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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 nor annual check-ins.*

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| **Background Information** |

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| Date: | IRB approval expiration date:  *(n/a for annual check-in’s)* |
| Principal Investigator: | |
| Study Title: | |
| IRB Study No: | |
| Brief Description of Study: | |
| Study start date: | Study end date: |

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| **Project Status** |

Study complete. Enrollment, treatment, data collection, follow-up, and analysis of identifiable data and/or biospecimen are complete. Continue.

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|  | Study started but closed prior to completion. No further data collection, including long-term follow-up or re-contact, is planned. Explain why this occurred and continue: |
|  | Study was never started, meaning participants were never enrolled and/or data was never collected. Explain why and skip to Principal Investigator Assurance Statement: |

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| **Participant Enrollment** |

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| 1. | Total number of subjects enrolled (or in the case of identifiable data and/or biospecimen reviewed, where no direct contact occurred with subjects, the number of subjects whose data was obtained for purposes of this research): | | |
| 2. | Approximate composition of enrolled subjects:        Females       Males  Race: | Transgender       Unknown | |
|  | % White       % Asian       % African American  Ethnicity:       % 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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| **Study Summary** |

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| 5. | Summarize the results of the study, including any plans for scientific presentations or publication: | |
| 6. | Have there been any presentations or publications resulting from this study since the last IRB review or check-in? If yes, attach copy of the abstract, or the publication. | Yes  No |
| 7. | 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 |
| 8. | Since the last PH IRB review or check-in, did data transfer/storage procedures change? If yes, describe changes: | Yes  No |
|  | Were these changes submitted for PH IRB approval prior to implementation?  If no, why not? | Yes  No  N/A |
| 9. | 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 |
| 10 | Was there a Data Safety Monitoring Board (DSMB) or Plan (DSMP) assigned to this study? If yes, provides copies of any relevant DSMB reviews and/or the Plan itself. | Yes  No |

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| **Update on Research Risks** |

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| 11. | | Since the last IRB review or check-in, were there any interim findings that might alter the risks or benefits? If yes, explain: | | | Yes  No | | | |
| 12. | | Since the last IRB review or check-in, did the risks and/or benefits change that may affect participants or the data collected? If yes, explain: | | | Yes  No | | | |
| 13. | | Was there a Certificate of Confidentiality associated with this study? If yes, provide a copy of the Certificate. | | | Yes  No | | | |
| 14. | | Since the last PH IRB review or check-in, 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: | | |  | | | |
|  | | 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: | | |  | | | |
|  | | 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 did in fact occur?  Yes  No  i. If Yes, explain: | | | | | | |
| e) Complaints made by participants? | | | | Yes  No | | |
| i. If Yes, explain: | | | |  | | |

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| **Storage & Disposition of Data** |

Data should only be stored and available after the completion of the study per the details outlined in the approved protocol. Data should be destroyed and disposed of in alignment with what was assured in the protocol and data use agreements.

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| 15. | Has data been de-identified? Meaning, there is no identifiable data or biospecimen being maintained or analyzed. | Yes  No |
| 16. | 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 |
| 17. | Is data being maintained and/or analyzed such that identifiers are NOT separated from protected health information? If yes, explain why: | Yes  No |
| 18. | Is there additional research planned beyond the original intent for this data?  If yes, explain: | Yes  No |

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| **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 or biospecimen 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 or biospecimen has been gathered and analyzed; * all data or biospecimen have at this point been de-identified properly and are only being retained (or have since been destroyed) as described above and in alignment with the approved protocol; and * final report(s) or publication(s) are complete and have been submitted to the PH IRB.                                         Signature Date |