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**HUMAN RESEARCH PROTECTION REVIEW**

**Form 1: Overview & Pre-Screening**

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| **SECTION 1: PROJECT OVERVIEW** |

**A. Project Title:**

**B. Study Lead & College Role:**

**C. Key Personnel:**

Key Personnel are those who participate in conducting the research study (e.g., interacting with participants, collecting data, analyzing data, etc.).

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| **Name** | **Department or Other Affiliation** | **Email** | **Project Role** | **Training Source & Date\*** |
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\*IRB Application will not be processed until all Key Personnel listed have completed training. This training can be [CITI Training](https://about.citiprogram.org/course/social-behavioral-educational-sbe-foundations/) (paid) or the US Department of Health and Human Services’ [Human Research Protection Foundation Training](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html) (free).

**D. Funding:** Is the proposed project funded through external funding source(s)? [ ]  **Yes** [ ]  **No**

*If yes, list External Funding Source(s):*

**E. Financial Conflict of Interest:** Do any of the Key Personnel / investigators 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?[ ]  **Yes** [ ]  **No**

*If yes, describe:*

**F. Proposed Project Duration:**

*Anticipated Start Date:*

*Total Project Duration (# of months):*

**G. Objectives:** *State the* ***purpose******and specific aims of the study****; include the hypotheses to be tested or the research questions that will guide the study. Use plain language and keep description brief.*

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**H. Rationale:** *Provide the scientific or scholarly* ***background*** *for,* ***rationale*** *for, and* ***significance*** *of the proposed study based on existing literature and explain how it will add to existing knowledge. Briefly summarize the relevant current context of the study and gaps in current knowledge. Use plain language and keep explanation brief.*

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**I. Subject Procedures:** *Briefly describe proposed study activities and indicate how project data will be gathered or generated. Describe how the investigator will recruit subjects to participate and explain consent/assent procedures, if applicable.*

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**J. Data Collection, Storage, and Sharing:** *What types of data will be collected and created? Where will active (live) data be stored and backed up? How will sensitive data be secured? How will the final research data be archived and shared (if applicable) after the study concludes? Please note that research projects receiving federal funding will likely require a Data Management Plan; please contact the Institutional Review Board at* *IRB@clackamas.edu*

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| **SECTION 2: HUMAN SUBJECTS RESEARCH PRE-SCREENING** |

Refer to the Appendix for some examples.

**A. RESEARCH DETERMINATION**

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| 1. Is the project intended to be 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 used consistently throughout data collection? Does this project incorporate data collection, either quantitative or qualitative, and data analysis to answer a question?
 | [ ]  **Yes** | [ ]  **No** |
| 1. Are the results of the project expected to expand the knowledge base of a scientific discipline, or other scholarly field or study, and be publicly disseminated so that the results can be used to develop, test, or support theories, principles, and statements of relationships or inform policy beyond the study?
 | [ ]  **Yes** | [ ]  **No** |
| 1. Will the results be applicable to a larger population beyond the site of data collection or the individual subjects? (Check “**No**” if the conclusions will apply only to the sample population).
 | [ ]  **Yes** | [ ]  **No** |

*If the answers to* ***ALL questions in Section 2A are NO****, it is likely the project does NOT meet the federal definition of research and IRB review is not required. Email this completed form to the Institutional Review Board at* *IRB@Clackamas.edu* *for confirmation.*

*If the answer to* ***ANY of the questions in Section 2A is YES****, it is possible this project meets the definition of research. Additional information is required.* ***Proceed to******Section 2B*** *of this form.*

**B. HUMAN SUBJECTS DETERMINATION**

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| 1. Will investigators use, study, or analyze information **about living person(s)**?
 | **☐ Yes** | **☐ No** |
| 1. Will investigators **obtain information through** **intervention or interaction with subjects**?

***Intervention or Interaction:*** *Any communication or interpersonal contact between investigator and subject, such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, or experimental procedures.* | **☐ Yes** | **☐ No** |
| 1. Will investigators obtain, use, study, analyze, or generate **identifiable private information?**

***Identifiable private information****:* *Information subjects expect would 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).****AND****The identity of the subject is or may readily be ascertained by the investigator or associated with the information.* | **☐ Yes** | **☐ No** |

*If the answers to* ***ALL questions in Section 2B are NO****, it is likely the research does NOT meet the federal definition of human subjects and IRB review is not required. Email this completed form to the Institutional Review Board at* *IRB@Clackamas.edu* *for confirmation.*

*If the answer to* ***Question 1 in Section 2B is YES and either Question 2 or Question 3 are also marked YES****, the research involves human subjects. Additional information is required:*

* *Form 1: Project Overview & Pre-Screening is now complete;* ***retain form for IRB submission and review.***
* ***Complete Form 2****: Exemption Certification to determine if the project qualifies as exempt.*

*This form was adapted from* [*Portland State University’s Form*](https://sites.google.com/a/pdx.edu/research/integrity/hrpp/forms)

[*Code of Federal Regulations, Title 45 CRF Part 46*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) *(referred to as the “Common Rule”)*

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| **APPENDIX: RESEARCH EXAMPLES** |

State-mandated or accrediting body-mandated assessment work is **unlikely** to be considered human subjects research.

Student evaluations or other survey work specifically designed to improve course delivery is **unlikely** to be a research project as this work is generally not intended to contribute to generalizable knowledge and is part of best practices for continual improvement.

Course assignments are **unlikely** to be research projects as this work is not generally disseminated to the public or used to expand our current understanding in a particular field of study. However, ethical research practices should be considered when designing and implementing these course assignments.

Sabbatical projects **could** be human subjects research projects, depending on the study design and intention to disseminate results.

Work done as part of a project that anticipates publishing the results or sharing the results with the public and using the results to add to the body of knowledge in a field of study, whether grant-funded or not, has a **greater chance** of qualifying as human subjects research.