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| **PUBLIC HEALTH DIVISION/MULTNOMAH COUNTY HEALTH DEPARTMENT**  **INITIAL REVIEW QUESTIONNAIRE (IRQ)**  **Application for Public Health Institutional Review Board (PH IRB) Review to Conduct Research**  *To be used for all initial applications beginning January 1, 2019*   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Per 45 CFR 46.102(l) research no longer encompasses the following (4) activities. If any of the following apply to your proposal, IRB oversight and the completion of this form is not required. Please continue to work with your Manager on potential next steps:**   1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. 2. Public Health (PH) surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a PH authority. Such activities are limited to those necessary to allow a PH authority to identify, monitor, assess, or investigate potential PH signals, onsets of disease outbreaks, or conditions of PH importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens PH (including natural or man-made disasters) 3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. 4. Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | ***Research as it is defined by the Federal Final Common Rule (45 CFR 46):***  *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [See Appendix A for a list of Definitions]* | | | | | | | Does your project involve a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge? |  |  | Yes |  | No | |  | | | | | | | | Will you obtain information or biospecimen through intervention or interaction with a living individual and use, study, or analyze that data, information or biospecimens? |  |  | Yes |  | No | |  | | | | | | | | Will you obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens about a living individual collected through means other than direct interaction? |  |  | Yes |  | No | |  | | | | | | | | | | | | | | | | | | | | |
| Project Title: | | | |  |  | Principal Investigator: | | | |  | | | |
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| **Funding Source** Name of Source:  NIH Institute? Yes  No  If grant, provide title:  [List of NIH Institutes, Centers, and Offices](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) Grant #:  Duration of Grant:  Final Common Rule Agency? Yes  No  [List of Agencies signed onto The Final Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/)  Other? Please specify:  Will you be contracting or subcontracting any of the work? Yes  No  If yes, with whom?  **NIH multi-site grant applications with due dates on or after 1/25/2018:** Must designate a single IRB (sIRB) to conduct the ethical review required for the protection of human subjects. This applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. Applicants are expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH.  **Cooperative research conducted or supported by a Federal department or agency (effective 1/20/2020):** Must rely upon approval by a sIRB for the portion of the research conducted in the United States. Cooperative research is defined as those projects that involve more than one institution. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.  Is this a NIH-funded multi-site study? Yes  No  Is this a cooperative research study supported/conducted by a Federal dept./agency? Yes  No  If yes to either of the above, specify the IRB designated as the sIRB here:  *\*Note: An internal initial administrative review by the PH IRB may still be required*  Researchers and institutions may also elect to have a deferral of review in place. Will you be requesting the PH IRB cede oversight to another IRB or accept oversight of the study?  Yes  No  If yes, please explain:  *\*Unless required, deferrals are not always granted and if asked to cede oversight to another IRB, an internal initial administrative review by the PH IRB may still be required.* | | | | | | | | | | | | | |
| List senior or key personnel involved with this study on our separate [PH IRB Study Personnel Tracker](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/forms.aspx).  Conflicts of Interest: If federally funded, PHD/MCHD personnel must submit a current [Financial Conflict of Interest Disclosure form](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/forms.aspx) and complete FCOI training as stipulated by [PHD FCOI policy](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Documents/coipolicy.pdf). If you need to make an update to your disclosure contact the PH IRB Coordinator. **It is the PI’s responsibility to ensure that research staff have complied with this requirement.**  **If you are an Investigator from an outside institution, you must provide evidence that your institution is in compliance with 42 CFR 50, Subpart F and that appropriate disclosures have been made, this can be in the form of your institutions FCOI Policy or the disclosures themselves.**  **With this submission, submit the P.I. and all Co-Investigator’s CV’s and proof of current human subject’s research training for all personnel.** | | | | | | | | | | | | | |
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| **NOTE:  Internal Investigators** |
| If this study is being conducted by staff working at the Oregon Health Authority (OHA), Public Health Division (PHD) or Multnomah County Health Department (MCHD), a supervisory manager must be listed as key personnel, and will be the responsible party overseeing the conduct of the study (for the purpose of federal research integrity and assurance). Designated Supervisory Manager: |
| **NOTE: External Investigators** |
