***Internal office use only:***

Full Board \_\_Expedited \_\_ Exempt\_\_

Approved by\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_

Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Application for the Involvement of Human Participants in Research**

###### *Institutional Review Board*

Violet Lumley Rau Building, Academic Affairs Office, 3240 Fort Road, Toppenish, WA 98948

(509)-865-8530 Nash\_K@heritage.edu

**[Place your responses in the boxes below the appropriate questions.]**

**SECTION I: Researcher Information**

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| --- | --- | --- | --- | --- |
| **Nature of Study:**  (Place an “X” in the column. Check only one.) |  | Faculty Research |  | Graduate Research |
|  | Dissertation |  | Undergraduate Research |
|  | Other |  | Staff Research |

**Study Title**:

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**Investigator Correspondent Information:**

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|  | **Principal Investigator (PI)** | **Student Investigator** (only for Student Initiated Research) | **Correspondent** (primary point of contact for correspondence, if applicable) |
| Name (First, Last, Degree): |  |  |  |
| Program: |  |  |  |
| E-Mail Address: |  |  |  |
| Preferred Phone #: |  |  |  |

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**SECTION II: Exempt Categories**

**Normal educational practices and settings**

**Anonymous educational tests, surveys, interviews, or observations**

**Identifiable subjects in special circumstances (e.g. public officials or candidates)**

**Collection or study of existing data**

**Public benefit of service programs**

**Taste and food evaluation and acceptance studies**

If you believe that your research is exempt, please *circle the category* above that describes it and complete Sections III through V below. Explain why you believe it fits into the category that you circled. Include an explanation of how you will gather data.

**SECTION III: The Research**

In the box below, describe your study in brief and include:

* An explanation of how you will gather data.
* An overview of the risks of the study.
* How you will select participants.
* Why do you believe it sits in the exempt category?

**Study Objective (short summary of study):**

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**SECTION IV: Informed Consent**

**As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about the study. (A checklist to help you create a consent form can be found as Appendix I on page 8. Following that, a template for an information sheet for your participants can be found as Appendix II on page 10.)**

**Consent Setting**

Describe the consent process including who will obtain consent, where and when will it be obtained, and how much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).

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**Capacity to Consent**

Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers, hearing & vision difficulty, literacy barriers or other impairments. If a participant is incapable of providing consent, you will need to obtain consent from the participant’s legal guardian (please see the IRB website for additional information).

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**Parent/Guardian Permission and Assent**

If enrolling children, state how many parents/guardians will provide permission, whether the child’s assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.

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**Documentation of Consent**

Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).

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**If you do not intend to apply for a waiver or alteration of consent, attach your consent form, sign this application on the last page and submit it. If you do intend to apply for a waiver, respond to the prompts below.**

**Waiver or Alteration of Consent**

The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a waiver of consent (i.e., participants will not be asked to give consent), an alteration of consent (e.g., deception) or a waiver of signed consent (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:

1. Why is the study considered to be minimal risk?
2. How will the waiver by the IRB committee affect the participants’ rights and welfare? The IRB must find that participants’ rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.
3. Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.
4. How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.
5. Waiver of signed consent (i.e. participants give consent only after reading an information sheet)
6. Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.
7. Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.
8. Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.
9. Indicate how you will provide the subjects with the required consent-related information about your study (e.g. an oral explanation or a written information sheet).

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**SECTION V: Human Participants**

**HU Students or Employees:**

Are you recruiting students who are in a class you teach or for which you have responsibility?

**Yes**

**No**

If ‘Yes,” explain why this population is necessary to the study and indicate precautions taken by the researchers to minimize potential undue influence or coercion:

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**Approximately how many participants will be enrolled?**

Note: Participants are generally considered to be ‘enrolled’ when they sign the consent form or have gone through an oral consent process. Therefore, be sure to account for attrition in your enrollment number.

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**Special Population(s):**

Identify any special participant population(s) that you will be **specifically targeting** for the study.

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| Check **all** that apply: (Place an “X” in the column next to the name of the special population.) |  | Children |  | Economically/Educationally Disadvantaged |
|  | Prisoners |  | Members of the Armed Forces |
|  | Pregnant Women/Neonates |  | Indigenous |
|  | Decisionally Impaired |  | Hispanic Latino |
|  | HU Students |  | Non-English Speaking |
|  | HU Employees |  | Individuals Living with AIDS/HIV |
|  | Other (Please identify): |  |  |

**Recruitment:**

Describe the recruitment process including *who* will recruit, *when* and *where* recruitment will take place and *how* participants will be identified and recruited (e.g., direct recruitment by study team in person, on the phone, by mail/email/internet, random sampling, referrals from other participants, snowball sampling and/or healthcare providers). Attach copies of all advertisement/recruitment materials for IRB review including phone scripts, web postings, newspaper advertisements. If recruiting at off-campus sites, written permission and/or local IRB approval may be required.

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**SECTION VI: Research Plan**

**Purpose**

State the reason for the study and the goals you hope to achieve.

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**Design, Procedures, Materials and Methods**

Describe the study design, including expected start and completion dates.

1. If the study involves use of deception, explain the reason why this is necessary.
2. If the research involves study of existing samples and or records, describe how authorization to access those samples/records will be obtained.
3. Describe the use of any audio and/or video recordings and provide justification for their use.
4. Be sure to submit copies of any surveys or interview questions.
5. In general, describe what participants will be asked to do.

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**Inclusion/Exclusion Criteria**

List major inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.

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**Risks and Inconveniences**

Describe the potential risks to participants (and secondary participants, if applicable) and *steps taken to minimize risks*. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).

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**Benefits**

Describe anticipated benefits to the individual participants or to society (e.g.. added knowledge to the field of study) or a specific class of individuals. Do not include compensation or earned course credits in this section.

