OHA Public Health Division REVIEW PROCESS for External Data Requests

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I. Purpose

This document outlines a process for responding to data requests from external investigators that is consistent across programs, sections, and centers. This document is intended to help managers and data owners in deciding whether such requests need to go to the Public Health Division's Institutional Review Board (PHD IRB), the Science and Epidemiology Council's Project Review Team (PRT) or can be responded to directly (with either an agreement or denial of data release).

Public health and scientific advancement are best served when data can be released to other public health agencies, academic investigators, and appropriate private investigators in an open, timely, and appropriate way. This document is intended to provide guidance on data release that balances the desire to disseminate data with the need to maintain high standards, protect individuals' privacy, and protect the confidentiality of the data.

II. Checklist of processes prior to data release

Prior to releasing any data to external investigators, Public Health Division (PHD) managers/ data owners should consider the following by completing the **Scientific Merit, Risks and Mitigation Review Tool** found at the end of this document:

1. Identify a PHD manager as the "PHD Responsible Party" for the request
2. Vet the background and expertise of the person requesting the data (i.e. Principal Investigator)
3. Evaluate the scientific merit of the project. Pay specific attention to whether the project will improve the health of the population of Oregon or is intended to develop generalizable knowledge
4. Assess type of data requested (i.e., identifiable, de-identified, anonymous, a limited dataset, aggregated data, etc.) and appropriateness of source data for requested purpose (e.g., sample is representative and other threats to validity of inferences are acceptably minor)
5. Make an executive decision regarding whether the request aligns with the PHD mission, and if the request will be approved or denied at the program level.
6. Determine whether the project needs review by the PRT or the PHD IRB. Consider review by the Center's Chief Science Officers for initial requests
7. Finalize a Data Use Agreement (DUA)
8. Assure quality of documentation (Protocol, PRT Request Form; PHD IRB Initial Review Questionnaire (IRQ), DUA, etc.)

*Additional details on each step provided below.

1. **Identify PHD manager as "PHD Responsible Party":** A manager within PHD must be designated as the "PHD Responsible Party" for the data request and project. This does not necessarily mean that the manager is working on the project; rather, that there is a manager who is familiar with the project and data and can vouch for its scientific merit and integrity. This person should be the manager or person within the program responsible for management of the requested data.

2. **Vet background and expertise of person (i.e., Principal Investigator) requesting data:** A Principal Investigator (PI) is the person designated as the individual responsible for the scientific and administrative aspects of the proposed project. The PI must have the technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out a sponsored project. The PI's affiliated institution's authority must be reviewed and be deemed appropriate to receive the data, as deemed by the institution having its own IRB.

   The vetting of the PI and his/her affiliated institution is the responsibility of the study's "PHD Responsible Party". Factors to consider include:
   - Is the PI appropriately trained and well-suited to carry out this work?
   - Has the PI conducted similar work previously? Has it been published in peer-reviewed literature?
   - Is the work proposed appropriate to the experience level of the PI?
   - Is the PI associated with an accredited research or recognized academic institution?
   - Does the PI have significant conflicts of interest (e.g., ties to industry or advocacy groups)?

3. **Scientific Merit Review:** Scientific merit looks at whether a study represents good science. For any study to have scientific merit, it should address the following components: pertains to an area of importance in science, follows established scientific principles, exhibits alignment within the study (consistency throughout study documentation), demonstrates how scientific knowledge will be gained from the study, and involves appropriately trained investigators. The Scientific Merit Review tool (found below) should be used by the PHD Responsible Party to establish that the proposed study for which data is being requested has the basic components of good science.

4. **Assess type of data requested**: The Public Health Division collects a variety of public health data. Some of the data contain personal identifiers, including name, date of birth, address, etc. Examples include birth certificates, death certificates, reportable diseases, cancer diagnoses, receipt of services (e.g., immunizations, HIV medical monitoring project, WIC, reproductive health). Other data may be anonymous (e.g., Student Health Survey, Behavioral Risk Factor Surveillance System (BRFSS)). Some data requests may be for individually identifiable records, and other requests may be for aggregated data. The PHD Responsible Party should determine whether release of data is allowable under statute, what potential risks are posed by release of the data, and how such risks can be mitigated in advance. Consider whether a Data Use Agreement needs to be in place (see below).

5. **Make Executive decision regarding the request:** It is important to keep in mind that not all external data requests must be granted. It is vital that the decision to release our data to external investigators only be made after a critical eye is applied to the request; ensuring that the data release aligns with our Public Health mission, the requestor's research or project will be conducted professionally, and the requestor has appropriate processes in place to ensure the confidentiality of the shared data in transit and in storage. The designated Responsible Party can consult with other managers, data stewards, and/or their Center's Chief Science Officer if needing assistance in making a decision about the request. *If the decision is "No", a formal communication of that decision should be made at the program level and the following will not apply.*

6. **Determine need for PRT or IRB review**: The Public Health Division has two bodies that can assist the PHD Responsible Party in ensuring that population data projects and research studies meet high standards, protect individuals' privacy, and protect the confidentiality of the data. These include the Science and Epidemiology Council Project Review Team (PRT) and the Public Health Institutional Review Board (PH IRB). While not every project involving release of data needs to go through the PRT or IRB, each of these groups can provide helpful insight regarding study methodology, participant protection, and confidentiality of data. It is up to the PHD Responsible Party to determine whether the project needs review by the PRT or IRB. Each Center's designated **Chief Science Officer and the State Health Officer** are available for consultation and technical assistance regarding the need for PRT or IRB review. Note: the PRT and IRB have specific forms that need to be filled out prior to consideration by either of these groups.