| You must have a manager within the Oregon Health Authority (OHA) who will sponsor the research. If the study is under review by the PH IRB due to Multnomah County Health Department’s (MCHD’s) involvement, a manager within MCHD must sponsor. This does not mean that the manager is working on the investigation; rather, it means that there is a manager who is familiar with the project and can vouch for its scientific and research merit and integrity. The [“Scientific Merit Pre-IRB Review Tool”](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/forms.aspx) must be completed by the Sponsor and accompany this document at the time of submission.  *\*If an internal Advisory Committee or Project Review Team reviews and approves this project to move forward to the PH IRB, documentation of that determination may be submitted and serve as sponsorship and the Pre-IRB Review Tool will not be required.*  If you are unsure about potential sponsors, please contact [Alayna.n.forrest@state.or.us](mailto:Alayna.n.forrest@state.or.us)  OHA/PHD or MCHD Responsible Party: |

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|  | | | **Project Description** – provide a lay language summary based on the protocol. If the protocol is a multi-site study, please provide detailed information on how the study will be conducted in Oregon. If you do not have a written protocol, you must provide detailed information for each of these categories: | | | | | | | | | | | | | |
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| **4**. a) | | | Describe the primary purpose of this protocol including the specific study aims: | | | | | | | | | | | | | |
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| b) | | | Describe the subject population, inclusion and exclusion criteria: | | | | | | | | | | | | | |
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| c) | | | Summarize how subjects are recruited and enrolled: | | | | | | | | | | | | | |
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| d) | | | Describe the consent process: | | | | | | | | | | | | | |
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| e) | | | Describe the procedures that subjects undergo: | | | | | | | | | | | | | |
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| f) | | | Describe survey or interview instruments, if applicable: | | | | | | | | | | | | | |
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| g) | | | Briefly describe the data you will obtain on subjects, how you will obtain it (direct interaction with the subject, Data Use Agreements for already existing data, both, etc.), and how all of it will be analyzed to address the purpose of the protocol: | | | | | | | | | | | | | |
| **5.** | | | **Clinical Trials −**  Note: *One IRB-approved informed consent form used to enroll subjects in a clinical trial must be posted on a publicly available Federal website, established as a repository for such informed consent forms, for each clinical trial conducted or supported by a Federal department or agency.*  **FDA:** Is this a clinical investigation regulated by the FDA or a clinical investigation that supports applications for research or marketing permits for products regulated by the FDA? If yes, briefly describe the drug and/or device to be researched (including intended therapeutic effects as well as potential adverse effects) and continue.  Yes (NOTE: The PH IRB does not have the expertise to provide reviews for certain FDA clinical trials. However, please continue to fill out this form & submit, keeping in mind that your next steps may differ from a PH IRB review).  No, skip to #6. | | | | | | | | | | | | | |
| a) | | | Is the drug and/or device approved for marketing and will you use it in accordance with its approved labeling? In other words, will you be using the item at hand “on-label”?  Yes, explain and skip to #6.  No, continue. | | | | | | | | | | | | | |
| b) | | | Will an investigational new drug (IND) application (21 CFR Part 312) be required?  Yes  No | | | | | | | | | | | | | |
| c) | | | Will an investigational device exemption (IDE) application (21 CFR Part 812) be required? Yes  No | | | | | | | | | | | | | |
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| **6.** | | | **NIH:** Is this a wholly or partially NIH-funded clinical trial as defined by NIH?:  *A research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or* ***behavioral outcomes****. This includes phase 1 trials of FDA-regulated drug and biomedical products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions.*  Yes  No  If yes, you must register the trial and submit its results information to ClinicalTrials.gov | | | | | | | | | | | | | |
| **7.** | | | **HHS:** Is this an applicable clinical trial as defined by 45 CFR 11?  *Certain interventional studies of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. This includes:*   * *prospective clinical studies of* ***health outcomes*** *comparing an intervention with a device product against a control in human subjects* * *clinical trials of drug and biological products that are controlled, clinical investigations of a product subject to FDA regulations*   *Note: Phase 1 trials of drug and biological products and feasibility studies of device products are excluded from this definition.*  Yes  No  If yes, you must register the trial and submit its results information to ClinicalTrials.gov | | | | | | | | | | | | | |
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| **8.** | | | Does the project involve any of the following (check all that apply): | | | | | | | | | | | | | |
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|  | | |  | | Survey, questionnaire, interview, or focus group procedures | | | | | | | | | | | |
|  | | |  | | Collection or study of existing data, documents, records, or specimen. Specify: | | | | | | | | | | | |
|  | | |  | | Collection of data through noninvasive procedures routinely employed in clinical practice (e.g. MRI, ECG, physical sensors, flexibility testing, etc.)  Specify: | | | | | | | | | | | |
