##### *Heritage University – Institutional Review Board*

# ADMINISTRATOR AND REVIEWER’S CHECKLIST – New Study Exempt Research

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| --- | --- |
| **Protocol #:** |  |
| **Title:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **ADMINISTRATIVE CHECKIST** | | | **COMMENTS** |
| Documentation for each researcher on file:   1. Names/signatures. 2. CV/resume, qualifications. 3. CITI training certificates 4. Conflict of interest statement. | YES | NO | List anything not documented, including qualifications: |
| Special Population(s) Identified | YES | NO | List populations identified: |
| \*Note: Any research on the Yakama Nation involving Yakama Nation people, land, space, names, heritages, traditions, languages, religion, etc., must also be approved by the official Yakama Nation Tribal Council Education Committee *prior to IRB review.*  *Has the researcher received a letter of approval?*    *Before the application is sent to the chair or reviewer, this documentation (or a description of the progress to receiving this approval) must be received.* | | | |
| Consent Document(s) Received | YES | NO\* | \_\_\_ Consent(s)  \_\_\_ Assent(s) for persons with reduced autonomy [script or form]  \_\_\_ Study Info Sheet(s)  \_\_\_ Waiver of Consent Requested. |
| Recruitment Material Received | YES | NO |  |
| Data Collection Instrument Received | YES | NO |  |
| Source of Funding Identified | YES | NO | Specify: |
| Human Subjects section of Federal Grant Application/Proposal Received | YES | NO | If Federally funded, a copy of the "Human Subjects” section of funding proposal is required |
| Is the type (if any) compensation disclosed for study participants? | YES | NO |  |
| Permission Letters / Off-Site Research Agreement Received | YES | NO | Specify: |
| If recordings are being made (audio, video, photograph) and will be kept beyond time for transcription purposes only, are participants consented and release forms used for this? | YES | NO |  |
| Protected Health Information (PHI) Accessed, Created, or Disclosed | YES | NO |  |
| If PHI is accessed, created, or disclosed, is one of the following (1-3) provided? Which. | YES | NO | 1. The facility’s standard HIPAA statement includes this research. 2. A new HIPAA PHI authorization form is created for this research. 3. A partial HIPAA waiver is requested for recruitment purposes only.\* (Reviewer, see page 2 for requirements). |

\*Please note that any waivers or alterations of HIPAA may only be granted via a convened meeting of the Board.

Administrator: List any questions that are unanswered on the application form:

Administrator: If vital questions are unanswered or clarifications are needed to answer these questions, please include any correspondence with the researcher(s) below.

##### *IRB Administrator Additional Documentation for the Reviewer or for the record:*

**ADMINISTRATIVE COMMENTS SUBMITTED TO THE LEAD RESEARCHER (LR) (and responses, if applicable):**

**Notes/questions from the administrator for the reviewer:**

**Notes/questions from the administrator or researcher for the chair or full IRB:**

|  |  |  |
| --- | --- | --- |
| Initial Review | Review of Contingencies | Change in Protocols |

REVIEWER'S CHECKLIST FOR EXEMPT PROTOCOLS

IRB Administrator, fill in the next 5 lines before submitting to reviewer:

**IRB #:**

**Reviewer:**

**Date:**

**Investigator:**

**Due Date for Review**:

Enclosed is a **HUMAN RESEARCH PROTOCOL** for review. Please address each of the categories numbered below. As you review the study, please check if the information is adequate. Please use the second checklist below while reviewing each element of the **RECRUITMENT STATEMENT/COVER LETTER** (if applicable). Organize your written comments/suggestions below or on additional pages using the same numbers as used for each category.

1. **Reviewer Conflict of Interest Certification:**

* I **do NOT** have a Conflict of Interest in reviewing this Protocol\*:

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* I **have** a Conflict of Interest on this Protocol\*:

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*If you are reporting a conflict of interest please sign and provide to the IRB administrator immediately to allow for reassignment to another reviewer

