serve on the IRB. Interested candidates must gain approval from the Executive Director for Academic Operations (EDAO) at their campus and send a letter of interest to the IRB Chair at irb@arizonacollege.edu. The IRB Chair will submit letters of interest to the provost for review and appointment. The provost will send an appointment letter to approved candidates to fulfill vacancies on the board.

1.3 IRB Meeting Schedule and Facilitation

Stated Meetings

The IRB conducts closed unrecorded 2-hour virtual stated meetings during the second week of each 8-week term for a total of 6 per calendar year. Meetings shall be moved to week 3 in instances of holiday or other unpreventable conflicts. The schedule for the calendar year is located on the IRB website: irb@arizonacollege.edu.

Each meeting is facilitated by the IRB Chair or Co-Chair pro tem according to Robert's Rules of Order following the structured format outlined in the table below.

Table 1.3a
Stated Meeting Agenda and Format

Agenda
A. Welcome and Roll Call of Voting Members B. Previous Minutes Approval C. Follow Up from Previous Meeting D. Other Old Business E. Report of Exempt and Expedited Reviews F. Protocol Revisions/Re-Approvals/Violations- Including report of unintended consequences G. New Protocol Applications H. Other New Business and Announcements I. Adjourn

Responsible Party	Actions
Chair or Co-Chair	1. Welcome and call meeting to order 2. Roll call of all voting members o Ensure quorum requirements are met for the duration of the meeting: i. Greater than 50% of voting members are present ii. One nonscientist member is present 3. Address outstanding old business 4. Provide report of exempt and expedited protocol reviews 5. Open floor discussion of protocol revisions
IRB voting member Primary and Secondary protocol Reviewers	6. Provide summary of protocol revisions and facilitate open discussion of the impact on minimizing risk to human subjects o If board determines that revisions are sufficient the Chair will call for a motion to vote on the protocol o If board determines that revisions are insufficient the Chair will summarize recommendations for the minutes and further communication with the Principal Investigator (PI) 7. Summarize board consensus for full **approval**, conditions for **conditional approval**, and reasons for **deferral** or **disapproval** determinations 8. Request a motion from the board members to vote on the determination and a second o Call for final vote on revisions to the protocol
Chair or Co-Chair	9. Provide summary of Protocol Renewals and allow for open discussion on granting a continuance of requests that require full board review o Call for motion to vote on granting a continuance of the research study for a defined period of time 10. Provide a summary of approved protocol violations including unintended consequences and outcomes 11. Open floor discussion on each new protocol for review with brief statement of the name of the research protocol and the PI
IRB Voting Member Primary and Secondary Protocol Reviewers	12. Primary reviewer provides a brief summary of the proposed study and highlights problems noted with method, risk, and supporting documents based on review using the Protocol Review Worksheet (see Appendix A).

	13. Secondary reviewer provides additional findings related to the review of the protocol
Voting Members	14. Open discussion regarding the findings presented for the protocol
Chair or Co-Chair	15. Summarize board consensus for full **approval**, conditions for **conditional approval**, reasons for **deferral** or **disapproval** determinations 16. Request a motion from the board members to vote on the determination and a second 17. Call for final vote on the protocol o Elevate an alternate to vote in instances where quorum is lost, or defer voting until quorum is re-established 18. Discuss new business and announcements 19. Adjourn meeting
IRB Administrator	20. Records minutes in accordance with OHRP guidelines: o Substance of all discussions o Voting members, alternates, guests in attendance o Member name and vote on each matter discussed inclusive of abstentions 21. Archive all meeting minutes in the IRB meeting minutes folder in the AZC Institutional Review Board SharePoint site 22. Document all actions taken by the board to be compiled and submitted in a quarterly report to the Provost

Conflicts of Interest

IRB members with financial and nonfinancial (participation or supervision of research under review) conflicts of interest (COI) shall not review protocols for which a conflict exists. Members with a COI will send written notification disclosing the COI to the Chair and Co-Chair within 2 business days of receiving the assigned review so that protocols may be rerouted to other voting members.

IRB members with financial and nonfinancial COI shall recuse themselves from voting. Members will send written notification to the Chair and Co-Chair of known COI within 2 business days of receiving the agenda for convened meetings. The IRB Chair will elevate an alternate to vote on protocol if quorum is lost due to member recusal. The IRB Administrator will document the recusal from deliberations and voting in the meeting minutes and the recused member will not be counted as part of the quorum for review of that protocol.

Special Meetings

The IRB Chair reserves the right to call a special meeting if needed to conduct any of the business that would routinely be done in a stated meeting. Members will receive a special email invitation for the closed virtual meeting and all minutes will be captured by the IRB Administrator. The same quorum requirements of stated meetings shall be maintained.

1.4 Human Subjects Research Requiring IRB Review

All Arizona College of Nursing affiliated research involving human subjects and/or their identifiable private information must be reviewed by the IRB. This rule is upheld regardless of the funding source and location of research activities. Research meeting review requirements include, but not limited to:

1. Research conducted by Arizona College of Nursing colleagues that engages faculty, staff, or students within the institution
2. Research that involves the usage of institutional facilities or equipment
3. IRB approved ongoing research that requires continuing review
4. Research conducted in courses that may result in generalizable knowledge
5. Research in the pilot phase
6. Research that leverages secondary data obtained from human subjects in earlier projects, when the data remains identifiable or uses identifiers or codes linked to individual participants
7. Research that involves using waste (material collected initially for clinical or diagnostic purposes, but not needed)
8. Ongoing research conducted by Arizona College of Nursing colleagues that was approved by another institution and seeks to continue recruitment and enrollment of new participants within the institution
9. Research involving protected health information as defined by Health Insurance Portability and Accountability Act regulations

1.5 Review of Research

Principal investigators are required to submit the following documents to irb@arizonacollege.edu to initiate the review process of the research protocol:

1. Completed IRB Application (see Appendix B)
2. Co-Investigator and Research Personnel form, if applicable (see Appendix C)
3. Data collection tools or measures
4. Recruitment materials (i.e., flyers, brochures, scripts, email templates)
5. Consent, assent forms, if applicable
6. Letters of support or collaboration, if applicable
7. Documentation of collaborative IRB approval, if applicable
8. CITI training certificates of completion for all research personnel

Upon receipt of a new protocol the IRB Chair or Co-Chair determines the appropriate level of review and follows the procedures for exempt, expedited, full, or continuing review accordingly. Once a determination is made on the level of review required, the IRB Chair will send written notification to the Principal Investigator that the protocol is under review.