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|  | | |  | | Collection of blood samples or other biological specimens. Specify: | | | | | | | | | | | |
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|  | | |  | | Collection of data from voice, video, digital, or image recordings made for research purposes. | | | | | | | | | | | |
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|  | | |  | | Other: |  | | | | | | | | | | |
| **9.** | | | |  |  | | --- | --- | | Does the study involve genetic research i.e. research using DNA samples, genetic testing, or information about an individual or the individual’s blood relatives obtained from a genetic test?  [***Refer to the Oregon Genetics & Privacy webpage for more information***](https://www.oregon.gov/oha/ph/DiseasesConditions/GeneticConditions/Pages/research.aspx) |  | |  | |  |  | Yes |  | No | |  | | | | | | | | | | | | | | |
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| **10.**  **11.** | | a) | | If you believe this project is exempt from IRB review, please explain under what category of 45 CFR 46.101(b) and why: [See Appendix B for Exempt categories] *Note: Although this project may be exempt from further IRB review, HIPAA safeguards, state law, and institutional policies may still apply.*    Is the information collected, recorded in such a manner that subjects  Yes  No | | | | | | | | | | | | |
|  | |  | | **cannot be identified**,directly or through identifiers linked to the subjects? | | | | |  | |  | |  | |  | |
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| b) | | | | *Could* the information recorded about the subjects, if it became known outside the research, place the subjects at risk of criminal or civil liability, or be damaging to the subjects’ financial standing, insurability or employability? | | | | | | Yes  No | | | | | | |
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|  | c) | | | Is the information collected from sources that are publicly available? | | | | | |  | Yes |  | | | No | |

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| **12** |  | | **Check any study population that will be…** | | | | | | | | | | | | | **Targeted** | | | | **Incidentally**  **Included** | | | | | | | | | | | |  | | |
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|  | | | Children [(Subpart D applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
|  | | | Pregnant women [(Subpart B applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb) | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
|  | | | Fetus/neonates [(Subpart B applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb)  Prisoners [(Subpart C applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc) | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
|  | | | Decisionally impaired [(46.111(b) applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111)  Economically/educationally disadvantaged [(46.111(b) applies)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111) | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
|  | | | Non-English speakers | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
|  | | | Unknown *(chart review only, will not be able to distinguish the above populations from review)* | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | |  | | |
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| **13.** a) | If any of the above specified populations under #12 will be involved in this research, they may be vulnerable to coercion or undue influence. Briefly describe the safeguards you have included in your procedures to protect the rights and welfare of these subjects: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| b) | If children will be included as subjects, describe plans to obtain parental permission and child assent. If you do not intend to obtain assent from children 7 years of age or older explain why: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| c) | If non-English speakers will be included as subjects, provide a plan for interpretation or translation. Explain how you would: communicate with your subjects, obtain written or oral consent, and assure the quality of interpreting and translations:    Languages to be included:  Material, if any, that will be translated:  Note, copies of translated documents must be submitted with this application with proof of certified translation. If the translation has been done by a native speaker, provide information on their qualifications to interpret the information: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| d) | If individuals with impaired decision-making capacity will be included as subjects, provide a plan for how you will identify impairment and how you would obtain written or oral consent: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **14.** | Maximum number of subjects you plan to enroll or obtain data on from Oregon: | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
|  | If multisite study, total number of subjects from all sites: | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **15.** | Estimated start date: | | | | | | |  | | | | | | Estimated end date: | | |  | | | | | | | | | | | | | | | | | |
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| **16.** | Describe and assess any potential risks (physical, psychological, social, legal, or economic) and assess the likelihood and seriousness of such risks. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | a) | | | | What are the risks and the probability of occurrence? | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
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|  | b) | | | | Is the likelihood and degree of harm or discomfort greater than those ordinarily encountered in daily life or during the performance of a routine physical or psychological exam or test? ***Explain*** | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
