Institutional Review Board (IRB) Manual for Protection of Human Participants in Research

(Rev: JUD_10_27_25)

Overview

The Institutional Review Board (IRB) for the Protection of Human Participants evaluates research proposals submitted by employees and/or students of Sura College to assure that the research is conducted in an ethical manner, and that any risk or actual harm that might come to someone who volunteers for research emerging from our College will be negated or minimized. This review is mandated both by federal law and College policy. The major goal of the IRB is the protection of human participants in research. Faculty, students, and staff who are conducting research under the auspices of Sura College must receive written IRB approval prior to initiating the study.

All deans, faculty, staff, students, and IRB members who assign, supervise, review, or conduct student or institutional research that involves human subjects should read and adhere to the policies and standards identified within.

To protect human subjects in Sura College research and to limit liability, Sura College hereby establishes an Institutional Research Review Board. Details of the IRB process are contained within this policy manual.

Protection of Human Participants in Research

Sura College has adopted policies for the Protection of Human Participants in Research. These polices provide detailed guidance about what types of projects are considered "research," how to appraise types of risk to human participants, levels of risk and the IRB review process, the informed consent process, what studies qualify for waivers and adaptation of the consent process, etc. Please read these guidelines prior to applying for approval of your research.

Sura College's IRB policies comply with the Code of Federal Regulations issued by the US National Science Foundation (NSF) as identified in Title 45 of the U.S. Code of Federal Regulations Part 690 (45CFR690).

The college IRB uses a common set of forms in application of initial IRB approval for the proposed research, applying for approval of proposed changes in the procedures of a previously approved study, renewing the approval of a study (approval lasts only for one year), and reporting adverse events. All research conducted under Sura College auspices requires IRB approval in writing before the study can begin.

Definition of "Research"

Research is 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:

- 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.
- 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 an event or crisis that threatens public health (including natural or man-made disasters).
- 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.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Composition Requirements of the IRB

The IRB at Sura College maintains a diverse membership roster consisting of the Chair and 4 additional voting members (Total = 5), one of which is internal and one of which is an external reviewer. 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 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 a nonscientific/external area. In addition to these distinctions, at least one member is not otherwise affiliated with the institution.

All IRB members are appointed by the Chief Academic Officer (CAO). All subsequent appointments made by the CAO will be for a 2-year renewable term. As such, the appointment terms will be as follows:

1. IRB Chair: 2-year renewable appointment
2. IRB voting member (external reviewer): 2-year renewable appointment
3. IRB voting member (internal scientific reviewer): 2-year renewable appointment
4. IRB Additional/Alternate Members (appointed as needed to fill necessary committee seats)

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

Responsibilities of IRB Members

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 OHRP training and continuing education to remain up to date on federal regulations governing human research protections ▪ Partners with IRB committee members to ensure accuracy and maintenance of all IRB records
Voting Members	▪ Holds an earned graduate degree ▪ Completes required OHRP training and continuing education to remain up to date on federal regulations governing human research protections ▪ Consistently attends full board and ad hoc meetings
Alternate Members	▪ Holds an earned graduate degree ▪ Completes required OHRP training and continuing education to remain up to date on federal regulations governing human research protections ▪ Consistently attends full board meetings

All voting and alternate members must have a research background, hold a graduate degree, and show proof of completing human rights protection certification training though the Office of Human Research Protections (OHRP) Human Research Protection Foundational Training courses to be eligible to serve on the board. The IRB Chair must meet the requirements of voting members, complete any necessary IRB Chair training coursework, and have an earned doctoral degree.

Human Subjects Research Requiring IRB Review

All Sura College 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 is not limited to:

1. Research conducted by Sura College 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.

Review of Research

Principal investigators are required to submit the following documents to the Sura College IRB to initiate the review process of the research protocol:

1. Completed IRB Application
2. Co-Investigator and Research Personnel form, if applicable
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. OHRP training certificates of completion for all research personnel

Upon receipt of a new protocol the IRB 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 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). During the review process, the IRB 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 of exempt determination. 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.
2. Research that involves educational tests, survey procedures, interview procedures, or observation of public behavior.
3. Research that involves benign behavioral interventions with collection of data from an adult participant through verbal or written responses.
4. Secondary research utilizing existing data, unidentifiable private information or biospecimens, documents, or records.

