PHD/MCHD/OSH
Public Health Institutional Review Board (PH IRB)

PROJECT REVISION/AMENDMENT FORM (PRAF)

For studies undergoing annual continuing reviews (CR's) or annual check-in's, researchers are not to wait until their given PH IRB approval expiration date to submit proposed changes, whether minor or major in nature. This includes all changes to personnel.

Studies initially reviewed and determined to be exempt must only submit proposed major changes, those that would result in a change in the level of risk to participants, or those that involve significant change to the study, its oversight, and its design and potentially alter its exempt status. **For such studies, an e-mail describing the change may first be sent to the PH IRB Administrator to determine whether a PRAF is needed.*

ALL personnel changes must be submitted for review, even for studies with an initial exempt finding.

Revisions are reviewed according to their type, as follows:

Minor –This includes changes in the protocol that are no more than minimal risk, or risks to subjects are not increased, and/or the revision is not a significant alteration of the study design. Such revisions may consist of, but are not limited to, changes to the number of participants included in the study population, addition or deletion of research team members, change in contact information related to the study, change to the amount or frequency of blood draws, or addition of non-sensitive questions to a questionnaire.

Major –This includes changes to the protocol that involve increased risk to subjects or significantly affect the nature of the study. Changes consist of, but are not limited to, changing or adding a study drug, revisions to the recruitment plan, adding or revising eligibility criteria, adding a research site, a new Principal Investigator, updating the consent form to include a newly identified side effect and/or risk, or the addition of a brand-new research arm to the study.

*Researchers should refer to their latest PH IRB approval memo for a reminder of their study's status or contact the PH IRB Administrator at alayna.n.forrest@oha.oregon.gov

Principal Investigator:		Date:	
E-mail:		Phone:	
Title of Research Project:			
PH IRB Protocol #:		IRB Approval Expiration Date: *(n/a for studies that no longer require continuing reviews)*	

Current Status of Study:	☐ Project not yet started (no subjects/data enrolled) ☐ Currently in progress - # of subjects/data enrolled: _____ ☐ Closed to enrollment but remains active – procedures continue as identified in the protocol - # of subjects in follow-up only: _____ ☐ Closed to enrollment, data analysis only - # of subjects/data enrolled: _____
This request changes the status of this study in the following manner: (check all that apply)	☐ Protocol revision (change in the IRB approved protocol) ☐ Protocol amendment (addition to the IRB approved protocol) ☐ Change to Principal Investigator *(fill out P.I. Assurance Statement and update Personnel Tracker Sheet)* ☐ Add or remove research staff *(update Personnel Tracker Sheet)* ☐ Revised consent and/or authorization form ☐ Addendum (new) consent and/or authorization form ☐ Adds a genetic component or storage of samples and/or data component (reference OAR 333-025-0100 through 0160 for further information on proper procedures for conducting genetic research). ☐ Suspend or re-open protocol to subject/data enrollment ☐ Terminate Study *(Fill out Final Study Report/Study Closure Form)* ☐ Other, specify: _____

Briefly describe and explain the reason for the revision or amendment. ***Include a copy of supportive documents with changes and/or additions red-lined or highlighted and deletions in ~~strikeout~~. Provide a clean copy of the document as well.***

Does the change affect subject participation (e.g., procedures, risks, costs, screening, recruiting, etc.)? Provide brief explanation.
☐ Yes
☐ No

Does the change result in additional data being disclosed or obtained? If yes, briefly describe and identify whether the change affects the way the data is secured or to whom the data is disclosed?
☐ Yes
☐ No

Does the change affect the consent document? If yes, briefly describe changes and attach new consent form identifying changes. ☐ Yes ☐ No
Will the changes result in enrolled subjects needing to complete a revised consent form? If yes, describe procedures that will be used in obtaining their revised consent. ☐ Yes ☐ No
Is this modification due to a protocol deviation, adverse event, or unanticipated problem reported to the IRB? If yes, attach a copy of the report and describe why the modification is being made. ☐ Yes ☐ No
This is a: ☐ MINOR revision involving minimal risk[1] to research subjects *(approval may be expedited)* ☐ MAJOR revision involving greater than minimal risk to research subjects *(approval may require a Full Board review).*

_____ _____

Principal Investigator Signature Date

[1] Minimal risk means that the likelihood and degree of harm or discomfort anticipated in the research are no greater in of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.