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|  | c) | | | | How are risks minimized? | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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|  | d) | | | | Have these risks been identified in the consent form or script? | | | | | | | | | | | | | N/A | |  | |  | | | Yes | | | |  | | | No | | | | | | |
|  |  | | | | ***If not, why?*** | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | e) | | | | Are the expected risks of the research such that a Data Safety Monitoring **Board** (DSMB)  has been established? If **yes**, provide a copy of the DSMB membership.  Yes  No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | f) Do you have a Data Safety Monitoring **Plan** associated with this study? If **yes**, provide the PH IRB with a copy.  Yes  No  *A* [*data safety monitoring plan*](https://grants.nih.gov/grants/guide/notice-files/not98-084.html) *assures the safety of subjects and the validity of the data.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | g) Describe how you plan to protect the data collected and monitor the study for any unanticipated problems/adverse events to ensure the safety of subjects. Explain whom the responsibility will lie with (e.g., P.I., independent reviewer, DSMB, etc.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | h) | | | | Will a Certificate of Confidentiality (CoC) be issued for purposes of this study?  Yes  No  If **yes**, and it has been obtained, provide a copy to the PH IRB.  *\*NIH funded researchers are automatically issued a CoC through their award, documentation of the certificate is not provided so a submitted copy will not be required.*  *\*Other Department of Health and Human Services (HHS) agencies issue CoC’s to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **17.** | Describe the potential benefits that may accrue directly to the subject. If **none**, state so.  *(Monetary compensation is NOT considered a benefit.)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | a) | | | | | Benefits to the subject: | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  | b) | | | | Benefits to society: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **18.** | Specify any monetary or other compensation for participation *(if gift card, specify the* *amount*  *and the vendor):* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **19.** | Describe why the benefits to subjects and the importance of the knowledge gained | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | outweigh the risks: | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **20.** | Describe how confidentiality of data and privacy of subjects’ involvement will be maintained [*(See OHA/DHS policy on Transportation of Information Assets)*](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/policy.aspx)*:* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| a) | | | | Will records or data that contain personal identification of subjects be | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | transmitted electronically outside of the institution where obtained? | | | | | | | | | | | | | | | | |  | | | Yes | | | |  | | | No | | | | | | |
|  | | | | If **yes**, describe how this information will be protected: | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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| b) | | | | Will records or data that contain personal identification of subjects be physically | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | transported outside of the institution where obtained? | | | | | | | | | | | | | | | | |  | | | Yes | | |  | | | No | | | | | | | |
|  | | | | If **yes**, describe what measures will be taken to protect the information during transit: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **21.** | If the research involves physical or behavioral interventions, identify alternative interventions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | that might be advantageous to the subjects, and their potential risks and benefits: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **22.** | Describe the scientific merit of the proposed study including what generalizable knowledge is to | | | | | | | | | | | | | | | | | |
|  | be gained from the research: | | | | | |  | | | | | | | | | | | |
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| **23.** | Will this project be reviewed by another IRB? | | | | | | | |  | | Yes | |  | | No | | | |
|  | If **yes**, provide name(s) of other IRBs involved and submit copies of approvals. | | | | | | | | | | | | | | | | | |
|  | Include correspondence on any issues that other IRBs required prior to approval: | | | | | | | | | | | | | | | | | |
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| **Informed Consent (IFC)**  *[See Appendix C for requirements of IFC]*  Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject’s Legally Authorized Representative (LAR).  *Note: IFC requirements are not intended to preempt any applicable Federal, state, or local laws, including tribal laws passed by the official governing body of an American Indian or Alaska Native (AI/AN) tribe, that require additional information to be disclosed in order for informed consent to be legally effective.*  *They also are not intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an AI/AN tribe).* | | | | | | | | | | | | | | | | | | |
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| **24.**a) | | | Will you obtain a signed, written consent form (including in an electronic format) from subjects or their LAR? | | | | | |  | | Yes | |  | | | | No | |