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. Secondary research that requires broad consent. Research that leverages identifiable private information or biospecimens.

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.

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. Blood specimen collections only involve non-pregnant adults 110lbs or greater.
2. Biological specimens are collected through noninvasive means (i.e., hair/nail clipping, skin cells collected by swab).
3. Data collection is completed through noninvasive procedures routinely employed in the clinical practice setting that do not involve radiation.
4. Research that leverages data, documents, records, or specimen collection for non-research purposes.
5. Data collection involves digital, video, or voice recordings made for research purposes. 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).
6. 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. 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 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 will assign a primary and secondary reviewer to evaluate the protocol using the Protocol Review Worksheet. 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 shall be sent to the principal investigator.

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
6. Projected rate of participant enrollment.

Principal Investigators who wish to continue a research study beyond the approved period must submit a Request for Renewal form. The IRB Chair shall complete a preliminary review of each renewal request to determine the appropriate level of review.

Requirements for IRB Approval

The IRB approves research only if the research plan meets all the following requirements:

1. The study includes a summary of the proposed research methods, including (but not limited to):
2. Hypothesis to be tested.
3. How data are to be collected
4. Sample size requirements necessary to meet an acceptable level of confidence/statistical significance.
5. The study procedures minimize risks to participants.

a. By using procedures that are consistent with sound research and that do not unnecessarily expose participants to risk,
b. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

The IRB determines that:

1. Risks to participants that may result from the research are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably be expected to result
2. That the researcher has a reasonable plan in place to deal with foreseeable injuries that could directly result from participating in the research
3. Research methodology is likely to produce statistically significant results that establish a logical progression toward testing the proposed hypothesis
4. Proposed research approach (including survey methodology) is free of bias.
5. Selection of participants is equitable considering the purposes of the research, the setting in which the research will be conducted, and special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
6. Informed consent procedures are appropriate (see section on Informed Consent).
7. The research includes a reasonable plan for monitoring the data collected to ensure the safety of participants.
8. The research procedures protect the privacy of participants and maintain the confidentiality of data.
9. The research procedures comply with relevant legal requirements of the state and/or country in which the research is conducted (e.g., HIPAA regulations, laws requiring disclosure of confidential information collected during the research, legal age at which minors become emancipated).

IRB Responsibilities

The campus IRB will maintain the following records:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, reports of injuries to participants, and statements of significant new findings provided to participants.
- Copies of documents related to amendments to approved proposals.
- Minutes of IRB meetings.
- Records of continuing reviews of research projects.
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members.
- Detailed written procedures for the IRB.

IRB minutes shall be retained for at least 5 years. Similarly, the IRB shall retain records relating to research which is conducted (e.g., written approval documents, protocols, and

protocol amendments) for at least 5 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the university at reasonable times and in a reasonable manner.

Investigator (Student) Responsibilities

The investigator must keep written records of IRB approval of the research project and make these available upon request of an authorized university administrator (e.g., the IRB Chairperson). Similarly, the investigator must obtain and keep documentary evidence of informed consent of the participants or their legally authorized representative. The investigator must retain these forms on file for a minimum of 7 years after the conclusion of the project.

Investigators are responsible for destroying or de-identifying any original forms, surveys, code books, code sheets, and other documents that link participant's identity with their data. This should be done as during a time frame consistent with the consent or assent forms (if used) or after a period not to exceed seven (7) years after the completion of the study. Sura College is not responsible for the maintenance or destruction of original forms, surveys, code books, code sheets, and any other documents that link participants' identity with their data held by the investigator. This policy does not apply to databases, questionnaires marked with numbers rather than names, aggregate data or data compiled in such a manner that does not in any way disclose the identity of participants in a study. Such data do not have to be destroyed.

