Washington State University **I**nstitutional **R**eview **B**oard (**IRB**)
Office of Research Assurances
PO Box 643005 Albrook 205
Pullman, WA 99164-3005
Telephone: (509)335-3668 Fax: (509)335-6410 Email: irb@wsu.edu Web site: www.irb.wsu.edu

Exemption Determination Application

IRB Use Only – Do Not Write or Mark in This Box

IRB Application No:_____

☒ **Certified Exempt under 45 CFR 46.101(b)…**
☐ **1** ☒ **2** ☐ **3** ☒ **4** ☒ **5** ☒ **6**
☐ **Exemption or approval not required due to: _____**
☐ **Research may not be certified as exempt due to: _____. Must be re-submitted on Non-Exempt Application**

Signature: _____Print Name: _____Date: _____

NOTE: EXEMPTION CERTIFICATION IS NOT APPROVAL. THE STUDY MATERIALS SHOULD NOT INCLUDE THE STATEMENT THAT WSU IRB HAS REVIEWED AND APPROVED THE STUDY FOR HUMAN SUBJECT PARTICIPATION.

Instructions:

- *WSU IRB will determine whether or not your research qualifies for exemption. Do NOT begin data collection prior to IRB determination.*
- *All materials must be typed; handwritten materials will be returned.*
- *DO NOT leave a question blank; write "n/a" if a question does not apply to the application.*
- *If WSU IRB determines that a study meets the criteria for exemption research, the regulatory requirements for informed consent do not apply. However, research that is exempt from federal regulations is not exempt from ethical standards as outlined in the Belmont Report. This means, for example, that if potential subjects will be interviewed in a study that qualifies for exemption, they must be fully informed and free to choose whether to participate.*
- *WSU researchers (faculty and staff) conducting research in Deaconess Medical Center, Holy Family Hospital, Sacred Heart Medical Center, St. Luke's Rehabilitation Institute, and Valley Hospital & Medical Center should contact WSU IRB at 335-3668 prior to filing this application.*
- *WSU researchers (faculty and staff) using DSHS records or facilities should contact WSU IRB at 335-3668 prior to filling this application.*

1. Principal Investigator (PI) Contact Information: (***PI must be WSU faculty or staff****, and will be the study supervisor at WSU. Students, post-doctoral researchers, and visiting faculty may not serve as PI, but may be listed as co-investigators in Section 4. All correspondence will be directed to the PI listed below*.)

   Last Name: Eide First Name: Phyllis WSU ID #: 10599407

   Department: Nursing Position: Associate Professor Campus: Spokane

   Address/Mail Code: 1495 Phone: x47246 E-mail: eide@wsu.edu

2. Study Title: _____

Answer the questions below:

1. ☒ Yes ☒ No Is the data being obtained about living individuals, directly or indirectly?

2. ☒ Yes ☒ No Is the data collected through intervention or interactions with individuals, including by internet or email?

3. ☒ Yes ☒ No Does the data contain identifiable private information?

If you answer "NO" to all the above questions, your research does not involve human participants and IRB review is not required.
If you answer "YES" to one or more of the above questions, your research involves human participants and you need to complete question 4 below.

4. ☒ Yes ☒ No Is the study a systematic investigation, including research development, testing and evaluation, and designed to develop or contribute to generalized knowledge?

If you answer "NO" to the above question, your study is not research and IRB review is not required. However your study may qualify for non-regulatory review. Please contact the Office of Research Assurances staff at 509-335-3668.

If you answer "YES" to the above question, your study is research and you need to complete sections 2 and 3 ('screening questions' and 'exemption categories and determinations').

Federal regulations specify that certain types of research pose low risk to participants, and therefore MAY qualify for EXEMPTION under federal regulations. To determine if your study is exempt, answer the following screening questions.

1. ☒ Yes ☒ No Will participants be asked to report their own or others' sexual experiences, alcohol or drug use, and will their identities be known to you?

2. ☒ Yes ☒ No Are the participants' data directly or indirectly identifiable, and could these data place subjects at risk for criminal or civil liability, or might they be damaging to subjects' financial standing, employability or reputation?

3. ☒ Yes ☒ No Are any participants confined in a correctional or detention facility?