Exempt Review

The IRB Chair or Co-Chair shall review all submissions that qualify for exempt determination in accordance with the guidelines set forth in the Code of Regulations (45 CFR 46.104) within 5 business days of receipt. During the review process, the IRB Chair or Co-Chair can determine that the study is exempt from further IRB oversight or refer it for expedited or full review. The Chair shall notify the PI by email within 3 business days of exempt determination. Even though the PI believes the submission is exempt, the research may not go forward until approved in writing by the IRB Chair. All exempt reviews shall be reported at the next convened full IRB meeting.

Categories of review eligible for exempt review under 45 CFR 46.104 regulations include:

1. Research conducted in established or commonly accepted educational settings that involve routine educational practices unlikely to have an adverse effect on students (i.e., comparison or effectiveness of instructional strategies, curricula, or classroom management techniques).
2. Research that involves educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior. **Except:**

a. When the identity of participants can be easily ascertained through the information recorded by the principal investigator and places the participant at risk for criminal or civil liability or damage to financial standing, employability, or reputation.

3. Research that involves benign behavioral interventions with collection of data from an adult participant through verbal or written responses. The participant must agree to the intervention and data collection, in addition to a minimum of one of the following criteria being met:

    a. The recorded information obtained does not identify the participants directly or through identifiers.
    b. Disclosure of participant responses will not place participants at reasonable risk of criminal or civil liability or damage financial standing, employment, educational advancement, or reputation.
    c. If the recorded information easily identifies the participant directly or indirectly through identifiers, the IRB conducts a limited review to make the determination required by 45 CFR 46.111 (a).(7).

    Benign behavioral intervention is defined as interventions that have a brief duration and remain harmless, painless, and physically noninvasive. The interventions are unlikely to have a significant adverse effect on participants. This exemption is nonapplicable to research involving deception unless the participant signs a prospective agreement declaring willing participation under circumstances where the participant may be misled regarding the authentic nature or purpose of the research.

4. Secondary research utilizing existing data, unidentifiable private information or biospecimens, documents, or records. Research involving publicly available data cannot identify participants directly or through identifiers.
5. Research of demonstration products conducted and/or supported by a federal department or agency and is designed to study, evaluate, improve, or examine public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies that meet the following criteria:
    a. Wholesome foods void of additives are consumed
    b. A consumed food containing an ingredient, agricultural chemical, or environmental contaminant is at or below the safe level as determined by the FDA or approved Environmental Protection Agency, or U.S. Department of Agriculture.
7. Storage and maintenance of identifiable private information or biospecimens for possible secondary research if an IRB completes a limited review and makes a determination as outlined in 45 CFR 46.111 (a)(8).
8. Secondary research that requires broad consent. Research that leverages identifiable private information or biospecimens must meet the following criteria:
    a. Broad consent for the storage, maintenance, and secondary research was obtained in accordance with 45 CFR 46.116(a)(1)- (4), (a)(6), and (d)
    b. Informed consent or waiver of informed consent was obtained according to the standards set forth in 45 CFR 46.117.
    c. IRB conducts a limited review to make a determination on whether the research is within the scope of the broad consent as outlined in 45 CFR 46.111(a)(7).
    d. The principal investigator has not incorporated the return of individual research results to participants as part of the submitted study plan.

Exempt projects do not require researchers to submit renewal information. Investigators are only required to submit amendments for proposed substantive changes (i.e., changes in research focus, study design, consent forms, instruments, personnel) and submit a final report to close the research protocol to the IRB (see Appendix C).

Expedited Review

Research that qualifies for expedited review involves no more than minimal risk to subjects as outlined in OHRP regulations (45 CFR 46.110) and human subject involvement falls within the following categories:

1. Clinical studies involving drugs or medical devices in which an investigational application is not required, or the medical device is being used in accordance with its approved labeling.

2. Blood specimen collections only involve non-pregnant adults 110lbs or greater.
3. Biological specimens are collected through noninvasive means (i.e., hair/nail clipping, skin cells collected by swab).
4. Data collection is completed through noninvasive procedures routinely employed in the clinical practice setting that do not involve radiation. If a medical device is used, the purpose of the study cannot be to evaluate its effectiveness and safety.
5. Research that leverages data, documents, records, or specimen collection for non-research purposes.
6. Data collection involves digital, video, or voice recordings made for research purposes.
7. Research is focused on individual or group behavior or characteristics (i.e., research on perceptions, cultural practices, focus groups, program evaluation, human factors evaluation, quality assurance, and surveys).
8. Continuing review of research that has been previously approved by the IRB.

The Chair may review and approve protocols that involve no more than minimal risk to the subject(s) or involve minor changes in previously approved protocols. The chair may designate such review and approval to be conducted by one or more experienced members of the board using the Protocol Review Worksheet (see Appendix A). Upon review, a determination will be made that the protocol can undergo expedited review or be referred for full board review. All expedited reviews shall be completed within 15 business days of receipt and reported to the full IRB at the next stated meeting.

Full Review

Protocol submissions that do not meet the criteria for exempt or expedited review/and/or involve vulnerable populations must be reviewed by the convened IRB. The IRB shall review such protocols and periodically conduct ongoing review of approved research studies.

Principal Investigators may submit a request for protocol review under exempt or expedited review guidelines. However, the IRB shall have final determination on appropriate level of review for each protocol submission based on the potential risk posed to participants. Protocols that fit within one or more categories (i.e., exempt and expedited) shall be reviewed under the higher level of review guidelines. Protocols that involve greater than minimal risk to participants and do not fall within the criteria of the expedited categories shall receive full IRB review.

The IRB Chair or Co-Chair will assign a primary and secondary reviewer to evaluate the protocol using the Protocol Review Worksheet (see Appendix A). The primary and secondary reviewers will present the protocol and any recommendations for revisions at the next scheduled full board meeting. Final determination and recommended revisions, if applicable shall be sent to the principal investigator via email within 3 business days of the convened full board meeting.

Continuing Review (Renewal)

The IRB shall conduct continuing review of research at intervals appropriate to the level of risk posed to participants. Initial approval of protocols may be for a period of 3 months, 6 months, 9 months or 1 year. The criteria used by the IRB to determine the frequency of continuing review is as follows:

1. Type of risk posed to participants
2. Degree of uncertainty regarding the risk
3. Population vulnerability
4. Experience of research personnel conducting the research
5. Prior compliance issues with research personnel (i.e., obtaining informed consent, participant complaints, nonadherence to protocol procedures)
6. Projected rate of participant enrollment
7. Whether novel interventions were introduced in the research

Principal Investigators that wish to continue a research study beyond the approved period must submit a Request for Renewal form (see Appendix E) that includes the following:

a. A description of study progress to date, number of participants enrolled, and disclose any issues encountered or changes made to the protocol.
b. Copy of all approved recruitment and consent materials
c. Submission of revised protocol documents with summary explanation for changes

The IRB Chair shall complete a preliminary review of each renewal request to determine the appropriate level of review (expedited or full board) within 5 business days of receipt. Renewal requests that fall under the guidelines of expedited review will be completed by the Chair or Co-Chair within 10 business days of receipt. Renewal requests that require a full board review will be added to the agenda for the next stated meeting to receive a final determination on continuance.