Faculty Responsibility

Students currently enrolled in a Sura College program who are the principal investigators on research studies involving human participants must have a core faculty member or other qualified Faculty Advisor who oversees their IRB submission. Qualified faculty for student research include core faculty, adjunct faculty operating in an official capacity regarding student research, and other individuals who hold the doctorate and serve at the university in administrative roles (e.g., Dean and/or Program Directors). Faculty Advisors of student research are responsible for ensuring that students' IRB protocols are complete and for overseeing students' compliance with IRB policies and procedures.

Faculty are also responsible for ensuring that students comply with any requirements of their academic program in terms of the timing of IRB submission (e.g., ensuring that a student's proposal has been approved prior to submitting a protocol to the IRB [or vice versa], if this is a requirement of the academic program)

Informed Consent

The informed consent process is a crucial component of research with human participants. Obtaining research participants' voluntary consent to participate in research involves more

than providing a prospective participant with a consent form and obtaining the person's signature. Instead, it is an educational process that in most cases involves interaction between the researcher and the potential participant. This process has four components:

- Providing sufficient information to participants for them to determine whether they wish to participate in the study;
- Documenting that a participant (or the person's legal representative) has received the information;
- Documenting that the participant freely agrees to participate; and
- Determining that the potential participant is capable or competent (legally and ethically) to consent. Consent therefore must be informed (i.e., based on participants' understanding of what participation will entail and likely risks and benefits) and voluntary (i.e., free from overt or implied coercion), and can only be given by an individual deemed competent to consent.

For research involving minimal and greater than minimal risk (Levels 2-4), Federal regulations require that informed consent be obtained and documented with research involving human participants. Under a few circumstances, as described below, the consent process may be waived or altered if the IRB grants permission in advance.

Providing Information for Obtaining Informed Consent

Informed consent requires that the researcher give participants the information they need to make an informed choice about whether to participate in a study. An informed consent process is required (unless waived; see below) for all research, regardless of methodology (e.g., electronic data collection, qualitative methods, survey research). This information should be provided in language that is easily understood by the participants, considering the possible range of ages, educational levels, (English or other primary) language proficiency, and socioeconomic status of any given group of potential participants. Consent forms should be written in language which is aimed directly at the participants and should avoid professional, technical and research language that impairs comprehension by the intended consumers, that is, the potential research participants.

If participants cannot read well enough to understand the material, this information should be read to them. In the case of research being conducted with persons whose primary language is not English, the researcher must arrange to have all needed material available in the primary language of the participants.

A second major component of the consent process is ensuring voluntary participation. The researcher should build in opportunities for prospective participants to ask questions or gain additional information about the research should they wish to do so before consenting or declining to participate. This process should permit the potential participant to ask questions or seek info about the study from an individual who is capable of understanding and responding to questions in a language in which the participant is fluent. Assistance of a

translator fluent in both the researcher's and the participant's primary languages is permissible, as is some equivalent process.

The consent process should be planned in ways that permit participants sufficient time to review written information and ask questions. The person obtaining the consent should be sufficiently knowledgeable to answer questions about the research and research procedures. If consent forms are distributed in ways that do not involve interaction with the researcher (e.g. internet consent), the participant must be provided with some way to contact the researcher for additional information, if needed.

The researcher should also take steps to ensure that those who consent do so freely, in the absence of coercion. Conducting research at institutions that provide services to participants may be perceived as implying that continued service is dependent upon participation in the research. Researchers are responsible for understanding and complying with other federal laws relevant to their research and for ensuring that their consent process and forms comply with these additional regulations.

Unanticipated Problems and Adverse Events

Investigators must report any unanticipated problem or unanticipated adverse event that occurs during the research to the IRB as soon as possible. An unanticipated problem is defined as a difficulty that is unexpected (in terms of nature, severity, or frequency) considering the research procedures described in the research protocol and informed consent forms approved by the IRB; and the characteristics of the participant populations being studied.