    - If PRT review needed: Assist the external investigator in getting in contact with one of your Center's Science & Epidemiology Council representatives. A current list of Council members can be found on the Council Charter found on the Science and Research intranet page. Request that they complete the PRT Request Form.
    - If IRB review needed: Assist the external investigator in getting in contact with the PH IRB Coordinator, alayna.n.nest@state.or.us. The IRB Coordinator will send the researcher the relevant PH IRB paperwork and request a copy of the **Scientific Merit, Risks and Mitigation Review Tool** which should have already been completed by the designated PHD Responsible Party. Until that tool is received, PH IRB will not begin.
    - If neither of the above apply, complete the **Scientific Merit, Risks and Mitigation Review Tool** found at the end of this document and continue getting agreements in place for the release of data in alignment with statute, program policy, and the joint DHS/OHA Policies on the release of data.
        - Release & Waivers for Use and Disclosure for Research and Reporting
        - De-identification of Individual Information and Use of Limited Data Sets

7. **Finalize a Data Use Agreement (DUA):** DUAs are used for the transfer of nonpublic data that may be subject to use restrictions. These Agreements serve to outline the terms and

conditions of the transfer, use, storage, and eventual retention or destruction of the data. They address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the re-release of the data, publication, and privacy rights that are associated with transfers of confidential or protected data.

The understanding established by a Data Use Agreement can help avoid later problems by clearly setting forth the expectations of the parties (provider and recipient). It is the responsibility of the program to ensure the statutes which govern their database and HIPAA protections (if applicable, OHA is a hybrid entity) are reflected within the agreement. Beyond this, assurance from the requestors and data security measures must be addressed in the DUA.

- Assurance**:** Assurance that the Principal Investigator is aware of the responsibilities related to conducting the work. May request additional documents, such as the PI's CV, relevant publications, and IRB review by the PI's institution.

- Data Use and Security**:** The Data Use and Security Agreement details how the data will be transferred, stored, retained for use, and destroyed by the PI. The purpose of this Agreement is to protect the security, confidentiality and integrity of the dataset while in the hands of the requestor.

8. **Quality Assurance of Documentation:** The above process should be documented by the PHD Responsible Party for *any and all* releases of data to external investigators. For studies deemed non-research, the PHD Responsible Party should document credentials of the Principal Investigator, study protocol, results of the PRT review captured on the PRT form (if applicable), and the finalized and signed Data Use Agreement. For studies deemed research, there are specific documents that are required to be submitted, including the study protocol, consent forms, interview script, etc. along with internal PH IRB paperwork. The PH IRB Coordinator will assist the PI in completing the correct documents.

III. Scientific Merit, Risks and Mitigation Review Tool

This tool is intended to help the PHD Responsible Party evaluate the scientific merit, risks and their mitigation of a proposed study using PHD data. This tool can be sent to the external Principal Investigator for their input. **This form can serve as documentation of the Scientific Merit Review of the study.**

Title of project:_____
Principal Investigator:_____
Date of review:_____
Name of PHD Responsible Party (primary reviewer):_____

Topic	Yes	No	Comments
Are the investigators appropriately qualified, knowledgeable, and experienced to perform the procedures included in the work? (see *below for considerations)			
Does the study benefit individual health outcomes of Oregonians?			
Does the study benefit community health outcomes of Oregonians?			
Does the study primary serve to generate generalizable public health knowledge?			
Are the Specific Aims and corresponding hypotheses clearly stated?			
Are the outcomes clearly stated and defined?			
Has a literature search supporting study rationale and providing sufficient preliminary data to justify the proposed research been performed?			
Will testing the hypothesis provide important knowledge for the field?			
Is the study design appropriate?			
Will the proposed tests/measurements answer the scientific question in a valid/reliable manner?			
Is the requested data the right information to answer the proposed question?			
Are the proposed analysis methods, including statistical methods, clearly stated?			
Do the statistical methods correlate with the study design?			
Is the sample size proposed adequately justified?			
Is the study timeline feasible?			
Are there sufficient resources to complete the study in the proposed timeline?			
If applicable, is the ability to recruit, retain, and/or follow subjects feasible?			

Legend:
0 – No risk
1 – Minimal risk
2 – More than minimal risk (needs mitigation)

Risk Type	Concern 0	1	2	Describe specific risk
Data characteristics that are a risk for re-identification				
Unique identifiers or numeric codes				
Small geographies or contextual variables describing geography				
Variables in combination could identify individuals				
Disclosure via re-identification				
Identifiable reference data source available to project team				
Identifiable external data source publicly available				
Administrative, physical, and technical safeguards to prevent intrusion				
Special data or population concern				
Vulnerable populations (minors, prisoners, etc.)				
Populations whose data requires additional safeguards (mental health, etc.)				
Linkage				
Project involves linkage to other datasets that presents a risk for re-identification of patients				

Mitigation – Describe how risks relating to the following are mitigated or whether risks need additional mitigation	
Data use agreement	
Institutional safeguards	
Relationship / trust	

Project team supervision	
Plan for data destruction after project	
Other mitigation strategies	

Summary of Reviewer's Comments and overall assessment:

_____ Protocol is acceptable, should go forward to the PHD Project Review Team or PH IRB.

- *If minor modifications are needed, please list. Note, these should be taken care of prior to the project being sent to the PRT or IRB:*

_____ Protocol is acceptable, no further review needed, will be approved at the program level.

- *If minor modifications are needed, please list and ensure Project Lead fulfills conditions prior to a formal Agreement being put into place with your program:*

_____ Protocol is not acceptable for the following reasons:

_____ At this time, the Oregon Public Health Division does not have the capacity to support this work.

Additional comments from reviewer(s):

Reviewer response to requested changes in protocol

_____ _____

Signature of Responsible Party *Date*