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**YES NO NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Funding source/conflict of interest/Qualifications** |  |  |  |
| 1. Researcher identifies funding sources or states there is none. |  |  |
| 1. There is no conflict of interest between funding sources and the project |  |  |  |
| 1. PI has qualifications required to oversee research |  |  |
| **2. Appropriate category for research** |  |  |  |
| 1. Meets the regulatory definition for human subject’s research. |  |  |
| 1. Application meets this qualification of exempt research.   Category: |  |  |  |
| **3. Recruitment** |  |  |  |
| 1. Researcher has provided sufficient information on recruitment methods (including copies of any recruitment materials) |  |  |  |
| **4. Participants** |  |  |  |
| 1. Researcher has identified the target number of research subjects/records/specimens to be examined |  |  |  |
| 1. “Section V: Spec. Pop. ID’s (x) children and (x) indigenous, must consult with local tribal council education committee for approval of study. |  |  |  |
| 1. Subjects are over age 18 and under age 89 |  |  |  |
| 1. Specifically targeted groups are identified (age, gender, etc). |  |  |  |
| **5. Consent** |  |  |  |
| 1. Method(s) for obtaining consent are appropriate |  |  |  |
| 1. If requested, waiver of consent is appropriate |  |  |  |
| 1. Consent form or written script for consent is included with proposal and is suitable |  |  |  |
| **6. Compensation** |  |  |  |
| 1. Type/amount of compensation (if any) is described |  |  |  |
| 1. If class credit is part of compensation, alternative method(s) for obtaining credit are explained and acceptable |  |  |  |
| **7. Data protection** |  |  |  |
| 1. Data will be kept in a secure location or on a password-protected computer |  |  |  |
| 1. Health information is not collected ***or***   Health information is collected and a HIPAA De-Identification Certification form is attached, ***or***  Research is covered under the facility’s current HIPAA disclosure, ***or***  A new HIPAA disclosure form approved by the facility will be signed by participants.  *(If identifiable data will be collected, the study does not qualify as exempt from IRB oversight.)* |  |  |  |
| **8. Abstract** |  |  |  |
| 1. Abstract addresses exemption categories selected (e.g., type of data collected is appropriate, subject categories are acceptable, etc.) |  |  |  |
| 1. Abstract describes study procedures sufficiently |  |  |  |
| 1. Abstract describes duration of project (including time subjects will take part) |  |  |  |
| 1. Abstract describes benefits/risks of research to subjects and society |  |  |  |
| 1. Abstract describes how confidentiality/anonymity of subjects will be maintained |  |  |  |
| **8. Conclusion** |  |  |  |
| 1. Do the benefits of the research outweigh the risks and/or are the risks minimal: |  |  |  |

RECRUITMENT STATEMENT/COVER LETTER and CONSENT FORM INCLUDES: YES NO

|  |  |  |
| --- | --- | --- |
| 1. Investigator's names ***and*** ranks |  |  |
| 2. Explanation of purpose ***and*** justification of research |  |  |
| 3. Description of subject's participation, procedures involved, ***and*** duration |  |  |
| 4. Description of risks ***and*** minimization of risks |  |  |
| 5. Explanation of how confidentiality/anonymity is protected |  |  |
| 6. Description of benefits to subject/society |  |  |
| 7. Explanation of voluntary participation, will not be treated any differently if they choose not to participate, and may withdraw from the research at any time. |  |  |
| 8. Statement naming investigator who will answer questions ***and*** phone number. |  |  |
| 9. Is the letter clearly written and in lay language? |  |  |
| 10. Is there a “key information” section at the beginning of the consent form that outlines the information from the consent template (can be removed for shorter consent forms, < 2000 words). |  |  |
| 11. If recruiting non-English speaking participants, is a translated consent form provided? Is there evidence that the translation is accurate?  Certified translation.  Attested translation.  Translation back from non-English language to English is comparable to original English translation. |  |  |
| 12. Is there evidence that the researcher understands that consent is more than just providing information and that the participants must also demonstrate understanding of the study? |  |  |

# **The following statements MUST ALL ALSO be true for the study to be exempt**

The research does not involve prisoners.

The **ONLY** involvement of human subjects will be in research activities that fall under one or more of the

exempt categories.

List the exempt category(ies): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

See the IRB manual for more information.

If there is an intervention, is it “benign, brief, and harmless” and not in children?

Is participation in the study anonymous OR is the data being collected non-sensitive and adequately secure?

**Reviewer’s recommendation (select only one):**

**This scholarly activity does not meet the regulatory definition of “human subject research”** and therefore does not need to be approved or monitored by IRB. Societal principles of respect for persons, justice, consent, avoidance of coercion, and other ethical principles should still guide this academic inquiry.

**Exempt status confirmed:** The study meets the criteria for exempt category(ies) # **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Revisions/clarifications required:** Comments/suggestions/objections are listed or are attached.

**There are aspects of this research protocol that I do not feel comfortable assessing. I require another IRB member or outside expert’s consultation and/or I would like to refer to the full board for discussion.** Comments/suggestions/objections are listed or are attached.

**Does not meet exempt status; requires full board or other review:** Comments/suggestions/objections are listed or are attached.

\*Upon indicating “Exempt status confirmed”, I have determined that the research study, as described, qualifies for exemption and that the protocol, as described, meets the ethical standards for research conducted at Heritage University. Specifically, the three key ethical principles of the Belmont Report, respect for persons, beneficence, and justice are adhered to.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Reviewer Date**

Note to Researcher: The recommendation provided on this form is that of one reviewer. It may be preliminary and may not necessarily reflect the discussion and final decision and/or recommendation of the IRB Chair or Full Board. The researcher will receive a letter signed by the chair of the final determination of the exempt status of research.