Not all adverse events and problems are unanticipated. Studies that involve more than minimal risk, for example, will likely have detailed procedures for dealing with problems that may occur. When these problems occur, they are "anticipated." The investigator must deal with these in an ethical manner and in accord with their approved protocols. Ordinarily, these events need not be reported to the IRB.

With some high-risk studies, however, the IRB may request that the investigator report any adverse events, whether anticipated or not. This request may be made at the time of initial approval as a condition of approval, or during ongoing review of the research. In those cases, the investigator should follow the procedures described here for reporting all adverse events.

Problems and adverse events are considered "unanticipated" when they are unforeseeable or not consistent with the known or anticipated risks associated with the research. An example of an unanticipated problem that should be reported is the theft of a computer containing sensitive data that can be linked to individual participants given the files contained on the computer. Examples of problems that would not be reported are the loss of de-identified information or the research taking longer than expected.

Investigators must report the following to the IRB in writing:

1. The title of the study and the investigator's name. If the investigator is a student, the investigator should also provide the name of the Faculty Advisor.
2. A detailed description of the adverse event, incident, experience, or outcome, and any effects the event has had on research participants.
3. An explanation why the investigator believes that the adverse event is an unanticipated problem.
4. A description of corrective actions that have been taken or are proposed in response to the unanticipated problem. Examples of changes include: methods of reducing harm to a participant or set of participants, changes to the protocol to reduce the likelihood of similar incidents occurring the future, and suspension or discontinuation of the research.

The IRB Chairperson should report such events to the CAO immediately upon receipt of this information. If the adverse event or unanticipated problem does not meet any of these criteria, the investigator must file the written documentation of the adverse event within two weeks of becoming aware of the problem.

Disciplinary Actions

The IRB Chair may suspend research upon receipt of credible information that an investigator is not complying with IRB policies or that serious harm has occurred. The IRB Chair must communicate that s/he is suspending the research to the investigator in writing and should inform the CAO that the research has been suspended. Serious harm should be documented using the procedures described in the separate "Adverse Events" section of these guidelines.

Failure to follow IRB policies and procedures in data collection is an ethical violation that can result in serious penalties for those involved. When the IRB receives credible information that a student, faculty member, staff member, or other individual associated with Sura College has failed to comply with IRB regulations or requirements, the IRB should investigate possible noncompliance with IRB procedures.

Following the investigation, the IRB should determine whether noncompliance has occurred, along with any corrective and/or disciplinary steps to be taken. Depending on the nature and severity of the noncompliance, these steps could range from corrective education to termination of the research. In the case of a student project, the IRB may prohibit the student from using the data to fulfill thesis requirements if those data were collected in violation of IRB policies or procedures.

Research may be terminated only after review by the full IRB. In determining whether to terminate research, the IRB will investigate the relevant dimensions of the concerns brought before it, the seriousness of these concerns, and the likelihood of recurrence. If the IRB

permits the research to continue, the IRB may require changes to research procedures or other corrective actions.

The IRB Chair will report the results of any IRB investigation undertaken in response to serious harm or allegations of noncompliance to the investigator and to the CAO. The report should be in writing and should describe the reasons for the IRB's findings and action(s). If the investigator is a faculty member, the IRB will provide the faculty member's Dean/Program Chair with a copy of the report. If the investigator is a student, the IRB will provide a copy of the report to the student's faculty advisor of the research as well as faculty member's Dean/Program Chair.

Graduate Student Nursing Research Exempt Process
(Non-Human Subject Research)

Steps 1 through 5 need to be completed prior to any data collection.

1. Early in the planning process of your rapid-cycle, evidence-informed, quality improvement project, contact the Sura College Practica and Project Coordinator at projectpractica@SURA.edu to review the capstone/project template.

2. Complete the capstone/project template to the best of your ability outlining your ideas for your rapid-cycle, evidence-informed, quality improvement project.