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**Risk/Benefit Analysis**

Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.

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**Economic Considerations**

Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan for compensation.

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**Data Safety Monitoring**

This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at Heritage University except for studies determined to be exempt from continuing IRB review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate.

Issues that should be addressed in the DSMP include the following:

1. frequency of the monitoring
2. who will conduct the monitoring (Under HU policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.)
3. what data will be monitored
4. how the data will be evaluated for problems
5. what actions will be taken upon the occurrence of specific events or end points
6. who will communicate to the IRB and how communication will occur

Sample response to issues listed above for minimal risk/slight increase over minimal risk-“Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (item 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6).”

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**Privacy/Confidentiality**

Explain how the privacy interests of participants will be maintained during the study (note that privacy pertains to the individual not to the data). Describe procedures for protecting confidentiality of data collected during the study and stored after study closure. Describe how data will be coded. Describe plans for storage and security of electronic data (plan must comply with the HU policy). If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether an limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.

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**SECTION VII: Avoiding Conflicts of Interest**

How is your research funded?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Do you anticipate financial gain from the research for yourself, your domestic partner, or your family members? If so, explain.

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**HIPAA Authorization**

On the HU campus, there are no sites that are covered entities under the Health Insurance Portability and Accountability Act. However, if research participants are recruited through entities such as Toppenish Hospital, Farm Workers Clinic, Children’s Village, etc., it may be necessary to obtain a Waiver of Authorization to allow you to access records for recruitment and an Authorization to use and disclose Protected Health Information (PHI). **Note:** Student Health Services is not covered by HIPAA; however, FERPA regulations apply.

**Appendix I**

**Consent Form for Participation in a Research Study**

Feel free to create your consent form in whatever format works for your study and is easy for your participants to understand. Include the following components:

**Checklist:**

* Researcher contact information for questions about the study
* Study title
* Purpose of study
* What will the participant be asked to do?
  + If there is a survey, describe the topics covered. Clarify that participants do not need to answer all questions, if they do not choose to.
  + Where and when will the research be conducted?
  + How much time will it take?
  + Will the participants be recorded, photographed, or videotaped?
* Describe the possible risks.
  + Identify steps taken to minimize risks.
  + If there are no known risks, then use the following **suggested statement** in this section: “We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study.”
* For biomedical research, describe what options are available.
* Disclose any financial relationship the researcher has with the study that might constitute a conflict of interest.
* If the research involves use of deception or incomplete disclosure, insert the following **suggested statement**: “Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study.” Please note: the last sentence can be further customized to say, “We will give you a full explanation as soon as you complete the study.
* Benefits of the study
  + Do not include payment or other incentive as a benefit.
  + If the research may lead to the development of a commercial product, make it clear whether or not the participant will share in the economic benefit.
* Will there be payment for participation? Are there costs to participate?
  + If participants will not receive payment and there are no costs, state “There are no costs and you will not be paid to be in this study.”
  + If the research involves HU students and they are rewarded with extra credit, offer other options for earning the extra credit.
* Describe how the participants’ personal information will be protected.
  + State how long study records will be kept, where they will be kept (consider long-term storage) and who will have access to them. If participants are audio or video recorded, describe who will transcribe or view the tapes. Please note: study records may be kept indefinitely, as long as the data has been stripped of identifiable information and described as such in the consent form.
  + Describe how identifiers are encrypted, e.g. “Records will be labeled with a code that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key and audiotapes will be destroyed after \_\_ years. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.”
  + For longitudinal studies, describe what happens to data already collected if the participant decides to withdraw from the study.
* Describe any situations in which confidentiality cannot be guaranteed (such as reporting requirements for child abuse and neglect
* Encourage participants to ask any questions that they may have about the study.
* Include the statement, “You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.”
* If you have any questions concerning your rights as a research participant, you may contact the Heritage University Institutional Review Board (IRB) at 509-865-2123.

**Documentation of Consent:**

[Use the following **required statement** and format for this section: “I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.”

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Participant Signature: Print Name: Date:

Relationship (only if not participant): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Signature of Person Print Name: Date:

Obtaining Consent

**Appendix II**

Template for Information Sheet for Participation in a Research Study

[Give participants a copy of the information sheet for your study.]

**Principal Investigator:**

**Student Researcher:** [Remove if N/A]

**Study Title:**

**Sponsor:** [Remove if N/A]

Introduction

You are invited to participate in a research study to …

# Why is this study being done?

What are the study procedures? What will I be asked to do?

What are the risks or inconveniences of the study?

What are the benefits of the study?

How will my personal information be protected?

I recognize that I can withdraw at any time.

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

# Whom do I contact if I have questions about the study?

We will be happy to answer any question you have about this study. You may contact the principal investigator, (insert name and phone number) or the student researcher (insert name and phone number). If you have any questions concerning your rights as a research subject, you may contact the Heritage University Institutional Review Board (IRB) at 509-865-8598.

Each application must be accompanied by the researcher’s signature below:

**Principal Investigator Certification**

I understand Heritage University’s policies concerning research involving human participants and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by Heritage University, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;
3. To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form;
4. To report to the IRB in accordance with IRB policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval/Completion Form as needed;
6. That my participation and the participation of any co-investigators does/do not violate the Heritage University policy on individual conflicts of interest in research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

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| **Original Signature of Principal Investigator** | **Print Name** | **Date** |

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| **Original Signature of Student Investigator**  **(Only for Student-Initiated Research)** | **Print Name—Student Investigator** | **Date** |

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| **Original Signature of Medical Monitor**  **(Required for all studies that will be monitored by a Physician)** | **Print Name of Medical Monitor** | **Date** |