4. ☒ Yes ☒ No Are participants involved who may not be legally/mentally/cognitively competent?

5. ☒ Yes ☒ No Are personal records (medical, academic, etc.) used with identifiers and without written consent?

6. ☒ Yes ☒ No Will alcohol or drugs be administered?

7. ☒ Yes ☒ No Will blood/body fluids be drawn?

8. ☒ Yes ☒ No Will specimens obtained from an autopsy be used?

9. ☒ Yes ☒ No Will you be using pregnant women by design?

10. ☒ Yes ☒ No Are live fetuses participants in this research?

If you answer "YES" to any of the above questions, then your research is NOT exempt and you need to fill out the non-exempt application.

<u>If</u> you answer "NO" to all the above questions, your research might be exempt if it fits into one of the 6 exemption categories in Section 3.

EXCEPTIONS: The exemption categories listed below do not apply when the research includes the following:

- Prisoners

- Survey or interview techniques which include minors as participants (this applies to exemption category #2 only)
- Observation of minors where the investigator participates in the activities being observed (this applies to exemption category #2 only)
- Food and Drug Administration (FDA) regulated research (this applies to exemption categories 1-5 and includes projects for which the data will be submitted to or held for inspection by the FDA, or research for which the investigator gathers data on participants who serve as controls for participants who receive FDA-regulated drugs or medical devices, other than in the course of medical practice.)

Research activities are exempt from the federal regulation 45 CFR 46.101(b) for the protection of human participants when the ONLY involvement of human participants falls within one or more of the categories below. Check the appropriate categories that apply to your research study:

1. ☒ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

   i. research on regular and special educational instructional strategies, **or**
   ii. research on the effectiveness of **or** the comparison among instructional techniques, curricula, **or** classroom management methods.

2. ☒ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   i. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; **and**
   ii. any disclosure of the human participants ' responses outside the research could reasonably place the participants at risk of criminal or civil liability; **or**
   iii. be damaging to the participants ' financial standing, employability, or reputation.

   PLEASE NOTE: According to 45 CFR 46.401(b), this exemption does NOT apply to survey or interview procedures when the participants are children.

3. ☒ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:

   i. the human participants are elected or appointed public officials or candidates for public office; **or**
   ii. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. ☒ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants. **PLEASE NOTE: According to the Office for Human Research Protections (OHRP), "to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; participants must consent to participation in research."**

5. ☒ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

i. public benefit or service programs;
ii. procedures for obtaining benefits or services under those programs;
iii. possible changes in or alternatives to those programs or procedures;
iv. possible changes in methods or levels of payment for benefits or services under those programs.

6. ☒ Taste and food quality evaluation and consumer acceptance studies:

i. if wholesome foods without additives are consumed **or**
ii. 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If you mark one or more of the six exemption categories above, complete the remainder of the application and submit to WSU IRB. WSU IRB will determine whether or not your research qualifies for exemption. Do <u>NOT</u> begin data collection without exemption certification from IRB.

Justification of Exemption Category

You must justify how your study qualifies for exemption by addressing the **<u>critical elements</u>** of the exemption category you choose. The critical elements for each category are:

Category 1: Specify whether 1(i) or 1(ii) applies and briefly explain.

_____

Category 2: Assure that condition 2(i) will be met and briefly explain how; and assure that condition 2(ii) applies; and attach a copy of test/survey/interview questions or items.

_____

Category 3: Explain why conditions 2(i) and 2(ii) cannot be met; and attach a copy of test/survey/interview questions or items; and either assure and briefly explain that condition 3(ii) applies, or explain subject's public office and how it precludes anonymity (i.e., 3(i)).

_____

Category 4: Briefly explain the nature of the existing data/documents and briefly explain either their public availability or the procedures to ensure anonymity and confidentiality.

_____

Category 5: Briefly explain method by which the project is reviewed and approved by a federal department/agency head; and identify and describe which of the 5(i) – 5(iv) categories apply.

_____

Category 6: Assure that condition 6(i) will be met; and assure via documentation regarding approved safety levels that condition 6(ii) will be met.