3. Make an appointment with the Practica and Project Coordinator to discuss your capstone/project ideas and receive guidance in completing the capstone/project template. The following items will also need to be developed as part of your capstone/project:
    a. Data collection forms, surveys, questionnaires, and/or educational materials.
    b. Timeline for completing the project including dissemination.
    c. Submission of required OHRP training and continuing education to remain up to date on federal regulations (Certification needs to be completed by the Principal Investigator [PI] and all study team members).

4. Submit your capstone/project template to be reviewed and approved by the Practica and Project Coordinator. The Practica and Project Coordinator will review/approve documents for:
    a. Scholarly soundness, literature to support study aims, clear definitions of timeframes, subject and interventions.
    b. Tools to be used in study.
    c. If your capstone/project is not approved, the template will be sent back to you with stipulations. Contact the Practica and Project Coordinator for guidance in how to address the stipulations for your capstone/project.
    d. If your capstone/project is approved, you will receive an approval letter from the Practica and Project Coordinator/IRB Chair.

5. Once you receive the approval letter for your capstone/project from the IRB Chair, you may begin your capstone/project.
    a. This letter is provided as verification that your capstone/project meets the criteria for a rapid-cycle, evidence-informed, quality improvement project and is not subject to IRB review and approval in accordance with Sura College IRB policy.
    b. This letter constitutes Sura College IRB approval and designation.
    c. It is the responsibility of the project PI to retain the letter. The letter may be scanned and submitted as needed for publication or academic use.

Graduate Student Nursing Research Exempt Template

(Non-Human Subject Research)

When submitting your rapid-cycle, evidence-informed, quality improvement capstone for designation as an exempt project, use the following template as a guide and do not include other specific headings.

Section I.

1. Principal Investigator:		
2. Sub Investigators:	1)	2)
	3)	4)
3. Study Contact:	☐ ***Practica and Project Coordinator:*** ***Projectpractica@SURA.edu***	☐ **Preceptor:**_____ _____
4. Participating Campus(es):	☐ _____ _____	☐ _____ _____
7. Project Title:	_____	
8. Introduction/ Significance to Nursing:	Brief overview of the purpose of the project (Limit 500 words). • Why the study is important for nursing (e.g., patient experience of care, patient or health outcomes, cost of care, nursing practice). • Problem statement; aims of the study; or PICOT question.	
9. Brief Literature Review:	Provide a brief summary of articles reviewed for the purpose of this study (Limit 1000 words). • What is currently known about the topic?	
12. Project Steps:	Provide a description of the steps of the project to be conducted. • Project objectives • Setting and needed resources (if any) • Data source • Measures/monitors: data collection forms for the project • Steps for Implementation of Project, including broad timeline description • Project Evaluation Plan	
13. Ethical Implications:	Identify any ethical implications r/t Data Source & Storage, PHI protection, PHI-Storage, etc.	

14. References:	Reference List (Brief list of approximately 2 – 5 references)

Other Required Items to submit:

1. **Submission of required OHRP training and continuing education to remain up to date on federal regulations.**

2. **You will need to upload any and all data collection forms with your submission. If you are using questionnaires, you will need to submit those as well. Form permissions must be documented as required.**

3. **You will also need to upload any educational and/or informational material that you plan to use for the project. You may submit a PowerPoint outline or other educational/informational handouts or WORD documents related to your project.**

You may not begin implementing your project until you receive the exempt approval letter from the Sura College IRB Chair.

Section II.

Do Not Write in this Space – Sura College IRB notation only

Approved by Sura College IRB Chair: _____

Approval Date: _____

Graduate Student Nursing IRB Approval Checklist

(Non-Human Subject Research)

Indicate type of Project: Research _____ Quality Improvement (QI): _____

Title of Project: _____

Name & Credentials of Project Principal Investigator (PI):_____

PI's Primary Institution (College/ University): _____

The Sura College Institutional Review Board (IRB) requires that all research projects must have review and approval from their designated departments before IRB review may begin.

