Oregon Public Health Division
PH Institutional Review Board

Protocol Deviation/Non-compliance Report

Once the PH IRB has approved a research protocol and supplemental research documentation, no changes may be implemented to the study without prospective review and approval via a Project Revision/Amendment Form (PRAF) unless necessary to eliminate apparent immediate hazards to the human subjects. Any inconsistency in a research study between the IRB-approved protocol and the actual activities being done will be considered a protocol deviation. Because the term "protocol deviation" is not defined by HHS and further, HHS and FDA guidance are inconsistent in addressing deviations, if minor in nature and noted during a PH IRB continuing review or annual check-in, the PH IRB will issue a warning and a reminder to report such changes in the future, prior to the continuing review or annual check-in. *See PRAF form and latest PH IRB approval memo for more details differentiating between what changes must be submitted for studies undergoing annual continuing reviews and annual check-ins vs. studies initially found to be exempt.*

Please complete this form in alignment with the *PHD Protocol Deviations and Noncompliance* guidance document

Principal Investigator:		Date:	
E-mail:		Phone:	
Title of Research Project:		Funding Source:	
PH IRB Study No.:		IRB Approval Expiration Date: *(n/a for studies that no longer require continuing reviews)*	
The study is (check one):	☐ Currently in progress (open to enrollment/data-pull) No. of subjects/data enrolled: No. of subjects still in treatment: ☐ Closed to enrollment (follow-up or data-analysis only)		
Date of Event:	Date of awareness of event:		

SELECT WHICH OF THE FOLLOWING CRITERIA THIS EVENT MEETS:

☐ Minor Deviation: departure from the procedures set forth in the IRB-approved protocol that does not affect subject rights, safety, or welfare, the integrity of the research data, nor alter risks to subjects.
E.g. administering a survey a day later than described in protocol, blood samples obtained at times close to but not at the time specified in the IRB approved protocol, having participants sign a non-stamped consent document, not providing the participant with copies of the consent documents, etc.

☐ Major Deviation: departure from the procedures set forth in the IRB-approved protocol that potentially affect subject rights, safety, and welfare, or alter risks to research participants and/or the integrity of their data. If this event caused or increased the risk of physical or psychological harm, or loss of privacy or confidentiality to a research participant or others, an

Unanticipated Problem/Adverse Event Report must be submitted to the PH IRB.
E.g. failure to obtain informed consent, informed consent was obtained after initiation of study procedures, enrollment of a subject who did not meet all inclusion/exclusion criteria, failure to follow the safety monitoring plan, etc.

☐ Non-compliance: failure to follow federal regulations, state and local laws, PH IRB policy governing human subject research, or the requirements or determinations of the PH IRB. Any serious or continuing non-compliance must be reported to the supporting HHS agency head and OHRP.
E.g. Failure to obtain IRB approval prior to conducting research, continuation of research activities after a study has expired, failure to obtain informed consent of research subjects, the occurrence of the same deviation (on multiple occasions) from the IRB approved protocol without submission of an amendment to change study procedures, any establishment of a pattern of behavior which results in noncompliance, etc.

The event was:
☐ Intentional *(changes in research that need prior IRB review/approval before implementation)*
☐ Identified before it occurred, but could not be prevented *(outside of the investigators' control)*
☐ Discovered after it occurred *(deviated from the protocol unintentionally)*
☐ Purposeful, to remove an apparent immediate hazard *(deviations in reaction to a perceived hazard in compliance with 45 CFR 46.108(3)(iii)*

Minor deviations must be reported to the PH IRB within 10 working days of the research team becoming aware. *If applicable and this report is being submitted > 10 days post-awareness, explain why:*

Major deviations must be reported to the PH IRB within 5 working days of the research team becoming aware. *If applicable and this report is being submitted to the PH IRB > 5 days post-awareness, explain why:*

Non-compliance must be reported as soon as the P.I. becomes aware. However, it is important to note that non-compliance will typically be recognized by the PH IRB itself. *If this report is being submitted to the PH IRB > 5 days post-awareness, explain why:*

NOTE: Any deviation involving significant harm or risk of significant harm to a subject must be reported to the PH IRB within 24 hours of discovery.

1. Describe the event in detail and explain why and/or how it occurred:

2. Explain how the event affected the participants' rights, safety, or welfare, and/or substantially altered the risks to participants, if "not applicable" please state so:

3. Explain how the event affected the integrity of the data, if "not applicable" please state so:

4. Has this event (or something similar) previously occurred in this study? If yes,

please describe the event(s), when it occurred, and the submission date of your previous report to the PH IRB: ☐ Yes ☐ No

Principal Investigator's Signature **Date**