_____

Human Participants Training: WSU IRB requires the PI and encourages all staff involved in this research to complete CITI training in the ethical use of human participants in research. Re-training is required every five years. For CITI training options, visit the CITI website at http://www.citiprogram.org. If you have any further questions, contact the IRB coordinator at 335-3668 or irb@wsu.edu. ***Attach documentation of training for PI.*** *The PI is ultimately responsible to adequately train all staff listed on the application in the protection of human participants in research.*

1. Human Participant Training Record (CITI –WSU) of Principal Investigator:

   Date of Training: _____ Ref #: _____

2. Co-Investigator(s) (Co-PIs) Contact Information and Role in study*: (Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up*. NOTE: *If necessary, attach a list of additional Co-PI's.)*

WSU I.D.#	Last Name	First Name	E-mail	Role in the study

3. Estimated Study Start Date: _____ Duration of the Study: _____

4. ☒ Yes ☒ No Is this research supported in whole or in part by a grant or contract?

   Funding Agency(s), Foundation, or Business: _____

   PI on Grant/Contract: _____ OGRD #: _____

   Grant Title/Contract: _____

5. ☒ Yes ☒ No Does the research require another IRB's review (US and International)?
   If **yes**, complete below.

   Name of the IRB: _____ FWA # or equivalent #: _____

(*NOTE: PI is responsible for securing approval and forwarding the documentation of approval to WSU IRB).*

6. ☒ Yes ☒ No Does the PI, Co-PI, or any other person responsible for the design, conduct, or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interest would reasonably appear to be affected by the results of the study? If yes, complete below:

Name of the person with potential conflict of interest (COI): _____

Explain the potential financial conflict of interest:

_____

Explain how the potential conflict of interest will be managed? (*If the economic interest is a "significant economic interest" as defined in WSU's Conflict of Interest Policy, submit the management plan established with the Conflict of Interest Committee.*)

_____

7. ☒ Yes ☒ No Is the proposed research study conducted at an outside (non-WSU) facility or entity (such as hospitals, clinics, schools, school districts, factories, offices, etc..,)? If yes, complete below.

The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e. agrees to participate). By signing this application, the researcher indicates they will comply with this requirement.

Name (s) of the facility or entity: _____

Provide below brief details of the proposed research. Use lay language and avoid technical terms.

1. Intent of the research study (hypothesis or research question of the study):

_____

2. Participants (describe your inclusion criteria and methods of recruiting):

_____

3. Procedures (describe your data collection methods etc.):

_____

4. Data confidentiality and security during collection, analysis, and storage:

_____

5. Risks (describe any potential risks to participants--physical, psychological, social, legal or other):

_____

6. Benefits (describe any benefits to the participants and society):

_____

Indicate that you have read and will comply with each statement.

1. ☒ I certify that the information provided in this application, and in all attachments, is complete and correct.

2. ☒ I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.

3. ☒ I agree to comply with all WSU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.

4. ☒ I certify that:
   - the study will be performed by qualified personnel according to the WSU IRB-approved application.
   - the equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
   - unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the WSU IRB Office (509-335-3668; irb@wsu.edu) and to my Departmental Chair/Director/Dean
   - I am familiar with the latest edition of the *WSU Manual for the Protection of Human Research* participants, available at www.irb.wsu.edu, and I will adhere to the policies and procedures explained therein.
   - student and co-investigators on this study have received adequate training and are knowledgeable about the regulations and policies governing this research.
   - I agree to ensure adequate supervision of all research study personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.

5. ☒ I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

PI Name: _____Signature*: _____Date: _____

* Only required if not submitted from the PI's WSU email account

How to Submit:

1. By email. You may attach the application and supporting materials (survey questions, interview guide, etc.) to an email sent to **irb@wsu.edu**. If sent from the PI's WSU email account, a physical signature is not required.

2. A hard copy of the application and supporting materials (survey questions interview guide, etc.) may be sent to the Office of Research Assurances. Interdepartmental mail may be directed to Campus ZIP **3005**, Intercampus Mail to **Albrook 205** or hard copies may be hand-delivered to **Albrook Hydraulics Lab, room 205**. If sending a hard copy, the application must bear the PI's physical signature. Hard copies must be single-sided and must not be stapled or folded.

Please allow for up to 10 business days for the ORA to complete exemption determination.