Quality Improvement (Non-Human Subject Research) projects may require review and designation for the purposes of an academic requirement and/or future publication of project results.

Attestation from Sura College Institutional Review Board:

On behalf of the PI's primary institution, I / We attest that all of the following conditions have been satisfied:

- The PI is an employee or student of the Institution and is in good standing;
- The PI is approved to devote the proposed time and effort to this project;
- The proposal is a complete and coherent one;
- It is feasible to implement and complete the identified project within the specified timeline;
- If the PI's proposal identifies a request for funds, space, and/or supplies required to support this project, the institution endorses this commitment;
- If the project is research, it has scientific merit, uses procedures consistent with sound research design, and is likely to yield knowledge;
- If the project is QI, it is sound and adheres to appropriate process improvement methods.

I / We have reviewed and confirmed the previously identified conditions have been met for this project.

Name: _____ Date: _____

SC EDON: _____

Name: _____ Date: _____

SC IRB Chair: _____

Institutional Review Board

IRB Application

Instructions: Incomplete applications will not be reviewed. The content of this application as well as all supporting documents will be kept confidential within the limits of the law. *All applicants must submit this completed application and await disposition of the application outcome before proceeding with the proposed project or study. Do not edit or revise the application form.*

I. INVESTIGATION TITLE:

II. PRINCIPAL INVESTIGATOR:

Name: Title:
Affiliated Program:

Mailing Address:

This address is: ☐ Home ☐ Work

Work Phone: _____ Home Phone: E-mail Address:

III. SUPERVISING FACULTY (if applying as a student):

Name: Title: Affiliated Program:

Mailing Address:_____

This address is: ☐ Home ☐ Work

Work Phone: _____ Home Phone: E-mail Address:

IV. PROJECTED DATES OF RESEARCH (Subject Recruitment, Data Collection, Data Analyses):
Start Date: End Date:

V. LOCAL LAWS
The investigator must ensure that components of the proposed project or study comply with local state laws relating to human subject protections. If applicable, the investigator must list local state laws that apply to the study, and explain how they have been incorporated for compliance. If no state laws apply to the study, please indicate this. No state law applies to the study, subjects will get informed consent

VI. SIGNATURES: The undersigned acknowledge that: 1. this application represents an accurate and complete description of the proposed research; and 2. research will be conducted in compliance with the recommendations of and only after formal written approval has been received from the Institutional Review Board (IRB). The principal investigator is responsible for reporting any serious or unexpected adverse events or problems to the IRB that occur during the implementation of the study or project, for requesting IRB approval for modifications, for requesting continuing review and approval, and for notifying the IRB of project completion.

A. Principal Investigator:_____
_____ TYPED NAME PLUS WRITTEN OR ELECTRONIC
SIGNATURE DATE

B. Supervising Faculty:_____
_____
(**If Student Application**) TYPED NAME PLUS WRITTEN OR ELECTRONIC SIGNATURE DATE

VII. EXISTING DATA

Will this study involve the use of existing data, documents, records, and pathological specimens?
No ☐ **Yes** ☐ If yes, include a **letter of authorization to access any data that are not publicly available**.

VIII. MULTI-CENTER STUDY

Will multiple institutions participate in this study? Yes ☐ No ☐
If "Yes", which institutions will participate? _____
How many subjects are anticipated at each site? _____

IX. STUDY DESCRIPTION

Note: Use SINGLE LINE spacing. Type in your answers in the gray box below each section (if you cut and paste from other documents, please make sure your formatting is consistent).

A. STUDY ABSTRACT / OVERVIEW. In **200 words or less**, describe in **lay language** the nature, purpose, methods, risks, and risk management procedures of the proposed study/ project.

B. STUDY PURPOSE OR AIMS. In **lay language**, briefly describe the overall purpose or aims of the study.

C. STUDY HYPOTHESES, QUESTIONS, OR OUTCOMES

1. List the study hypotheses, research questions, or study outcomes.

2. Briefly describe how hypotheses will be tested, questions answered, and/or outcomes measured.

3. Are you using a questionnaire, survey instrument, or interview as part of your procedure?
Yes ☐ No ☐

If yes, submit a copy of the questionnaire(s), survey(s), or interview questions.

