***Doctoral Dissertation Research Approval Form***

***General information:***

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

1. What is your intent of the research study (hypothesis or research question of the study)?

Click here to enter text.

2. Is the project a systematical investigation, including research development, testing and evaluation?

Click here to enter text.

3. Participants: describe your subjects and methods of recruiting them. Also describe anything that would cause you to exclude a particular subject, and why.

Click here to enter text.

4. Procedures: describe your data collection methods, such as “Survey” or “Public observation,” etc.

Click here to enter text.

5. Will you collect subject identities in conjunction with the data? If so, how will you prevent disclosures?

Click here to enter text.

6. Will the subject’s participation be recorded (audio/video)?

Click here to enter text.

7. How will you store the data after you complete the research (data retention schedule)?

Click here to enter text.

8. Will the subjects be offered an incentive to participate or compensated for their time?

Click here to enter text.

9. Does your research pose risk of harm to subjects? Describe any foreseeable risks and your plan to reduce or eliminate them.

Click here to enter text.

10. Will the research utilize existing or secondary data which contains individually identifiable private information?

Click here to enter text.

11. Can subjects reasonably expect a direct benefit from participation? Describe any foreseeable benefit to the subjects.

Click here to enter text.

12. How will society benefit from your research? Is the project designed to contribute to generalizable knowledge?

Click here to enter text.

**Section 1, Human Subject Research Determination**

*Answer the questions below:*

1. Will your investigation gather information about living human individuals?

 [ ]  Yes [ ] No

1. Will you be interacting with the respondents or intervening in their daily routine, including via the internet or over the phone?

 [ ]  Yes [ ] No

1. Are you collecting data that would allow you or another researcher to identify the participants (examples: Name, Social Security Number, phone number, mailing address, email, medical record number or any other number or code that pertains specifically to an individual)?

 [ ]  Yes [ ] No

1. Is the data collected considered to be private information, which the participant expects will not be made public, or collected within a context which an individual would not otherwise expect to be observed or recorded (such as in their home)?

 [ ]  Yes [ ] No

**If you answer “NO” to EACH of questions 1-4, your research does not involve human participants and HRPP 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.**

1. Are you conducting an investigation, a searching inquiry to gather facts, or an examination of a phenomenon?

 [ ]  Yes [ ] No

1. Is it systematic, involving a system, method, or plan that will be employed consistently throughout data collection?

 [ ]  Yes [ ] No

1. Will your findings be presented beyond the university setting, such as presented at a conference, or published in a peer-reviewed journal **or** used in a dissertation?

 [ ]  Yes [ ] No

1. Will your conclusions be presented as representative of the larger population from which your sample was recruited? (Mark ‘No’ if the data collected applies only to the sample population)

 [ ]  Yes [ ] No

*If you answer “NO” to questions 5-8, your study is not research and HRPP review is not required.*

*However your study may qualify for non-regulatory review.*

*If you answer “YES” to one or more of questions 5-8, your study is research.*

*Continue to Section 2.*

**Section 2, Screening questions**

*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. Will participants be asked to report their own or others' sexual experiences, alcohol or drug use, and will their identities be known to you?

[ ]  Yes [ ] No

2. 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?

[ ]  Yes [ ] No

3. Will you be recording the subjects’ participation by video or audio for reasons **other** than transcription?

[ ]  Yes [ ] No

4. Are any participants confined in a correctional or detention facility, including involuntary assignment to community-based alternatives to incarceration (drug treatment facilities, etc.)?

[ ]  Yes [ ] No

5. Are participants involved who may not be legally/mentally/cognitively competent?

[ ]  Yes [ ] No

6. Are personal records (medical, academic, etc.) used with identifiers and without written consent?

[ ]  Yes [ ] No

7. Will alcohol or drugs be administered to the subjects?

[ ]  Yes [ ] No

8. Will blood/body fluids be drawn from participants?

[ ]  Yes [ ] No

9. Will specimens obtained from an autopsy be used?

[ ]  Yes [ ] No

10. Are live fetuses subjects in this research?

[ ]  Yes [ ] No

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.

If you answer “NO” to all the above questions, your research may be exempt.

Complete Sections 3-4

**Section 3, Exemption categories and determinations**

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,

• Observation of minors where the investigator participates in the activities being observed,

• Food and Drug Administration (FDA) regulated research.

*This applies to exemption categories that include 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 IUL HRPP. The IRB committee will determine whether or not your research qualifies for exemption. Do NOT begin data collection without exemption certification from IRB committee.*

**Justification of Exemption Category**

You must justify how your study qualifies for exemption by addressing the critical elements 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.

Click here to enter text.

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.

Click here to enter text.

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)).

Click here to enter text.

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.

Click here to enter text.

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.

Click here to enter text.

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.

Click here to enter text.

**Section 4, Investigator’s responsibilities and assurances**

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 information contained in this 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 IUL Office and to the Campus Director

• I am familiar with the latest edition of the IUL 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 exemption has been certified.

Name: Click here to enter text.: Date: Click here to enter a date.

How to Submit:

*Attach the application and supporting materials (recruiting materials, survey questions, interview guide, etc.) to an email sent to* *dbastudies@aulm.us* *.*

*Please allow for up to 10 business days for review of your application determination.*