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

*If funded by an agency that has adopted the Final Common Rule Regulations for the Protections of Human Subjects, a research project no longer requires a continuing review if it is eligible for expedited review or has progressed to the point that it involves one or both of the following:*

* *Data analysis, including analysis of identifiable private information or identifiable biospecimens*
* *Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care*

*If you believe the above apply or if you believe your study is ready to be closed out with the PH IRB, please contact PH IRB Coordinator at* *Alayna.n.forrest@state.or.us* *for further direction.*

**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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| **Background Information** |

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| Date:       | Current IRB approval expires:       |
| Study Title:       |
| 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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| **Project Status** |

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| **If recruitment/enrollment is ongoing, attach a copy of the current approved protocol and consent form (and/or assent form, parental permission form, authorization form).** |

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| 1. |  Estimated study completion date:       |
| 2. | [ ]  | Active (check one of the following): |
|  |  | [ ]  No enrollment to date |
|  |  | [ ]  Enrollment has begun and is ongoing |
|  |  | [ ]  Long-term follow-up of subjects continues |

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| **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 |       |       |       |       |       |
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| **Update on Research Design and Procedures** |

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| 9.a. | Have any changes (*minor or substantive*) occurred to the protocol or design of the study since the PH IRB’s last review? If yes, provide brief description and continue. **If no, skip to #10**:       | [ ]  Yes [ ]  No |
|  b. | Were these changes submitted for PH IRB approval prior to implementation in the form of a PRAF? If no, why not?      If not, please note a *Protocol Deviation Report* may need to be submitted at this time and the PH IRB may file this as non-compliance.  | [ ]  Yes [ ]  No |
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| 10. | 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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| 11. | Since the last PH 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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| 12. | Have there been any presentations or publications resulting from the data collected for this study since the last PH IRB review? If yes, attach copy of the abstract or the publication. | [ ]  Yes [ ]  No |
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| **Research Risks Update and Event Reporting** |

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| 13. | Have the risks or benefits changed in a way that may affect participants or the data being collected? If yes, explain:       | [ ]  Yes [ ]  No |
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| 14. | Have there been any changes to the data confidentiality measures described in the PH IRB approved IRQ or protocol? If yes, explain:       | [ ]  Yes [ ]  No |
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| 15. | Since our last PH IRB review, have any deviations from the approved protocol taken place and/or have any adverse events or unanticipated problems occurred? This includes any breaches. If yes, explain what happened, when you were made aware, and when you notified the PH IRB:     Note, if the PH IRB is just now being notified, a *Protocol Deviation Report* may need to be submitted, and this may be deemed non-compliance. | [ ]  Yes [ ]  No |
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| 16. | Since our last PH IRB review, have any complaints been made by participants about this research? If yes, we ask to be notified via e-mail immediately. Please describe the complaint and explain when the PH IRB was notified:      Note, if the PH IRB is just now being notified, a *Protocol Deviation Report* may need to be submitted, and this may be deemed non-compliance. | [ ]  Yes [ ]  No |

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| **Safety Monitoring** |

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| 17. | Is there a Certificate of Confidentiality associated with this study? If yes, provide a copy of the Certificate. | [ ]  Yes [ ]  No |
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| 18. | Has this study been approved or modified by other IRBs? If yes, provide a copy of their most recent IRB approval and any conditions. | [ ]  Yes [ ]  No |
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| 19. | Is there a Data Safety Monitoring **Board** (DSMB) or **Plan** (DSMP) assigned to this study? If yes, provides copies of any relevant DSMB reviews and a copy of the plan itself, or point it out to us in the protocol. | [ ]  Yes [ ]  No |

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| **Conflict of Interest Disclosure** |
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| 20. | Have the financial interests of key research staff changed since the studies initial review or last renewal? If yes and the effected researcher is from within the OHA or the MCHD, complete and return an updated Conflict of Interest Disclosure Statement found here: <http://www.healthoregon.org/irb> | [ ]  Yes [ ]  No |

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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:* Any remuneration received from a publicly-traded entity in the 12 months preceding the disclosure, if when combined with the value of any equity interest in the entity at the time of the disclosure, exceeds $5,000 (e.g. salary, stock, stock option, or other ownership interest and any payment for services not otherwise identified as salary such as consulting fees, honoraria, and paid authorship.
* Any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator/Key Personnel (or spouse/dependent children) holds any equity interest.
* Any financial interest from intellectual property rights and interests upon receipt of income related to such rights and interests.
* All reimbursed or sponsored travel related to the individual’s institutional responsibilities which IS NOT reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

*If your research team is from an external institution, that institution is liable for ensuring all senior and key personnel have current HSR training on file and accurate FCOI disclosures have been made*. If you are an internal researcher from within the OHA or the MCHD, the PH IRB Coordinator will now match records to ensure all key personnel are up-to-date on their HSR and FCOI training and a current FCOI disclosure form has been submitted (if applicable). **For that reason, at this time, submit the most up-to-date version of your Personnel Tracking Sheet. If you are not submitting any changes to personnel at this time, it should match PH IRB records.** |

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| **G. 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 (minor or substantive) to the project and understand that no changes can be implemented prior to PH IRB review and approval;
* promptly report any protocol deviations, 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;
* promptly notify the PH IRB via e-mail of any complaints received throughout the duration of this study;
* promptly respond to all requests made by the PH IRB for review of this activity;
* assure that identifiable information or biospecimen 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 and the confidentiality of their data.

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