SUBJECTS: Fill in as applicable if you will be recruiting human subjects

1. Subjects to be Recruited (check all that apply)

- ☐ Adults (18-65 years)
- ☐ Children and Minors (< 18 years)
- ☐ Cognitively Impaired Persons
- ☐ Prisoners
- ☐ Elderly/Aged Persons (>65 years)
- ☐ Minorities

2. **Data will include** (check all variables included)

- ☐ Income
- ☐ SS #
- ☐ Job title
- ☐ Names of employers
- ☐ Types of employers
- ☐ Names of people
- ☐ Addresses
- ☐ Phone numbers
- ☐ Age
- ☐ Gender
- ☐ Ethnicity (Hispanic)
- ☐ Marital status

3. **Total number of subjects who will be contacted to participate:** ☐

4. **Total anticipated number of subjects who will participate:** ☐

5. **Does this study involve participants who are not fluent in English?** Yes ☐ No ☐

6. **For how long a time will each subject be involved in this study?**
(If you are using your subjects on more than one occasion, indicate the number of such occasions and their duration.)

7. **Recruitment Source**. Identify the location from which subjects will be recruited (e.g., schools, university campus, fitness facilities, hospitals, etc.).

8. **Recruitment Methods**. Describe how subjects will be identified and recruited. If subjects are identified from private or student records, provide documentation that authorizes your access to those records (HIPAA or FERPA forms). The official holder of the record must make initial contact of subjects identified through records to initiate involvement in the research protocol. ***Please submit advertisements, flyers, contact letters, telephone contact protocols/scripts, web site template, or other recruitment materials proposed for use in subject recruitment as appendix attachments***.

9. **Equity**: Explain how you will achieve equitable subject representation from the subject population in the following categories. Please explain why any category will be excluded.
    a. Age (minors, elderly):
    b. Gender:
    c. Ethnic and racial minority populations:
    d. Socioeconomic status:
    e. Persons with limited English-language skills:

10. **Inclusion Criteria**: What characteristics must subjects have to be in this study?

11. **Exclusion Criteria**: What characteristics would exclude subjects who are otherwise eligible from this study?

D. INFORMED CONSENT PROCESS

Typically, signed informed consent is required for adult subjects. For non-emancipated minors, signed informed consent must be obtained by the minor's parent or legal guardian. In addition, verbal assent from the minor must be obtained prior to participation. If the minor is capable of reading and understanding information about the study, a signed assent form should be obtained from the minor as well.

The need for signed consent and assent forms, however, may be waived by the IRB for studies examining common educational practices and tests conducted in common educational settings, for studies observing public behavior, or for other situations described in Title 45 Section 46.101. Additionally, the requirement for documentation of signed informed consent form may be waived by the IRB if all apply:

a. The study involves no more than minimal risk, **AND** consent would not be needed for the procedure/ intervention if it was occurring outside a research study;

OR

b. The major risk in the study is a breach in confidentiality, **AND** the consent form is the only way to link subjects to the study.

In addition, the requirement for signed informed consent may be waived if it would be impractical or jeopardize the integrity of the findings, as long as the study involves only minimal risk, the lack of a signed informed consent will not jeopardize the rights and welfare of subjects, and the signed consent form would be the only document identifying the subjects.

If signed informed consent is NOT obtained, adult subjects should still receive written information about the study and that participation is completely voluntary.

Please check all that apply:

This study will include:

Signed informed consent form
Yes ☐ No ☐

Parental/ Guardian signed informed consent form Yes ☐ No ☐

Minor assent form
Yes ☐ No ☐

Written information about the study (if not using consent form) Yes ☐ No ☐

If any of these forms will be used, please submit a copy with the IRB submission. *(Note: All forms should be in a reader-friendly format and provided at a reading level appropriate to the subject population.)*

If **NONE** of these forms will be used, please provide an explanation.