| b) | | | Will you obtain a short form written informed consent form stating that the required elements of IFC have been presented orally to the subject or the subject’s LAR?  [See 45 CFR 46.117(b)(2) for further requirements of short form and written summaries.](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117) | | | | | |  | | Yes | |  | | | | No | |
| c) | | | Will you obtain oral consent over the phone (e.g. for survey or interview)? | | | | | |  | | Yes | |  | | | | No | |
| d) | | | Will you obtain oral consent in person (e.g. for focus group discussion)? | | | | | |  | | Yes | |  | | | | No | |
| e) | | | If you answered yes to any of 24 a - d, a written copy of the form should be given to the subject or LAR, how will it be provided?  In person  By mail  n/a  If not providing a copy, explain why: | | | | | | | | | | | | | | | |
| f) | | | Will subjects be asked to return the original to investigators? | | | | | Yes |  | | No | | | | | |  | |
| g) | | | Specify the reading level of the consent form/script:  The PH IRB recommends that the consent form be at an 8th grade reading level or less, however, we note that if the consent form is merged with an Authorization form, this may not be possible. | | | | | |  | | N/A | |  | | | |  | |
|  | | | If needed, provide further clarification with regard to the consent form: | | | | | | | | | | | | | | | |
| h) | | | If obtaining consent, will non-English speakers be included in this study? If yes, continue. If no, explain why not: | | | | | | | | | | | | | | | |
|  | | | i. | | | Will you obtain oral consent *in* person using an interpreter? | | |  | | Yes | |  | | No | | | |
|  | | | ii. | | | Will the subject receive a translated version of the full consent form? If no, you must provide, at minimum, a translated “short form” written consent. *A short form consent is a document stating that the elements of informed consent have been presented orally to the subject or the subject’s LAR. If using this method, a witness must be present at the oral presentation and the witness must sign both the short form and a written summary of what is to be said to the subject.* ***Provide the IRB with a copy of the short form and written summary.***  [*OHRP Guidance on obtaining and documenting informed consent of subjects who do not speak English.*](http://www.hhs.gov/ohrp/policy/ic-non-e.html) | | |  | | Yes | |  | | No | | | |
|  | | | | | | | | | | | | | | | | | | |
| i) | | | If you do not intend to obtain **a signed copy** of the consent form, the IRB must issue a waiver of documentation of consent. For such a waiver to be granted, *one of the following* must be true. **If you will obtain signatures, skip to j** otherwise please complete i - iii: | | | | | | |
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|  | | | i. | | | Is the only record linking the subject and the research the informed consent form, and is the principal risk to subject’s potential harm resulting from a breach of confidentiality? *If yes, note, each subject or LAR must be asked whether they want documentation linking them with the research, and the subject or LAR’s wishes must govern*. | | | |  | Yes |  | | | | No | | |
|  | | | ii. | | | Does the research present no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside the context of the research? OR | | | |  | Yes |  | | | | No | | |
|  | | | iii. | | | The subject’s or LAR’s are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to them, and there is an appropriate alternative mechanism for documenting that IFC was obtained.  *Note: There are scenario’s in which research teams obtain oral consent over the phone and request a signed copy of the informed consent form to be submitted, but the subject who offered oral consent does not do so. If in the verbal script, the research team explains that their oral consent will stand even in the case the subject forgets to submit the written, signed, hard-copy, the PH IRB may waive the requirement for documentation. If this is applicable, please fill out i – iii above.* | | | |  | Yes |  | | | | No | | |
| j) | | | Are you requesting:   * A waiver of informed consent? * An alteration of informed consent (omitting or altering some or all of the elements)?   **If no to both, skip to # 25**.  \*Note: If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information (IPI) or identifiable biospecimens (IB) in accordance with the requirements of 45 CFR 46 broad consent provision, and refused to consent, a waiver or alteration of consent for the storage, maintenance, or secondary research use of the IPI or IB will not be granted. | | | | | | |  | Yes  Yes |  | | | | No  No | | |
| k) | | | Does your research involve public benefit and service programs conducted by or subject to the approval of state or local officials? **If no, skip to l.**   1. Is your research designed to study, evaluate, or otherwise examine any of the following:   Public benefit or service programs;  Procedures for obtaining benefits or services under those programs;  Possible changes in or alternatives to those programs or procedures; or  Possible changes in methods or levels of payment for benefits or services under those programs.  Explain why your research could not practicably be carried out without the waiver or alteration? **Then skip to #25** | | | | | | |  | Yes |  | | | | No | | |
| l) | | | Are you requesting a waiver because you plan to obtain information or biospecimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or their LAR?  **If no, skip to m.** | | | | | | |  | Yes |  | | | | No | | |
|  | | | | | | | | | | | | | | | | | | |  | 1. Will you obtain information through oral or written communication with the prospective subject or LAR?   Yes  No  OR   1. Will you obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens?   Yes  No |
