**Nursing Research Council**

**Scientific Review Tool**

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| **Principal Investigator (PI):** | **Date:** |
| **Study Name**: | |

***Instructions for Reviewer:*** *Please enter your scientific review comments in the sections below in demonstration of a full scientific review. Include both positive and negative comments as applicable.*

*Please list any items needing further attention in closing comments. (See Guide to Assist the Reviewer)*

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| **Hypothesis/Problem Statement**: Is the research hypothesis/problem statement clear? |
| **Purpose of Research:** |
| **Study Design:** Is the design sound? Are subject recruitment and study procedures clear? |
| **Literature Review/Background:** Does it support study objectives? Is it complete? |
| **Data Analysis:** Are endpoint(s) and data analysis clear and justifiable? |
| **Human Subject:** Are all risks addressed for human subjects (physical, financial, employability, emotional, psychological, loss of privacy, loss of confidentiality)? Have these risks been minimized? Are they reasonable? |
| **Data Management:** Are methods for properly securing data during the study and destroying data after the study clearly described (for protection of confidentiality)?  *(Note: The research team is responsible for maintaining a safe research environment. Prior to initiating the study, all team members will be informed of this safety plan. Each month while the study is in progress the principal investigator (PI) and Co-PI will review the data safety and monitoring plan and identify actual or potential threats to the safety of the patients and the integrity of the data. Although the procedures to be used in this study pose minimal risk to study participants, the research team will be prepared to address all levels of adverse events if they occur. Any adverse event will be immediately reported to the NRC & SRHS IRB. The SRHS IRB will make a decision about the safety and continuation of the study, and whether meetings must be called by the respective groups to evaluate the situation).* |
| **Consent:** (Use the SRHS standard consent template) |
| **Reviewers Recommendation for IRB Review** (See Research Status Determination Guidelines)  1. Full Review Yes\_\_\_\_\_ No\_\_\_\_\_  2. Expedited Yes\_\_\_\_\_ No\_\_\_\_\_  3. Exempt Yes\_\_\_\_\_ No\_\_\_\_\_ |

**Closing Comments**:

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**Reviewer’s Recommendation**: □ Approval □ Return to PI to address above comments

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**Reviewer Name, Credentials, Department, Phone Number** **Date**

Instructions to principal investigator (PI) student if not approved \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Maintain completed form for 36 months past completion of study. 2018/19

**Guide to Assist the Reviewer When Using the Scientific Review Tool**

**PRINCIPLE INVESTIGATOR:**

-Name of the nurse researcher

**CO-INVESTIGATOR:**

-Anyone actively assisting with data collection and/or analysis of the results

-Does not usually include instructor if doing in conjunction with degree requirement

**TO BE CONDUCTED AT:**

-Identify areas of facility impacted by research proposal

**HYPOTHESIS/PROBLEM STATEMENT:**

-What are they expecting to prove/disprove by the research?

-Should be as concrete as possible so results can easily be determined

and bear out their expectation

-Should be kept simple

**PURPOSE OF THE RESEARCH**

-What is the issue?

-Why is it of interest to the principle investigator?

-What do they expect to get out of the research?

-Benefit to nursing

-Benefit to patients, staff

-Benefit to facility

**STUDY DESIGN**

-Qualitative versus Quantitative?

-Descriptive?

-Blinded?

-Controlled?

**PROCEDURE**

-Sample size

-Limitations/exclusions

-Instruments

-Any instruments obtained from other sources (requires permission from

creator)

-Instruments they have developed (include information of reliability and

validity tests they have done with the instrument).

-Methods

-How are they going to carry out the research?

-ID and contact persons to survey

-Distribution and collection of surveys

-When & how collect data

-Timeline

-Date ranges for research data

**PROCEDURE CONT.**

-Timeline of project expectation from start to finish with milestones

Included:

-Proposal

-Completion of CITI Course

-Approval from committee if degree project

-Approval for scientific merit

-IRB approval

-Completion of data collection and interpretation

-Write up

-Return to nursing to share results

**DATA ANALYSIS:**

-How do they plan to evaluate the data you have collected?

-What statistical measures/tests are they going to apply to the data?

-What confidence interval are they going to shoot for?

**HUMAN SUBJECTS RESEARCH:**

-Identify any risks to subjects

-Discuss how they will minimize any physical, emotional or other risk the

subject may be exposed to as a result of your research proposal.

-Any consent required to collect the data?

**DATA MANAGEMENT:**

-Who is collecting the data?

-How is it being collected to ensure patient health information (PHI) anonymity is maintained?

-Are they using a statistician to summarize and test their data?

**DATA SAFETY AND MONITORING PLAN:**

-How frequently will the program be evaluated to identify threats to safety

of patients and integrity of the data?

-What is the plan if a subject appears to have suffered an adverse event

during the research?

-What is the plan if it appears that the security of the data or any PHI

contained in the data has been compromised?

**REFERENCES AND RESOURCES:**

-Are the references appropriate for the study?

**RESEARCH STATUS DETERMINATION GUIDELINES**

**FOR IRB APPLICATION**

**IRB REVIEW OPTIONS:**

**FULL REVIEW:** The probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**EXPEDITED:** Research activities that present no more than minimal risk to human subjects **AND** (ii) involve only procedures not impacting patient outcomes or disease processes.

1. Clinical studies of drugs and medical devices only when condition (a) **OR** (b) is met: a. drugs for which an investigational new drug application is not required. (***NOTE:*** Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible); b. research on medical devices for which 1) an investigational device exemption application is not required or 2) the medical device is cleared
2. or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
3. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a. from healthy, non-pregnant adults who weigh at least 110 pounds, not to exceed 550 ml/8 weeks/2 items per week; or b. from other adults and children, considering the age, weight, and health, collection procedure, amount of blood to be collected, and frequency; not to exceed lesser of 50 ml or 3 ml/kg/8 weeks/2 times per week.
4. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings in a non-disfiguring manner; deciduous teeth when they fall out or if care indicates extraction; permanent teeth if indicated for extraction; excreta and external secretions (including sweat); noninvasive saliva collected stimulated by chewing or stimulation of taste buds; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; dental plaque and calculus, not more invasive than routine prophylaxis; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.
5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; weighing or testing sensory acuity; MRI; ECG, EEG, thermography, detection of naturally occurring radioactivity, electroretinography, US, diagnostic infrared imaging, Doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing appropriate given the age, weight, and health of the individual.
6. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
7. Collection of voice, video, digital, or image recordings made for research purposes
8. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**EXEMPT:** Certain categories of research have been designated as exempt related to the use of human subjects. Institutions may choose to recognize these categories of exemption and waive the requirement for review by an Institutional Review Board (IRB).

1. Conducted in established or commonly accepted educational settings, involving normal educational practices, such as a. regular/ special ed instructional strategies, or b. the effectiveness/comparison among instructional techniques, curricula, or class methods.
2. Use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: a. information recorded in so human subjects can be identified, directly or indirectly through identifiers linked to the subjects; **AND** b. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects’ financial standing, employability, or reputation.
3. Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
4. Research and demonstration projects which are conducted by or subject to approval of [federal] department or agency heads, and which are designed to study, evaluate, or otherwise examine a. public benefit or service programs; b. procedures for obtaining benefits or services under these programs; c. possible changes or alternatives to those programs or procedures; or d. possible changes in methods or levels of payments for benefits or services under those programs.
5. Tests and food quality evaluation and consumer studies, a. if wholesome food without additives is consumed, or b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the USDA.