Does this study involve:

a. Incomplete disclosure to subjects at the onset of the study? Yes ☐ No ☐
b. Deception of subjects? Yes ☐ No ☐

If "Yes" to either, please explain why incomplete disclosure or deception is necessary and describe the procedure you will use to debrief you subjects. ***You must indicate a willingness to allow subjects to withdraw from the study after debriefing and remove from your data all records of their involvement***. Please submit a copy of the debriefing script you will use.

E. STUDY LOCATION

Identify the location and describe the setting of where the subjects will participate in this research (i.e., where will the study procedures be carried out. ***Please submit copies of IRB approvals or letters of cooperation from non-Sura College research sites, if necessary as appendix attachments.***

F. STUDY PROCEDURES

Please describe in sufficient detail and in lay language the procedures you will be doing to or with your subjects.

For faculty conducting research, please describe the planned roles, activities, and preparation for using students as research assistants. (If non-applicable, indicate "N/A".)

G. RISKS AND BENEFITS

1. **Identification of Risks**. Describe nature and degree of risk of potential injury, stress, discomfort, invasion of privacy, psychological harm, and other possible risks from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires.

2. **Management of Risks**. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare.

3. **Identification of Benefits**. Describe the anticipated direct and/or indirect benefits of this research for individual subjects.

H. COSTS, COMPENSATION AND INCENTIVES

1. **Costs**. Describe any costs that the subject (or third-party payors) may incur as a result of participation (e.g. charges for tests, travel costs, etc.).

2. **Compensation and Incentives**. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ Yes ☐ No.

   If "Yes", provide details of this compensation. Describe how and when compensation will be provided. Describe how compensation will be determined and provided should a subject withdraw from the study.

I. CONFIDENTIALITY OF RESEARCH DATA

1. Will you obtain from your subjects information about their private behavior, economic status, sexual activity, religious beliefs, or other matters which, if made public, might impair their self-esteem or reputation, or could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing or employability? ☐ Yes ☐ No

   If "Yes," describe the means you will use to ensure that all your data are kept secure and confidential until they are destroyed.

2. How will you protect subjects' confidentiality?

3. How and to whom will data/ results from this study likely be shared or disseminated?

4. How will you destroy data and records at the end of the study? In general, it is Sura College IRB practice to store hard copy data for seven (7) years in a locked file or password protected device. After seven (7) years, all hard copy data should be shredded and video and/or audiotapes erased.

K. CONFLICT OF INTEREST

The Sura College IRB considers the investigator's financial interests when evaluating the protection of human subjects. If a financial interest is reported, the Sura College IRB will assess the investigator's objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. The Sura College IRB may also review disclosures when a financial interest is reported.

Does any member of the research team have a financial interest in the research or its products or in the study sponsor? ☐ Yes ☐ No

Please explain in detail any financial interest involved (a letter stating the nature of the financial interest may be requested by the IRB):

X. ADDITIONAL INFORMATION

Please identify which of the following documents are provided with this submission:

- ☐ Documentation of completion of OHRP modules (Required)
- ☐ Assurance of Confidentiality Agreement (Required)
- ☐ Full study protocol (Required)
- ☐ Recruitment materials: Identify:
- ☐ Questionnaires/ surveys/ interview questions/ tools: Identify:
- ☐ Informed consent form
- ☐ Parent/ guardian consent form
- ☐ Assent form
- ☐ Written information provided to subjects
- ☐ Permissions/ authorizations/ approvals from IRBs from other institutions: Identify:

☐ APPROVE ☐ DISAPPROVE

INSTITUTIONAL REVIEW BOARD Chair: _____ DATE _____

Subject to the following conditions _____

_____

_____

Period of Approval is **ONE** year, from _____ through _____

Review Category: ☐ Full Review ☐ Expedited ☐ Exempt

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED