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|  **Public Health Division/Multnomah County Health Department**  **ANNUAL CHECK-IN with the PH IRB** |  |

**This form is to be used only with proposals submitted to the PH IRB for initial review after 12/21/2018 as those proposals were reviewed in alignment with the revised regulations at 45 CFR 46.**

*Per 45 CFR 46.109(f)(1), continuing reviews are no longer required for a study that is eligible for an expedited review nor a study that 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*

*The PH IRB elects to still check-in regarding the status of your study on an annual basis. As your study no longer holds a PH IRB approval expiration date, the responsibility for the annual check-in will fall upon the PH IRB Coordinator. Limited study information is requested below, please complete and submit. If you would like to* ***close*** *this study, please contact the PH IRB Coordinator for next steps.*

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| **Date:**  |  |
| Study Title:       |
| PH IRB Tracking #:      **Funding Source:** NIH Institute? Yes [ ]  No [ ]  [List of NIH Institutes, Centers, and Offices](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices)  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:      **Estimated study completion date**:      **Current status of this study:****[ ]  no enrollment and/or data extraction to-date****[ ]  enrollment and/or data extraction has begun and is ongoing****[ ]  long term follow-up of subjects and/or data analysis continues****Is data identifiable?** **[ ]  Yes** **[ ]  No****Brief summary of the study status and results thus far:** **Have any publications and/or presentations resulted from this research since our last check-in? If yes, submit a copy or abstract for our records.** [ ]  Yes [ ]  No**Is another IRB also reviewing this study? If yes, submit their latest continuing approval memo.** [ ]  Yes [ ]  No |

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| 1. | Have any changes (both minor or major) occurred to the protocol or design of the study since the PH IRB’s last review/check-in? Provide a brief description of the changes and the date they were approved by the PH IRB:       | [ ]  Yes [ ]  No |
| 2. | All changes to personnel must also be submitted prior to implementation, using a PRAF and submitting it alongside your revised Personnel Tracker. Have any changes to personnel occurred since the PH IRB’s last review/check-in? If yes, explain:       | [ ]  Yes [ ]  No |
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| 3.4. | Were these aforementioned changes in #1 and/or #2 submitted for PH IRB approval prior to implementation? If no, why not?      If not, a *Protocol Deviation Report* may need to be submitted at this time and the PH IRB may file this as non-compliance. With this annual submission, at this time are you submitting any changes for review and approval? If so, explain and submit the relevant revised documentation for PH IRB review:       | [ ]  Yes [ ]  No[ ]  N/A[ ]  Yes [ ]  No |
| 5. | Since our last review/check-in, 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 or Adverse Event/Unanticipated Problem Report* may need to now be submitted, and this may be deemed non-compliance. | [ ]  Yes [ ]  No |
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| 6. | Since the last PH IRB review/check-in, have any complaints been made by participants about the research? If yes, we ask to be notified via e-mail. Please describe the complaint and explain when the PH IRB was notified:       | [ ]  Yes [ ]  No |
|  | 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. |  |

**Conflict of Interest Disclosure**

**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.

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| 7. | 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 |

**Training and FCOI:**

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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| **Principal Investigator Assurance** |

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| Name: 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 substantive changes to the project and understand that no such changes can be implemented prior to PH IRB review and approval;
* promptly notify the PH IRB of any changes to personnel and understand that no such changes can be implemented prior to PH IRB acknowledgement of such changes;
* promptly report any protocol deviations, unanticipated problems, and/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 retained or destructed in accordance with the provisions outlined in the approved Data Use Agreements and/or approved consent and authorization forms; 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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