Considerations for Research with Special Populations

Inclusion of Children in Research

Federal guidelines require that human subjects research include children as participants unless the protocol presents acceptable ethical or scientific rationales for exclusion. Research involving children shall be reviewed by a convened full board. The IRB shall review protocols to ensure that sufficient provisions are made for children to provide assent. In instances, where children are unable to consent, provisions must be made for parents or legal guardians to grant permission for children to be participants in research. Both parents must give permission for children to participate in research, except in instances where one parent is deceased, unknown, declared legally incompetent, is reasonably unavailable, or has sole custody of the child.

Inclusion of Pregnant Women or Fetuses in Research

Research involving pregnant women or fetuses shall be reviewed by a full convened board. Consistent with federal regulation 45 CFR 46.204 pregnant women or fetuses may participant in research when all of the following criteria are met:

1. Clinical studies on animals and nonpregnant women have been conducted to identify potential risks to pregnant women and fetuses.
2. Risk is minimized to achieve the research objectives.
3. The risk to the fetus is exclusively caused by interventions that hold out the prospect of direct benefit to the pregnant woman or fetus.
4. If the risk is more than minimal and holds out the prospect of direct benefit to the pregnant woman and fetus and the purpose of the research is to generate biomedical knowledge that cannot be obtained by any other means, informed consent must be provided.
5. If the research holds out the prospect of direct benefit only to the fetus, then the pregnant women and father must provide informed consent except in instances where the father is unable to consent due to acceptable unavailability, incompetence, incapacity, or pregnancy resultant from rape or incest.
6. Each person providing consent is fully informed of potential impact of research on the fetus.
7. No inducements will be provided to terminate the pregnancy.
8. Research personnel will not participate in the decision making or procedures involved in terminating a pregnancy.
9. Research personnel will not participate in determining the viability of the neonate.

Inclusion of Prisoners in Research

In accordance with federal guidelines set forth in 45 CFR 46.304 research involving prisoners shall be reviewed by a full convened board. The majority of the board members shall have no affiliations with the prison(s) where the research will be conducted. A minimum of one board member must be a prisoner or the board shall have a consultant for prisoner representation for the protocol to be reviewed. In accordance with 45 CFR 46.305 the board shall only approve research that fall within one of the acceptable categories:

1. The risk posed to prisoner participants are commensurate with that deemed acceptable of non-prisoner participants.
2. Recruitment procedures detail a fair selection process that is free from influence by prison authorities or prisoners.
3. Recruitment practices provide sufficient information in the appropriate language to the population.
4. Assurances are provided that prisoners will be informed that participation in the research will have no bearing on their parole eligibility.
5. Protocol contains sufficient provisions for follow-up care or exams after participation is complete.

1.6 Special Circumstances

Amendments

Amendments are defined as modifications to the IRB approved protocol and/or procedures used to recruit and enroll participants into the research study. All proposed amendments to previously approved research protocols must be submitted for review by the IRB using the Research Protocol Amendment form (see Appendix F) regardless of initial level of review. The review is conducted to determine the impact of the proposed amendments on risk posed to participants.

1. Amendments to exempt protocols shall be reviewed within 5 business days in accordance with exempt procedures to determine if the proposed changes impact the exempt status of the study. The Chair or Co-Chair reserve the right to change the level of review to expedited or full convened board in instances of substantive changes or more than minimal risk is involved.
2. Amendments to expedited protocols shall be reviewed within 15 business days in accordance with expedited procedures to make a determination that a) the research does not pose more than minimal risk to participants and b) revised procedures remain consistent with expedited categories. Amendments that do not meet these criteria will require a full board review at the next stated meeting.
3. Amendments to full review protocols will be reviewed by the full convened IRB at the next scheduled meeting unless the modifications qualify under minor change criteria:
    a. Proposed changes do not significantly impact the risk/benefit analysis
    b. Proposed changes do not substantially modify the study design or specific aims

    Minor changes that fall within the stated criteria shall be reviewed in accordance with expedited procedures within 15 business days.

4. Administrative amendments that involve proposed changes in research personnel or funding shall be reviewed by the IRB Chair or Co-Chair within 5 business days of receipt.

The processing of final determinations on amendments shall be communicated to the principal investigator via in writing.

1. Approved Amendments shall include the following information in the communication:
    a. Summary of approved changes
    b. Reminder of principal investigator's responsibility to submit any additional amendments to the IRB as applicable for the duration of the research study.
2. Deferred Amendments shall include the following information, as applicable:
    a. Summary of issues that must be addressed for approval
    b. Request for additional information
    c. Recommendations for a change in the level of review

Adverse Events

Adverse events are defined as unanticipated medical or non-medical events that are possibly or directly related to participation in an approved research protocol and suggest that participants may be at increased risk of physical, psychological, economic, or social harm. Principal investigators are required to report adverse events to the IRB using the Reportable Adverse Event Form (see Appendix G) immediately, but not more than 5 business days of becoming aware of an incident.

The completed report form is reviewed by the Chair or Co-Chair for the following:

1. The reported event is an unanticipated problem that poses increased risk to participants or others
2. The event is related to noncompliance with approved protocol procedures
3. The research merits suspension or termination of IRB approval
4. Whether additional reporting to institution officials or federal agencies is warranted

Adverse events shall be reviewed within 3 business days of receipt. After final review of the reported event the Chair or Co-Chair shall notify the principal investigator in writing of one of the following determinations:

1. Require modifications to the protocol, consent process, and/ or supporting documents
2. Require re-consent of all current and former participants
3. Require additional research personnel training
4. Implement research monitoring
5. Suspend or terminate research
6. Refer report to full IRB committee for review and final determination
7. Determine that the reported event is not an unanticipated problem involving increased risk to participants resulting in no further action by the IRB

Suspension or Termination of Research

Research approved by the IRB may be suspended or terminated by the principal investigator at any time. Such investigator-initiated suspensions or terminations are not deemed reportable events unless noncompliance with approved protocol procedures or adverse events posing increased risk to participants has occurred.

The IRB Chair, Co-Chair, and Provost reserve the right to suspend or terminate IRB approved research between scheduled full board meetings in urgent instances that involve continued noncompliance or adverse events. Such suspensions or terminations will be reported out during the next convened full board meeting.

