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|  |  **Public Health Division/Multnomah County Health Department**  **FINAL STUDY REPORT/STUDY CLOSURE FORM** **Application to close out a study with the PH IRB** |

*A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing of identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing review.*

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| **A. Background Information** |

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| Date:       | IRB approval expiration date:       |
| Principal Investigator:       |
| Study Title:       |
| IRB Study No:       |
| Brief Description of Study:       |
| Study start date:       | Study end date:       |

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| **B. Project Status** |

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| [ ]  | Study completed (enrollment, treatment, data collection, follow-up, & data analysis are complete.) Complete remainder of form and submit a summary of study findings or final report. |
| [ ]  | Study was started but closed prior to completion and no further data collection (including long-term follow-up or re-contact) is planned. Explain why and complete remainder of form:       |
| [ ]  | Study was never started and participants never enrolled or data collected. Explain why and skip to section H:       |

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| **C. Participant Enrollment** |

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| 1. | Total number of subjects enrolled (or in the case of identifiable data reviewed where no direct contact occurred with subjects, the number of subjects referenced by the study):       |
| 2. | Approximate composition of enrolled subjects:      Females       Males Race: |       Transgender       Unknown |
|  |      % White     % Asian     % African AmericanEthnicity:     % Hispanic or Latino     % Not Hispanic or Latino     % Unknown |      % American Indian/Alaska Native     % Native Hawaiian/Pacific Islander     % More than one race     % Unknown     % Other (specify):       |
| 3. | During the course of the study, did any participants withdraw from the research? If yes, explain why:       | [ ]  Yes [ ]  No |
| 4. | During the course of the study, were any complaints made by participants about the research? If yes, explain why:       | [ ]  Yes [ ]  No |

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| **D. Study Summary** |

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| 1. | Summarize the results of the study, including any plans for scientific presentations or publication:       |
| 2. | Have there been any presentations or publications resulting from this study since the last IRB review? If yes, attach copy of the abstract, or the publication. | [ ]  Yes [ ]  No |
| 3. | Have there been any significant new findings or other information that should be provided to participants? If yes, describe plans to share information:       | [ ]  Yes [ ]  No |
| 4. | Since the last IRB review, did data transfer/storage procedures change? If yes, describe changes:       | [ ]  Yes [ ]  No |
|  |  a. Were these changes submitted for IRB approval prior to implementation?  If no, why not?       | [ ]  Yes [ ]  No[ ]  N/A |
| 5. | 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 |
| 6. | Was there a Data Safety Monitoring Board (DSMB) assigned to this study? If yes, provides copies of any relevant DSMB reviews. | [ ]  Yes [ ]  No |

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| **E. Update on Research Risks** |

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| 1. | Since the last IRB review, were there any interim findings that might alter the risks or benefits? If yes, explain:       | [ ]  Yes [ ]  No |
| 2. | Since the last IRB review, did the risks and/or benefits change that may affect participants or the data collected? If yes, explain:       | [ ]  Yes [ ]  No |
| 3. | Was there a Certificate of Confidentiality associated with this study? If yes, provide a copy of the Certificate. | [ ]  Yes [ ]  No |
| 4. | Since the last IRB review, were there any of the following? |  |
|  | a) Changes to the research study? | [ ]  Yes [ ]  No |
|  | 1. If Yes, was a PRAF submitted and approved?
 | [ ]  Yes [ ]  No |
|  | 1. If a PRAF was not submitted, explain why not:
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|  | b) Unanticipated problems or adverse events? | [ ]  Yes [ ]  No |
|  | 1. If Yes, was an UAP/AE Report submitted?
 | [ ]  Yes [ ]  No |
|  | 1. If a Report was not submitted, explain why not:
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|  |  c) 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:       |  |
|  | d) Un-reportable events? Meaning, anticipated events that occurred? | [ ]  Yes [ ]  No |
|  |  i. If Yes, explain:       |  |

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| **F. Update on Significant Financial Interest Disclosure** |

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| **Significant Financial Interests:** A Significant Financial Interest is defined as an interest valued at greater than $10,000 or an equity ownership of more than 5% held by an investigator and/or the investigator’s spouse, domestic partner or dependent children. |
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| 1. | Did the financial interests of key research staff change 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>. (Key personnel include the principal investigator, co-investigators, other research team members, and any of their spouses, domestic partners, or dependent children.) | [ ]  Yes [ ]  No |

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| **G. Storage & Disposition of Data** |

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| 1. | Has data been de-identified? (There is no identifiable protected health information being maintained or analyzed). | [ ]  Yes [ ]  No |
| 2. | Is data being maintained such that identifiers are separated from protected health information via the use of a code? If yes, how long do you intend to keep this link to the PHI?:       | [ ]  Yes [ ]  No |
| 3. | Is data being maintained and/or analyzed such that identifiers are NOT separated from protected health information? If yes, explain why:       | [ ]  Yes [ ]  No |
| 4. | Is there additional research planned beyond the original intent for this data?If yes, explain:      (If new hypothesis or study goals are developed, study will require new IRB review.) | [ ]  Yes [ ]  No |

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| **H. Principal Investigator Assurance** |

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| Name: (please print or type):I certify that the information provided above is complete and accurate and that:* Interaction/intervention with subjects is complete and identifiable data is no longer being obtained;
* Participation in activities related to the research have been completed and there is no further follow-up planned;
* all identifiable data has been gathered and analyzed; and
* final report(s) or publication(s) are complete and have been submitted to the PH IRB.

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