|  | | | | | 1. Will you obtain information through oral or written communication with the prospective subject or LAR?   Yes  No  OR   1. Will you obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens?   Yes  No | | | | | | | | | | | | | |
|  | | | | | **If no to both i and ii, fill out m.**  **If yes to either i or ii. Skip to #25.** | | | | |  |  | | |  |  | | |
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| m) i. | | | | | Does the proposed research present no more than minimal risk to the study subjects?  Explain:  Yes  No | | | | | | | | | | | | | |
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|  | | ii. | | Explain why the research could not practicably be carried out without the requested waiver or alteration: | | | | | | | | | | | | | | |
|  | | iii. | | If the research involves using identifiable private information or identifiable biospecimens (IPI/IB) explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format: | | | | | | | | | | | | | | |
|  | | iv. | | Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects: | | | | | | | | | | | | | | |
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| v. | | | | Describe plans you may have to provide additional pertinent information to the subjects or LAR’s after participation/at the conclusion of the study. If the study is not designed to yield  information that would be pertinent to the subjects whose data will be used, please explain why: | | | | | | | | | | | | | | |
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| **HIPAA’s Privacy Rule** | | | | | | | | | | | | | | | | | | |
| The Privacy Rule establishes minimum Federal standards for protecting the privacy of individually identifiable health information, but it applies only to covered entities; it does not apply to all persons or institutions that collect individually identifiable health information. It may, however, affect other types of entities that are not directly regulated by the Rule if they, for instance, rely on covered entities to provide information. The Rule is not intended to impede research. The following questions are designed to help researchers be aware of how the Rule might affect them in the various types of organizations in which they operate, and what they may have to do in order to begin a new research effort.  *See Appendix D for definitions related to individually identifiable health information & the Privacy Rule.* | | | | | | | | | | | | | | | | | | |

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| **25.** | | | Will your research involve using or disclosing individually identifiable health information? | | | | | | | | | | | | | | | | |  | | | | Yes | |  | | | | No | | |
|  | | | If ***no***, skip to question 30. | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| Individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records, **is defined as protected health information (PHI) and HIPAA’s Privacy Rule may apply.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **26.** | | | a) | | | Will your research be conducted by a covered entity*? (Both the Oregon Health Authority and the Multnomah County Health Department are hybrid entities. If you are unsure of the status of an applicable program/division, please contact the PH IRB Coordinator).*  Name of entity: | | | | | | | | | | | | | |  | | | | Yes | |  | | | | No | | |
|  | | | b) | | | Will the research obtain protected health information from | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  | | |  | | | a covered entity? **If no to both** a) and b), although state law and internal privacy policies will apply, the HIPAA Privacy Rule will not. Skip to question 30.  Name of entity: | | | | | | | | | | | | | | |  | | | Yes | | |  | | | | No | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | When obtaining PHI from a covered entity for research purposes, you must obtain the research subject’s authorization unless a waiver of authorization is granted. The Privacy Rule also permits a covered entity, without obtaining an Authorization **or** documentation of a waiver or alteration of Authorization, to use and disclose PHI if any of the following apply. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **27.** | | | Does the research involve any of the following?  [*If yes, please complete the relevant form found here*](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/forms.aspx)*, attach to this application, and* ***skip to question 30****. If no, please continue.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | a) | | The sole use or disclosure of individually identifiable health information in order to prepare a research protocol or for similar purposes preparatory to research (e.g. identifying potential subjects). If yes, complete the *Access to PHI Preparatory to Research form*. | | | | | | | | | | | | | | |  | | | | | Yes | |  | | | | | No |
|  | | | b) | | The sole use of de-identified health information. If yes, complete the *Principal Investigator Certification Deidentified PHI form*. | | | | | | | | | | | | | | |  | | | | | Yes | |  | | | | | No |
|  | | | c) | | The use or disclosure of individually identifiable health information that is solely a limited data set? If yes, complete the *PHI Included in a Limited Data Set form.* | | | | | | | | | | | | | | |  | | | | | Yes | |  | | | | | No |
|  | | | d) | | The sole use or disclosure of individually identifiable health information on decedents. If yes, complete the *Research on Decedents’ Information form*. | | | | | | | | | | | | | | |  | | | | | Yes | |  | | | | | No |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **28.** | | | Will you obtain protected health information under a valid authorization of | | | | | | | | | | | | | | | | |  | | | | |  | |  | | | | |  |