In non-urgent instances of initial or continued noncompliance, the full convened board will review the noncompliant actions or events. The board will consider the following in making a final determination:

1. Protecting the welfare of participants currently enrolled in the research study
2. Procedures for withdrawal of enrolled participants
3. Plan for informing participants of research suspension or termination
4. Prior reports of adverse events or outcomes to the IRB related to research study

The final determination and rationale for suspending or terminating research shall be documented in the meeting minutes. Within 3 business days of the final determination, the IRB chair shall notify the principal investigator in writing of the suspension or termination and any additional requirements for notifying participants and/ or follow-up data that must be reported to the IRB.

The PI has the right to appeal a suspension or termination rendered by the IRB. The PI shall submit a request to appeal the decision to the provost using the Research Protocol Appeal of Determination form (see Appendix H). The provost will have 10 business days to launch an inquiry into the request and send the final determination to the PI and the IRB Chair in writing. The decision of the provost is final and cannot be appealed. The IRB Chair will

submit the completed Research Protocol Appeal of Determination form to the IRB Administrator to file in the Submissions and Terminations subfolder of the protocol in the AZC Institutional Review Board SharePoint site within 3 business days of receipt. The IRB Chair will report the final determination of the provost during the next convened full board meeting.

1.7 Categories of IRB Action

The IRB reserves the right to make any of the following determinations upon review of a protocol, amendment, or renewal submission:

1. **Full Approval:** The IRB may approve the protocol, amendment, or renewal without requesting additional information, clarification, or revisions. The IRB chair will send official copies of all informed consent, recruitment, and other supporting documents attached to the approval email. These documents will expire a maximum of one year from the approval date unless a renewal is submitted by the PI. Following receipt of approval the PI may begin participant recruitment and data collection for the research study.
2. **Conditional Approval:** Protocols shall receive this determination when the IRB requests minor revisions to the protocol and/or supporting documents or additional information is needed to provide clarification. The PI will be given up to 4 weeks to submit revisions before the protocol will be closed for review. Revisions may be reviewed by the IRB Chair or other voting members within 15 business days. If the revisions are satisfactory to the IRB, the protocol shall receive full approval. If additional revisions or information is needed the IRB will send written notification to the PI, and revisions will continue until full approval is granted or the application is withdrawn.
3. **Deferral:** Protocols reviewed by the IRB and determined to have insufficient information presented in the protocol to complete a risk assessment or major questions have been raised by board members regarding study procedures will receive this determination. The IRB Chair will notify the PI in writing of the deferral and request additional information to be reviewed for the next scheduled meeting. The PI will be given up to 4 weeks to submit revisions and additional information before the protocol is closed for review.
4. **Disapproval:** Protocols reviewed by the IRB may receive a disapproval determination when the risks posed to the participants outweigh the benefits or potential knowledge gains from conducted research or study procedures present major ethical concerns. The IRB Chair will send written notification to the PI detailing the reasons for the disapproval.
5. **Reports of Action:** Written reports of actions by the board on suspensions, terminations, or monitoring of research will be sent by the Chair to the PI within 3 business days of Chair, convened board, or sub-committee decision.

1.8 Research Closure and Submission of Final Report

Principal investigators must submit written notification to the IRB within 5 business days of the conclusion of research activities using the Final Report Form (see Appendix D) and retain research records for a minimum of 3 years. Closure of the active research protocol is appropriate when the following criteria have been met:

1. Data collection is complete
2. There will be no further contact with participants enrolled in the study
3. Data analysis is complete, or data is de-identified (no identifiers or codes available to link participants with the research) if analysis is ongoing

Upon receipt of the Final Report form, the IRB Administrator will file it and archive the protocol according to the procedures outlined in section 1.9 IRB Records Storage.

1.9 IRB Records Storage

The AZC Institutional Review Board SharePoint site will be the repository for documentation related to all IRB activities. In accordance with 45 CFR 46.115, the institution shall maintain adequate documentation of the following:

a. Copies of all research proposals reviewed, consent forms, and any progress reports or adverse event reports submitted by the principal investigator
b. Meeting minutes that detail attendance, actions taken by the IRB, details of the vote breakdown of members for, against, and abstentions, along with a summary of controverted issues discussed with outcome.
c. Records of continuing review activities with rationale as described in §46.109(f)(1).
d. Correspondence between the IRB and principal investigator(s).
e. List of current IRB members inclusive of:
    i. Name
    ii. Earned degrees
    iii. Representative capacity
    iv. Professional experience (certifications, licenses), work history that demonstrates contribution to IRB deliberations
    v. Employment status or relationship with the institution
    vi. Completed research protections trainings
        i. Certificates of completion for OHRP and CITI Training Modules shall be maintained in each board member's respective file under the IRB Member Training Documentation folder in the AZC Institutional Review Board SharePoint site
f. Written procedures for conducting initial and continual review of research, determining protocols that require review more frequently than annually, and ensuring that research is conducted in accordance with the terms and conditions of IRB approval until proposed protocol changes have been approved.
g. Statements of significant new findings provided to participants in accordance with §46.116(c)(5).
h. Rationale for expedited reviewers' determination showing that is poses more than minimal risk.
i. Assurance that the IRB will ensure compliance with these requirements

All records related to correspondence and research activities of active protocols shall be placed by the IRB administrator in an electronic file labeled with the protocol number in the Active Research folder until completion. Once the Final Report form has been received the IRB administrator will archive the file in the Completed Research folder indefinitely.

To maintain standardization of all electronic files each protocol folder will contain subfolders labeled with the following headings:

1. **Approved Protocol**: Folder shall contain the approved protocol, supporting materials (i.e., recruitment documents, surveys, etc.) and a copy of all correspondence related to the protocol between the IRB and principal investigator.
2. **Monitoring Reports and Research Renewals:** Folder shall contain copies of data or research monitoring reports submitted to the IRB, and correspondence related to approvals of research renewal requests.
3. **Adverse Events:** Folder shall contain a copy of the submitted Reportable Adverse Events form and all correspondence between the IRB and PI related to the reporting and resolution of unanticipated problems or events of active research.
4. **Suspensions and Terminations**: Folder shall contain all correspondence related to protocol suspensions or terminations between the IRB and PI.
5. **Amendments:** Folder shall contain the Research Protocol Amendment form, supporting documents, and correspondence between the IRB and Principal Investigator.
6. **Final Report:** Folder shall contain the submitted Final Report form to close the research study and any related correspondence between the IRB and PI.

Meeting minutes from full convened board meetings will be prepared electronically by the IRB Administrator. Minutes will be stored in the Meeting Documentation folder of the AZC Institutional Review Board SharePoint site within 5 business days of board approval. Each file will be labeled as follows: meeting month.date.year.IRB Meeting Minutes.

2.0 Review of Standard Operating Procedures

The standard operating procedures contained in this manual shall be reviewed biannually in May and November at convened full board meetings. The policies will be reviewed and updated to ensure adherence to institutional, state, and federal regulations. The review process will include the following:

1. IRB Administrator will send SOP to IRB members for review 2 weeks prior to the scheduled full board meeting.
2. Discussion of required updates will be an agenda item at the next scheduled full board meeting.
3. The IRB Administrator will document all the suggested revisions in the meeting minutes.
4. The IRB Chair will make the required revisions and send to all board members for review within 1 week.
5. Board members will have 1 week to review the revised SOP and approve through electronic vote.
6. Once the SOP is approved through the board it will be sent to the Provost for final approval.
7. Implementation of the revised SOP manual will be effective immediately upon receipt of final approval from the Provost.

Appendix A
Protocol Review Worksheet

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

Protocol Review Worksheet

PI Name: _____ Reviewer Name: _____

Protocol Number: _____ Review Level: ☐ Full ☐ Expedited ☐ Exempt

Date: _____

Please indicate whether the Principal Investigator (PI) has provided sufficient consideration and safeguards to the following areas of concern:

1. SPECIFIC AIMS, BACKGROUND, AND SIGNIFICANCE	YES	NO	N/A
Study objectives are clearly specified	☐	☐	☐
Sufficient preliminary data to justify research	☐	☐	☐
Adequate references have been provided	☐	☐	☐
Appropriate justification for this research protocol	☐	☐	☐
Comments/Questions for PI to address:			

2. INCLUSION/EXCLUSION CRITERIA FOR PARTICIPANTS	YES	NO	N/A
Inclusion/Exclusion criteria are clearly stated and reasonable	☐	☐	☐
Process for selection of participants is appropriate and equitable	☐	☐	☐
Vulnerable populations are included in the study design	☐	☐	☐
The inclusion or exclusion of vulnerable populations is justified	☐	☐	☐
Safeguards are in place to protect the rights and welfare of participants vulnerable to coercion or undue influence	☐	☐	☐
Comments/Questions for PI to address:			

3. PARTICIPANT RECRUITMENT AND ENROLLMENT	YES	NO	N/A
There is an acceptable procedure for screening participants prior to recruitment	☐	☐	☐
Recruitment materials were submitted with research protocol	☐	☐	☐
Recruitment language, text, and formatting are understandable at 8th grade level and non-coercive	☐	☐	☐
Recruitment method is well defined for all participant groups	☐	☐	☐
Location, setting, and timing of recruitment are acceptable	☐	☐	☐
Comments/Questions for PI to address:			

4. RESEARCH DESIGN	YES	NO	N/A
Research design is appropriate to answer the study's question(s)	☐	☐	☐
Research design is adequately described	☐	☐	☐
Study aims are likely to be achieved within proposed timeline	☐	☐	☐
Comments/Questions for PI to address:			

5. RESEARCH PROCEDURES	YES	NO	N/A
Research procedures are acceptable and adequately described with appropriate rationale	☐	☐	☐
Co-investigators performing research procedures are sufficiently trained	☐	☐	☐
A plan for dissemination of research results to participants is described	☐	☐	☐
Comments/Questions for PI to address:			

6. DATA ANALYSIS	YES	NO	N/A
The rationale for the proposed number of participants is reasonable	☐	☐	☐
The plan for statistical analysis of data is well defined and acceptable	☐	☐	☐
The Data and Safety Monitoring plan incorporates adequate provisions for monitoring data	☐	☐	☐
Comments/Questions for PI to address:			

7. RESOURCE AVAILABILITY	YES	NO	N/A
There are sufficient resources to conduct the research safely (i.e., equipment, funding, space, staff)	☐	☐	☐
A plan for monitoring participants during and after research has been sufficiently described	☐	☐	☐
Counseling and/or support services will be available, if applicable	☐	☐	☐
Provisions are included for research related injuries, if applicable	☐	☐	☐
Comments/Questions for PI to address:			

8. RISKS AND BENEFITS	YES	NO	N/A
Identified risks have been sufficiently described and evaluated	☐	☐	☐
Risks are reasonable in relation to the benefits to be gained in conducting the research	☐	☐	☐
Risks are minimized to the greatest extent possible	☐	☐	☐
Comments/Questions for PI to address:			

9. PARTICIPANT PRIVACY AND CONFIDENTIALITY	YES	NO	N/A
Sufficient provisions are in place to protect the privacy of participants	☐	☐	☐
A detailed plan for protecting the confidentiality of data during and after research is provided and appropriate (i.e., storage, coding, de-identified data)	☐	☐	☐
Comments/Questions for PI to address:			

10. PARTICIPANT COMPENSATION	YES	NO	N/A
Compensation provided to participants is reasonable so as not to be deemed coercive in nature	☐	☐	☐
Process for compensation is clearly defined and reasonable with provisions for participants that do not complete the study	☐	☐	☐
Comments/Questions for PI to address:			

11. ADDITIONAL RESEARCH MATERIALS	YES	NO	N/A
Recruitment materials are included and deemed acceptable without any noted conflicts of interest (i.e., brochures, flyers, scripts, emails)	☐	☐	☐
Survey materials are included and deemed acceptable without any noted conflicts of interest	☐	☐	☐
Comments/Questions for PI to address:			

12. INFORMED CONSENT/ASSENT PROCESS	YES	NO	N/A
Process is well defined and has minimized risk of coercion	☐	☐	☐
Process incorporates an appropriate setting with adequate privacy and sufficient time to complete the consent/assent process	☐	☐	☐
Process includes considerations for autonomous decision-making	☐	☐	☐
The individual(s) obtaining consent/assent are appropriate and have received sufficient training	☐	☐	☐
Comments/Questions for PI to address:			

13. INFORMED CONSENT/ASSENT CHECKLIST	YES	NO	N/A
Consent/ assent is written in easily understandable language to prospective participants	☐	☐	☐
Translation of consent/assent form for non-English speaking participants, where applicable	☐	☐	☐
Incorporates statement that the study involves research	☐	☐	☐
Purpose of the study and reason for participation are described	☐	☐	☐
Description of study design (number of groups, subjects, and randomization)	☐	☐	☐

Description of study procedures are provided	☐	☐	☐
Potential risks and benefits are disclosed	☐	☐	☐
Alternative procedures/ treatments are disclosed	☐	☐	☐
Provisions for maintaining confidentiality of data are described	☐	☐	☐
Statement regarding compensation and treatment should an injury occur in research with greater than minimal risk	☐	☐	☐
Contact information is presented for questions regarding research, participant's rights, and research related injuries	☐	☐	☐
Statement of voluntary participation	☐	☐	☐
Compensation for participation, if applicable	☐	☐	☐
Statement of circumstances under which participation may be terminated, if applicable	☐	☐	☐
Additional costs associated with participation in the study, if applicable	☐	☐	☐
Statement of how significant findings will be disclosed to participants	☐	☐	☐
Consequences of participant's decision to withdraw from the study	☐	☐	☐
Disclosures of conflicts of interest, if applicable	☐	☐	☐
Parental Consent Requirements: ☐ Consent of One Parent Required ☐ Consent of Both Parents Required			
Assent from Children and Witness Signature (Required unless child is incapable due to age, psychological state, or sedation): **Assent Required** ☐ Yes ☐ No ☐ Assent is on Informed Consent form ☐ Separate assent form is required			
Comments/Questions for PI to address:			

14. WAIVER OR MODIFICATION OF INFORMED CONSENT	**YES**	**NO**	**N/A**
The following criteria for waiver or modification of informed consent documentation have been met:			
1. The consent form would be the only documentation that links the participant with the study, and a potential risk would be breach in confidentiality.	☐	☐	☐
2. The study poses no more than minimal risk to participants and does not involve procedures for which written consent is normally required outside the research context.	☐	☐	☐
3. The waiver of modification of consent form will not adversely affect the rights and welfare of participants.	☐	☐	☐

4. The study would not be feasibly carried out without a waiver or modified consent form	☐	☐	☐
If informed consent documentation is waived, the PI is required to provide a statement regarding the research to participants	☐	☐	☐
For research involving children, the following criteria for waiver of parental/guardian consent have been met: 1. IRB has determined parental/guardian consent is not a reasonable requirement to protect participant rights 2. Appropriate provisions exist to protect minor participants	☐ ☐	☐ ☐	☐ ☐
Comments/Questions for PI to address:			

15. Reviewer's Final Recommendation	
The protocol and additional materials present an acceptable risk/benefit ratio, and no additional changes are warranted	☐ **Approve**
☐ Minor edits to the protocol and/or additional materials are required ☐ Minor clarifications(s) related to the study protocol are required	☐ **Conditionally Approve**
The submitted protocol presents an unacceptable risk benefit ration and requires significant revisions due to: ☐ Protocol lacks sufficient information regarding the justification for research, study procedures, provisions to reduce risk, etc. ☐ Ethical concerns that can be addressed by providing additional information and/ or making modifications to the research design and procedures.	☐ **Defer**
☐ Risks associated with carrying out the study far outweigh the potential knowledge to be gained. ☐ The protocol as written raises serious ethical concerns and the study is therefore deemed unacceptable	☐ **Disapprove**
Additional Comments	

Appendix B
IRB Application

Institutional Review Board (IRB) Application for Research Protocol Approval

Arizona College of Nursing's Institutional Review Board (IRB) reviews all research protocol requests to determine if it is human subject research that meets definitions in *The Common Rule* and therefore requires review and oversight by the IRB. It is the investigator's responsibility to give complete information regarding procedures and the informed consent process. After submitting the application, the IRB will notify the applicant, in writing, of its decision or if additional information is needed.

Checklist

Please submit the following items along with this application for your submission:

1. This application
2. A copy of all questionnaires and surveys to be used (*if applicable*) as well as all recruitment materials including flyers, recruitment scripts.
3. Informed Consent – attach all informed consent documents that will be provided to each participant before they participate
4. Confidentiality and Anonymity – attach information to describe how participant's private information will be maintained and how confidentiality will be guaranteed
5. A copy of your CITI Certification (free certification for Arizona College affiliates through the IRB website) should be sent to irb@arizonacollege.edu
6. A copy of the application and approval letter from any external IRB (*if applicable*)
7. Responsibilities and Signatures page with all signatures.

Form Submission
The Principal Investigator must submit this completed form and supporting documents as indicated in the checklist above to irb@arizonacollege.edu. **Note:** The **Co-Investigator and Research Personnel** form must be completed for all additional

research personnel that will participate in data collection for this research protocol.

Step 1: Your Information

Project Title:	
Principal Investigator:	
Is the Research Funded:	☐ No ☐ Yes, internally ☐ Yes, externally List Funding Source: _____
Check One: Arizona College	☐ Student ☐ Faculty ☐ Staff ☐ Administrator ☐ Not affiliated with Arizona College of Nursing
Your Email:	
Primary Phone Number:	

Step 2: Location, Faculty, and Date Information

Campus Location and all external locations (if any)		
Faculty/Sponsor Information (*if student PI*):	Name:	
	Email:	
	Phone:	CITI Completed? ☐ No ☐ Yes
Projected Start Date:		
Projected Completion Date:		

Step 3: Research Overview

For each research question your study is designed to answer, use the P.I.C.O.T. model below. P = population I = intervention or issue of interest C = comparison intervention or issue of interest O = outcome T = time frame (note: timeframe is not always required to be specified) **Example:** In (your specific population), how does (your specific intervention) compare to (your specific comparison intervention or issue of interest) and influence/affect/impact (outcome) within/over (timeframe)?
Research Question 1 **Research Question 2**

Research Question 3

Project Abstract

Provide a brief summary (250 words or less) of the proposed research including the purpose, variables, value of the study, and the intended method of use and/or publication of the knowledge gained from the study.

Methodology

Provide a description of your research methodology. Include the measures, where and how you plan to collect data, and over what time period. Identify all personnel who will participate in this research and outline their qualifications or submit a Curriculum Vita for each.

Data Security

Provide a description of your data security plan for both physical and electronic data that includes protected or identifying personal information. Include where the data will be stored for a minimum of three (3) years after the research has been completed, the security of the location or computer system, the proposed length of retention of the data, and the method of disposition of old data.

Step 4: Participant Information

Are all participants members of a population who can provide informed consent?	☐ Yes ☐ No
Will any of the participants be younger than 18 years old?	☐ Yes ☐ No
Will the participants be Arizona College of Nursing students, faculty, or other staff? (**Note: If yes, your study requires full IRB review**)	☐ Yes ☐ No
Will participants receive compensation?	☐ Yes ☐ No
If participants receive compensation, please detail the compensation here	
Describe how participants will be selected or recruited.	

Risks Describe all known, anticipated, or possible risks to the participants below (psychological or physical). For each possible risk, the possible effects of each risk on the participants and outline the measures to mitigate such risk.

Benefits Please describe the anticipated benefits to the participants below

Step 5: Acknowledgement of Responsibilities and Signatures

Responsibilities (*Please Read Carefully*):

1. Any additions or changes must be submitted to the IRB for written approval prior to these changes being implemented.

2. Once the project has begun, any adverse effects or unanticipated problems connected with human subjects **must be communicated immediately to the IRB** by emailing irb@arizonacollege.edu
3. All informed consent documents must be kept by you for a period of three (3) years following the completion date of the project
4. Any data collected from Arizona College of Nursing students, alumni, faculty and/or staff and/or any other constituents for purposes of this study is proprietary. Any publication of findings may not identify or implicate the Arizona College of Nursing. Any external report produced on findings generated by this study, including any presentation or publication, may not identify, reference or implicate Arizona College of Nursing in any way.
5. Upon completion of the study, a copy of the final deliverable will be submitted to Arizona College of Nursing by emailing the completed study to: irb@arizonacollege.edu
6. Any and all additional publications or presentations produced based upon this study will be submitted to Arizona College of Nursing at irb@arizonacollege.edu

I certify to the best of my knowledge the information presented is an accurate reflection of the proposed research project.

Principal Investigator (PI) Signature: _____ Date: _____

Print Name _____

Faculty Sponsor Signature*: _____ Date: _____
*Required if PI is a student. The faculty signing above confirms the application is accurate and accepts responsibility as Co-PI.

Print Name _____

Campus EDAO Signature: _____ Date: _____

Print Name _____

Appendix C
Co-Investigator and Research Personnel form

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

Co-Investigator and Research Personnel Form

Date: _____

Form Submission
This form should be completed and submitted to irb@arizonacollege.edu as part of the protocol submission to identify all research personnel that will conduct research procedures. **Note: All research personnel must complete CITI training prior to participating in research procedures.**

Project Demographics	
Principle Investigator	
Protocol Number	
Project Title	

Additional Research Personnel			
Name			
Phone		Email	
Role	☐ Co-Investigator ☐ Research Staff ☐ Other, specify:		
Describe Research Duties			
CITI Training	☐ Complete ☐ Pending ☐ Certificate attached for nonaffiliated personnel		

Additional Research Personnel			
Name			
Phone		Email	
Role	☐ Co-Investigator ☐ Research Staff ☐ Other, specify:		
Describe Research Duties			
CITI Training	☐ Complete ☐ Pending ☐ Certificate attached for nonaffiliated personnel		

Additional Research Personnel			
Name			
Phone		Email	
Role	☐ Co-Investigator ☐ Research Staff ☐ Other, specify:		

Describe Research Duties	
CITI Training	☐ Complete ☐ Pending ☐ Certificate attached for nonaffiliated personnel

Additional Research Personnel			
Name			
Phone		Email	
Role	☐ Co-Investigator ☐ Research Staff ☐ Other, specify:		
Describe Research Duties			
CITI Training	☐ Complete ☐ Pending ☐ Certificate attached for nonaffiliated personnel		

Additional Research Personnel			
Name			
Phone		Email	
Role	☐ Co-Investigator ☐ Research Staff ☐ Other, specify:		
Describe Research Duties			
CITI Training	☐ Complete ☐ Pending ☐ Certificate attached for nonaffiliated personnel		

Principle Investigator Assurance

I certify that the information provided in this form is complete and accurate to the best of my ability and that all persons working on this protocol have received proper training to conduct research on the approved protocol and have completed CITI training.

Principal Investigator's Signature: _____ Date_____

Appendix D
Final Report Form

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

Final Report Form

PI Name: _____ Reviewer Name:_____

Protocol Number: _____ Date: _____

Project Title: _____

Initial Approval Level: Full ☐ Expedited ☐ Exempt ☐

Form Submission
This form should be completed and submitted to irb@arizonacollege.edu for the following: 1. IRB approval for the research protocol has lapsed 2. The IRB approved the research protocol, but the study was never initiated 3. The Principal Investigator(s) voluntarily want to close the study

Reason for submission of Final Report form (Select all that apply.)
☐ Project was not initiated (skip to assurance signature section)
☐ Project was initiated, but there were no participants enrolled or data collected (skip to assurance signature section)
☐ Project is complete
☐ Project has been terminated
☐ Principal investigator is leaving or has left Arizona College

Participant Summary	
Number of participants that enrolled in the research study	Click or tap here to enter text.
Number of participants that completed the research study	Click or tap here to enter text.
Number of participants that declined to participate in the research study	Click or tap here to enter text.

Provide rationale for participants that declined participation, if applicable	Click or tap here to enter text.

Summary of Participant Complaints and Adverse Events
Have and participants or their legally authorized representatives made complaints about the research since initial or last approval? ☐ **Yes** ☐ **No**
If yes, please provide a summary of the complaints and resolutions in the box below.
Click or tap here to enter text.
Has the Principal Investigator been made aware of any unanticipated problems or adverse events that pose increased risk to participants since initial or last protocol approval? ☐ **Yes** ☐ **No**
If yes, provide a summary of the unanticipated problems or adverse events and the outcome in the box below.
Click or tap here to enter text.

Assurances
I certify that the information provided in the Final Report form is complete and accurate to the best of my ability. As the Principal Investigator, I understand that I am responsible for protecting the rights and welfare of human subjects enrolled in the approved research study. By signing this form, I attest that I have complied will all Arizona College, state, and local laws related to the ethical conduct of research.

Principal Investigator's Signature: _____ Date_____

Appendix E
Request for Renewal Form

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 irb@arizonacollege.edu 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? ☐Yes ☐ 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? ☐Yes ☐ No

Provide a summary of the specific aims/goals of the research study and method
Click or tap here to enter text.

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 ☐ Yes ☐ No Click or tap here to enter text.

Informed Consent
Are there plans to recruit and enroll additional participants into the research study? ☐Yes ☐ 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
Click or tap here to enter text.
Have participants declined to participate in the research since initial or last approval? ☐ Yes ☐ No
Provide a summary of the number of participants declining and cited reasons since initial or last approval
Click or tap here to enter text.
Have any participants withdrawn from the research study after initial enrollment? ☐ Yes ☐ No
Provide a summary of the number of participants that have withdrawn from the research study and the reasons, if applicable.
Click or tap here to enter text.

Have participants been withdrawn from the research study by the principal investigator since initial or last approval?
☐ Yes ☐ No

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

Click or tap here to enter text.

Participant Complaints

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

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

Preliminary Findings or Results

Are there preliminary findings or results? ☐ Yes ☐ No

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

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

Click or tap here to enter text.

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

Click or tap here to enter text.

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

Click or tap here to enter text.

