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| **Public Health Division/Multnomah County Health Department**  **CONTINUING REVIEW QUESTIONNAIRE (CRQ)**  **Application for a PH IRB continuing review** |  |

**Funding Source** Name of Source:

NIH Institute? Yes  No  If grant, provide title:

[List of NIH Institutes, Centers, and Offices](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) Grant #:

Duration of Grant:

Final Common Rule Agency? Yes  No

[List of Agencies signed onto The Final Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/)

Other? Please specify:

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| **A. Background Information** |

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| Date: | Current PH IRB approval expires: |
| Study Title: | |
| PH IRB Study No: | |
| Brief Description of Study: | |
| If a multiple phase study, identify which phase(s)/aim(s) have been completed and which phase/aim you are seeking continuing approval for: | |
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| **B. Project Status** |

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| 1. | Estimated study completion date: | |
| 2. |  | Active – open to enrollment: |
|  |  | No enrollment to date |
|  |  | Enrollment has begun and is ongoing  Analyzing identifiable data, documents, or specimens |
|  |  | Active – closed to enrollment (check one of the following): |
|  |  | Long-term follow-up of subjects continues  All research related interventions have been completed  Data analysis only. If checked, is the data identifiable and private information?  Yes  No  \*If all research-related interventions or interactions with participants have been completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished, the study may be closed with the IRB. [Find the Final Study Report/Closure Form here](https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/forms.aspx). |

If the study was closed prior to completion (study will no longer be pursued) or the study is complete (enrollment, treatment, data collection, follow-up and data analysis of identifiable private data are complete) stop and complete the Final Study Report/Closure Form.

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| **C. Update on Subject Selection and Recruitment** |

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| 3. | |  | Target enrollment: (provide estimate for studies where enrollment is based on reportable condition) | | | | | | | | | | | | | | |  | | |
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| 4. | |  | Number of subjects enrolled to date (or in the case of identifiable data reviewed where no direct contact occurs with subjects, the number of subjects referenced by the study): | | | | | | | | | | | | | | |  | | |
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| 5. | |  | Number of subjects enrolled and remain in follow-up (e.g. continuing to collect health or other information or are returning for visits): | | | | | | | | | | | | | | |  | | |
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| 6. | |  | Number of subjects withdrawn since the last continuing review (provide brief explanation for withdrawals): | | | | | | | | | | | | | | |  | | |
| 7. | |  | If enrollment is occurring at a much slower rate than expected, provide explanation and any plans to increase enrollment: | | | | | | | | | | | | | | | | | |
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| 8. | Ethnic Category | | | | |  | | | Sex/Gender | | | | | | | | | | | | | | | |
|  |  | | | | Female | | Male | | | | Transgender | | | Unknown | | | Total | | | | | |
|  | Hispanic or Latino | | | | |  |  | | | |  | | |  | | |  | | | | | |
|  | Not Hispanic or Latino | | | | |  |  | | | |  | | |  | | |  | | | | | |
|  | Unknown | | | | |  |  | | | |  | | |  | | |  | | | | | |
|  | Total: | | | | |  |  | | | |  | | |  | | |  | | | | | |
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|  | Racial Category | | | | | | | Female | | Male | | | Transgender | | | Unknown | | | Total | | |
|  | American Indian or Alaskan Native | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Asian | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Black or African American | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Native Hawaiian or other Pacific Islander | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | White | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | More than one race | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Other | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Unknown | | | | | | |  | |  | | |  | | |  | | |  | | |
|  | Total: | | | | | | |  | |  | |  | | |  | | | |  | |
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| **D. Update on Research Design and Procedures** |

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| 9.a. | Have any changes occurred to the protocol or design of the study since the PH IRB’s last review (include changes submitted to the PH IRB by PRAF)? If yes, provide brief description of changes: | Yes  No |
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|  | b) Were these changes submitted for IRB approval prior to implementation?  If no, why not? | Yes  No |
|  | c) Are you submitting any changes now to be considered as part of this continuing review? If yes, describe proposed changes and attach revised protocol and applicable documents: | Yes  No |
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| 10. | Have there been any presentations or publications resulting from the data collected for this study since the last IRB review? If yes, attach copy of the abstract or the publication. | Yes  No |
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| **E. Update on Research Risks** |

