**Scientific Merit, Risks and Mitigation Review Tool**

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This tool is intended to help the PHD or MCHD Responsible Party (i.e. sponsor/primary reviewer) evaluate the scientific merit, risks and their mitigation of a proposed study using PHD or MCHD data. This tool can be sent to the external Principal Investigator for their input if needed but should be completed and signed off on by the Sponsor. This form will serve as documentation of the Scientific Merit Review of the study, required for PH IRB review.

*Note to Responsible Party:* For further details regarding this review process and the expected procedures to be used, please visit the Public Health Science and Research Intranet page where this Tool is located within the larger “OHA/PHD Review Process for External Data Requests”.

Title of project:
Principal Investigator:
Date of review:
Name of PHD Responsible Party:

|  |  |  |  |
| --- | --- | --- | --- |
| **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 risk1 – Minimal risk2 – More than minimal risk (needs mitigation) |
| Risk Type | Concern | Describe specific risk |
| 0 | 1 | 2 |
| **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 | [ ]  | [ ]  | [ ]  |      |

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| **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):

Investigator comments regarding review:

Reviewer response to requested changes in protocol

*Signature of Responsible Party Date*