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OHA Public Health Division PRE-IRB REVIEW PROCESS for External Projects

I. Background: OHA-PHD is in need of a pre-IRB scientific review process that is consistent across programs, sections, and centers. This scientific pre-review will not replace IRB review, but the results will help the IRB complete their deliberations with a more complete understanding of the importance of the scientific question being addressed.

Public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. To meet this policy, organizations that conduct public health surveillance and collect surveillance-related data should provide leadership, expertise, and service and devote resources to nurturing new data-sharing arrangements and to support existing ones. The goal is to have guidance on data release and sharing that balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect individuals' privacy and the confidentiality of the data. Specifically, data-use agreements should be shared widely to provide models for others interested in sharing data; data sharing should be promoted by developing supportive funding mechanisms, devoting resources, fostering partnerships and centralizing support; and methods and procedures should be standardized across datasets.

II. Checklist of forms and processes prior to IRB Review

The IRB application and review process can be lengthy and time consuming. Identifying and addressing potential road blocks in the application and review process prior to completing the IRB application can save valuable time in addition to providing additional assurances to protect all involved parties. There are FIVE (5) pre-IRB forms and/or processes that need to be completed prior to IRB review of an application (additional forms may be required for certain data sets):

1) Assignment of PHD manager as the "PHD Responsible Party" for IRB submission
2) Scientific Merit Review
3) Vetting of Principal Investigator
4) Data Use Agreement
    a. Data Security Agreement
    b. Researcher Assurance Agreement
5) Quality assurance of documentation (protocol, IRQ, etc.)

Additional details for each form/process are provided below.

☐ **Assignment of PHD manager as "PHD Responsible Party":** A manager within the OHA/PHD must be designated as the "PHD Responsible Party" for the study. This does not necessarily mean that the manager is actually working on the investigation; rather, it means there is a manager who is familiar with the project and data and can vouch for its scientific and research merit and integrity. This person should be the program manager or person within PHD responsible for management of the requested data. This person must sign off on the Initial Review Questionnaire as the "OHA/PHD Responsible Party" (page 12 of the IRQ). The IRB coordinator will copy this person on all approvals granted (initial, continuing, and amendments) throughout the duration of the study.

☐ **Scientific Merit Review:** Scientific merit looks at whether or not a study represents good science. For any study to have scientific merit, it should address the following components: address an area of importance in science, utilize established scientific principles, exhibit alignment within the study, demonstrate how scientific knowledge will be gained from the study, and involve appropriately trained researchers.

The Scientific Merit Review tool (found on page 4) 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. As needed, ad-hoc reviewers from outside PHD may be utilized if they possess a specific expertise needed that is not available within PHD to review the protocol or if all potential PHD reviewers are conflicted.

☐ **Vetting of Principal Investigator (P.I.):** A Principal Investigator is the person designated as the individual responsible for the administrative and programmatic aspects of the proposed project. The Principal Investigator must have the technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out a sponsored project. The P.I.'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 P.I. and his/her affiliated institution is the responsibility of the study's "PHD Responsible Party".

☐ **Data Use Agreement (DUA):** Data Use Agreements are used for the transfer of nonpublic data that may be subject to some restriction on its use. Data Use Agreements serve to outline the terms and conditions of the transfer. Data Use Agreements address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use 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 issues 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 are reflected within the agreement. Beyond this, researcher assurance and data security measures must be addressed in the DUA.

- Researcher Assurance**:** Assurance that the Principal Investigator is aware of the responsibilities related to conducting the research. May request additional documents as back up, such as the P.I.'s CV, relevant publications, and evidence of the receiving entity's' authority as evidenced by having their own IRB and funding. There are a number of provisions that HIPAA's Privacy Rule requires a DUA to include when dealing with research. They are listed below:

    - Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).
    - Identify who is permitted to use or receive the limited data set.
    - Stipulations that the recipient will
        - Not use or disclose the information other than permitted by the agreement or otherwise required by law.
        - Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to

the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
    - Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the DUA with respect to the information.
    - Not identify the information or contact individuals.

- Data Security**:** The Data Security Agreement details how the data will be transferred, stored, and destroyed by the principal investigator. The purpose of Data Security Agreement is to protect the security, confidentiality and integrity of the dataset.

☐ **Quality Assurance of Documentation:** A number of documents must be submitted to the IRB coordinator for review of the study. This includes the study protocol, consent forms, interview script, study flyers, etc. As part of the PH IRB internal review, an "Initial Review Questionnaire" must be submitted in conjunction with the protocol. It is the duty of the study's PHD Responsible Party to review the documentation prior to the P.I.'s submission to the IRB Coordinator; checking for consistency and completion throughout.

III. Scientific Merit Pre-IRB Review Tool

This is intended to help the "PHD Responsible Party" determine the level of scientific merit a proposed study holds. Please send this forward to the External Principal Investigator in conjunction with your approval or denial of the Data Use Agreement. Ultimately, this form should be sent forth to the PH IRB Coordinator as documentation that the PHD Responsible Party has performed a Scientific Merit Review on the study.

Title of Research Project:_____
Principal Investigator:_____
Date of review:_____
PHD Responsible Party (primary reviewer):_____

Topic	Yes	No	Comments
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?			
Do all of the proposed tests/measurements answer the scientific 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?			
Are the researchers appropriately qualified, knowledgeable and experienced to perform the procedures included in the study? (see *below for considerations)			
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?			

Summary of Reviewers Comments and overall assessment:

_____Protocol is acceptable as written

_____Protocol requires these minor modifications to be acceptable:

_____Protocol is not acceptable for the following reasons:

_____At this time, the Oregon Public Health Division does not have the capacity to support this Research Project

Additional comments from reviewer(s):

Investigator comments regarding review:

Reviewer response to requested changes in protocol

_____ _____

PHD Responsible Party *Date*

* Appropriately qualified, knowledgeable and experienced researchers—details to consider:

- Is the principal investigator appropriately trained and well suited to carry out this work?
- Has the principal investigator conducted similar research previously? Has this research been published in peer-reviewed literature?
- Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?
- Is the principal investigator associated with an accredited research or recognized academic institution?

PHD programs/sections that have data that is asked for and/or shared

- Vital records
- OSCAR
- Emergency Response
- Trauma registry
- Radiation Protective Services
- Drinking Water Protection
- Immunization
- Communicable Disease
- Medical marijuana
- Genetics
- BRFSS
- OHT
- Maternal/child health
    - PRAMS
- WIC