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| 11. | | Have the risks or benefits changed in a way that may affect participants or the data being collected? If yes, explain: | Yes  No | |
| 12. | | Since the last IRB review, have there been any publications in the literature, developments in the field, or other information that might affect the risks associated with this study. If yes, explain: | Yes  No | |
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| 13.a. | | Have there been any changes to the data confidentiality measures or data transfer/storage procedures described in the IRB approved IRQ or protocol? If yes, explain: | Yes  No | |
|  | | b) Were these changes submitted for IRB approval prior to implementation?  If no, why not? | Yes  No | |
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| **F. Event Reporting/Safety Monitoring** | | |

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| 14. | | Since the last PH IRB review, were there any of the following?  a) Unanticipated problems or adverse events (includes breaches of confidentiality)? | | Yes  No | |
|  | | 1. If Yes, was an UAP/AE Report submitted to the PH IRB? | | Yes  No | |
|  | | 1. If a Report was not submitted, explain why not: | |  | |
|  | | b) Protocol deviations or non-compliance? | | Yes  No | |
|  | | i. If Yes, was a Protocol Dev./Non-Compliance Report submitted? | | Yes  No | |
|  | | ii. If a Report was not submitted, explain why not: | |  | |
|  | | c) Un-reportable events? Meaning, expected problems that involve risks previously described to the IRB and/or participants? | | Yes  No | |
|  | | i. If Yes, provide a summary: | |  | |

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| 15. | Since the last IRB review, have any complaints been made by participants about the research? If yes, describe: | Yes  No |
| 16.a. | Is there a Data Safety Monitoring **Plan (DSMP)** included for this study?  *\*Required for NIH sponsored Phase I, II, & III clinical trials and multi-site clinical trials involving interventions with potential risks to participants. Also required for more than minimal risk studies (e.g. new/unfamiliar interventions not otherwise categorized as phase III clinical trials, multi-site research where the Public Health Division or MCHD is the coordinating site, or research that is blinded, multi-site, targets the enrollment of vulnerable populations, or employs high-risk intervention).* | Yes  No |
|  | b) If Yes, have you followed the approved monitoring plan for your study? If not, how has the plan been modified?  *Note: All changes to the DSMP must be submitted to the IRB for review.* | Yes  No |
| 17. | Is there a Data Safety Monitoring **Board (DSMB)** assigned to this study? If Yes, submit the most recent DSMB report to the PH IRB.  *\*A committee that collects and analyzes data during the course of a research study to monitor for adverse events and other trends that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial. Most appropriate for studies that involve blinded study treatment groups, multiple clinical sites, high risk interventions, etc.* | Yes  No |
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| 18. | Is there a Certificate of Confidentiality associated with this study? If yes, provide a copy of the Certificate. | Yes  No |
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| 19. | Has this study been approved or modified by other IRBs? If yes, provide a copy of the most recent IRB approval and any conditions. | Yes  No |
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| **G. Significant Financial Interest Disclosure** |

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| **Significant Financial Interest:** A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator’s spouse and dependent children) that reasonably appears to relate to the investigator’s institutional responsibilities:  a. Publicly-traded entity, if the value of any remuneration received from entity when combined with the value any equity interest exceeds $5,000;  b. Non publicly-traded entity, if the value of any remuneration received, when aggregated, exceeds $5,000, or when the investigator holds any equity interest; or  c. Intellectual property rights and interests. | | |
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| 20. | | Have the financial interests of key research staff changed since the studies initial review or last renewal? If yes, complete and return the Conflict of Interest Disclosure Statement found at: <http://www.healthoregon.org/irb>. (Includes the P.I., Co-I’s and other key personnel and any of their spouses or dependent children). | Yes  No | |

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| **If recruitment/enrollment is ongoing, attach a copy of the current approved protocol and consent form.** |

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| **H. Principal Investigator Assurance** |

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| Name: (please print or type):  I certify that the information provided is complete and accurate and I will continue to:   * conduct this study in compliance with the protocol as reviewed and approved by the PH IRB; * promptly notify the PH IRB of any proposed changes to the project and understand that no changes can be implemented prior to PH IRB review and approval; * promptly report any unanticipated problems or adverse events which become apparent during the course or as a result of the research and the actions taken as a result. In the case of DHHS sponsored research, I will also report such matters directly to DHHS; * promptly respond to all requests made by the PH IRB for review of this activity; * assure that identifiable information will be protected from improper use and disclosure; and * be responsible for the ethical conduct of this project, and for protecting the rights and welfare of participants in the research.                                         Signature Date |