Unanticipated Problems or Adverse Events
Have there been any unanticipated problems involving increased risk to participants or adverse events since initial or last approval? ☐Yes ☐No

Date of Event	Event or Problem Description	Event or Problem Related to Research	Date Reported to IRB	Outcome
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

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 ☐ 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_____

Appendix F
Research Protocol Amendment Form

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

Research Protocol Amendment Form

PI Name:_____ Reviewer Name: _____

Protocol Number:_____ Date: _____

Project Title: _____

Initial Review Level: ☐ Full ☐ Expedited ☐ Exempt

Form Submission
In accordance with the federal regulations, the IRB must approve all proposed changes to approved protocols and supporting documents prior to implementation. Amendments are processed within 15 business days of receipt. **The following documents are required to be submitted with this form to irb@arizonacollege.edu:** i. Clean version of the amended protocol ii. Clean version of the amended supporting documents

Contact Information	
Name: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Email: Click or tap here to enter text.	

Purpose for Amendment(s) (Select all that apply)
☐ Update Personnel (Note: if this is the only amendment skip to the personnel change section of this form. ☐ Revisions to protocol procedures and/ or supporting documents ☐ Update regulatory documentation (i.e., funding)

Amendment Summary
Provide a summary of the proposed changes to the research protocol and supporting documents and a rationale for all changes in the box below.
Click or tap here to enter text.

Current Status of Research	Participant Enrollment	
☐ Research study has not commenced ☐ Research is subject to active participant enrollment ☐ Research is closed to participant enrollment	Total number of participants consented Number of active participants Number of completed participants	

Amendments to the Consent Form and Re-consent Plan
Does the proposed amendment(s) change the content of the consent form? ☐ Yes ☐ No
If yes, provide the re-consent plan: ☐ N/A- no participants have enrolled ☐ All active and completed participants will be re-consented ☐ Only select participants will be re-consented ☐ There are no plans to re-consent participants
Provide rationale for selected consent plan: Click or tap here to enter text.

Changes to the Risk/Benefit Profile of the Research Study
Provide a statement on whether any components of the proposed amendment(s) pose new or increased risk to participants in the box below.
Click or tap here to enter text.

Personnel Changes					
☐ No personnel changes			☐ Updating CITI training for existing Personnel ***Note:*** *must submit CITI training certificate*		
☐ **Adding New Personnel**			☐ **Removing Personnel**		
Name	Affiliation	Role in Study	Name	Affiliation	Role in Study

Principal Investigator's Signature: _____ Date_____

Appendix G
Reportable Adverse Event Form

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

Reportable Adverse Event Form

PI Name:_____ Reviewer Name: _____

Protocol Number:_____ Date: _____

Project Title: _____
Initial Review Level: ☐ Full ☐ Expedited ☐ Exempt

Form Submission
This form should be used to report the following types of adverse events in participants: 1. Unexpected events that are probably or definitely related to participation in the approved research protocol 2. Unexpected non-medical reportable events that are probably or definitely related to participation in the approved research protocol The IRB requires the Principal Investigator to report adverse events using this form immediately, but not more than 5 business days of notification from participant or research personnel. Reporting is required immediately, but not more than 3 calendar days in instances where the adverse event involved unforeseen death of a participant. **The following documents are required to be submitted with this form to irb@arizonacollege.edu:** iii. All supplemental reports, documents, or communications related to the event, if applicable **Note: The IRB should not receive any identifiable participant information. Please ensure all supporting documentation is de-identified prior to submission.**

Contact Information	
Name: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Email: Click or tap here to enter text.	

Category of Report and Review Status	
Category of event reporting	☐ Medical Adverse Event ☐ Non-medical Adverse Event
Type of report	☐ Initial Report ☐ Follow-up Report

Resolution of adverse event	☐ Resolved ☐ Unresolved
Oversight entities (Federal Agency, Funding Agency, Other IRB, etc.) notified	☐ Yes ☐ No ☐ N/A

Summary of Adverse Event
Reporting of New Event
Provide a summary of the adverse event in the box below that includes the following: 1. Event Date 2. Date research personnel became aware of the event 3. A detailed description of the event, including number of participants involved and follow up actions taken by research personnel or other entities in response to the event 4. If the event is unresolved, provide a detailed plan of the additional actions that will be taken to resolve the event
Click or tap here to enter text.
Follow-up Report on Event
Provide a summary of participant and research outcomes since the initial report of the adverse event in the box below.
Click or tap here to enter text.

Response to the Adverse Event	
Does the proposed amendment(s) change the content of the consent form?	☐ Yes ☐ No
Does the adverse event require any changes to the approved protocol and/ or supporting documents?	☐ Yes ☐ No
If yes, submit an amendment to the IRB **If no,** provide an explanation of why amendments to the approved protocol and supporting documents is not warranted in the box below	
Click or tap here to enter text.	
Do current and/ or past participants need to be notified of adverse event?	☐ Yes ☐ No
If yes, describe communication plan including timeline for notification **If no,** provide justification for not notifying participants in box below	
Click or tap here to enter text.	

Risk/Benefit Analysis
Provide a summary in the box below of your risk/benefit analysis that includes: 1. If risks to participants remain reasonable in relation to potential benefits 2. If adverse event suggests that remaining participants are at increased risk than initial projection
Click or tap here to enter text.

Principal Investigator's Signature: _____ Date_____

Appendix H
Research Protocol Appeal of Determination Form

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

Research Protocol Appeal of Determination Form

PI Name: _____ Date: _____

Protocol Number: _____

Project Title: _____

Form Submission
The Principal Investigator should complete sections A through G of this form and submit with supporting documentation to irb@arizonacollege.edu with the email subject heading: *Appeal of IRB Determination* for the following: 1. To appeal a suspension of research determination from the IRB 2. To appeal a termination of research determination from the IRB **Note:** The determination made by the provost upon review of this appeal is FINAL

A. Contact Information	
Name: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Email: Click or tap here to enter text.	

B. Reason for Appeal	**C. Former IRB Determinations**	
☐ IRB suspension of an approved research protocol	Research activities of the protocol have been suspended by the IRB prior to this occurrence	☐ Yes ☐ No
☐ IRB termination of an approved research protocol	Research activities of the protocol have been terminated by the IRB prior to this occurrence	☐ Yes ☐ No

D. Provide the rationale listed in IRB correspondence for any prior occurrence(s) of suspension or termination of research activities related to this protocol

E. Participant enrollment prior to current suspension or termination of research activities	
Total number of participants consented	_____participants
Number of active participants	_____participants
Number of completed participants	_____participants

F. Provide the rationale listed in IRB correspondence for current suspension or termination of research activities

G. Provide a statement addressing the concerns presented by the IRB regarding the current suspension or termination of research activities

H. Final Determination of Appeal	☐ Approved ☐ Denied
Provide rationale for final determination	
List any additional actions that must be taken by the Principal Investigator to resume or close research activities related to the protocol	

Provost Signature: _____ Date_____