|  | | | the research subject or personal representative of the subject?  *This is similar to obtaining the subject’s consent to participate in the research but is specific to getting the subject’s approval to use or disclose their health information that is protected by the HIPAA Privacy Rule.* | | | | | | | | | | | | | | | | |  | | | | | Yes | |  | | | | | No |
|  | | | ***If yes****, see Appendix D for guidance on Authorizations. Attach a copy of the authorization form or attach a copy of the consent form highlighting the authorization elements,* ***then skip to question 30****. If no, please continue.*  ***NOTE: PHI obtained as a result of public health reporting requirements or an investigation may NOT be used for research purposes without obtaining the research subject’s authorization or requesting a waiver of such authorization from the IRB****.* | | | | | | | | | | | | | | | | |  | | | | |  | |  | | | | |  |
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| **29.** | | | a) | | | Are you requesting a waiver or alteration of the research subject’s | | | | | | | | | | | | |  | | | | | |  | | |  | | | |  |
|  | | |  | | | authorization? If yes, continue. *(If obtaining authorization orally, you must request an alteration of the research subject’s authorization as the Privacy Rule requires written, signed authorization).*  If no, identify under what authority the information can be collected without authorization and **skip to question 30** *(ref. 45 CFR 164.512):* | | | | | | | | | | | | |  | | | | | | Yes | | |  | | | | No |
|  | | |  | | |  | | | | | | | | | | | | |  | | | | | |  | | |  | | | |  |
|  | | | b) | | | Provide a brief description of the protected health information you wish to use or disclose | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | and the location of the information: | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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| c) | | | | | | Will the information you access and record, include any of the following identifiers (check all | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | that apply): | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | Names | | | | |  | | Certificate/license #s | | | | | | | | | | | | | | | | | | |
|  | | | | | | Telephone #’s | | | | |  | | Vehicle ID or serial #s, including license plate # | | | | | | | | | | | | | | | | | | |
|  | | | | | | Fax #’s | | | | |  | | Device identifiers or serial #s | | | | | | | | | | | | | | | | | | |
|  | | | | | | E-mail addresses | | | | |  | | Web universal resource locators (URLs) | | | | | | | | | | | | | | | | | | |
|  | | | | | | SSN’s | | | | |  | | Internet protocol (IP) address #s | | | | | | | | | | | | | | | | | | |
|  | | | | | | Medical record #s | | | | |  | | Biometric identifiers, including finger and voice | | | | | | | | | | | | | | | | | | |
|  | | | | | | Health plan beneficiary #s | | | | |  | | Prints | | | | | | | | | | | | | | | | | | |
|  | | | | | | Account numbers | | | | |  | | Any elements of dates directly related to the | | | | | | | | | | | | | | | | | | |
|  | | | | | | Full face photo images or any | | | | |  | | individual (DOB, DOD, admission/ discharge, | | | | | | | | | | | | | | | | | | |
|  | | | | | | comparable images | | | | |  | | etc.) | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | Address, specify: (e.g. street address, city, county, precinct, ZIP, geographical codes):  Any other unique identifying #, characteristic, or code. Describe:   |  |  | | --- | --- | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | d) Will you be obtaining any of the following from DHS or OHA?   * Information about an individual’s infection with AIDS or HIV  Yes  No * Psychotherapy notes  Yes  No * Information related to alcohol and drug treatment  Yes  No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| e) | | | | | | Explain why the use or disclosure of the information in (b) and (c) involves no more than a minimal risk to the privacy of research subjects. Include a detailed list of the source(s) of the information: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| f) | | | | | | Describe plans to protect the information from improper use or disclosure. Include information about how the PHI will be transmitted, where the PHI will be stored, and identify all study staff or institutions who will have access to the information: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| g) | | | | | | PHI used for this study cannot be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. Provide adequate written assurance that this is true for this proposal: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| h) | | | | | | Will you destroy identifiers at the earliest opportunity consistent with | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  | | | | | | the conduct of the research? | | | | | | | | | | | | | | | |  | | Yes | |  | | | | | | No |
|  | | | | | | If **yes**, describe when and explain the procedures you plan to use to destroy them: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | ***Absent a health or research justification for retaining them or a legal requirement to do so, identifiers must be destroyed at the earliest opportunity, or a waiver cannot be granted.***  If **no**, explain why not: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| i) | | | | | | Explain why this research cannot practicably be conducted without access to and use of | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | protected health information: | | |  | | | | | | | | | | | | | | | | | | | | | | | |
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| j) | | | | | | Explain why this research cannot practicably be conducted without the waiver or alteration of | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | authorization: | |  | | | | | | | | | | | | | | | | | | | | | | | | |
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| k) | | | | | | You are required to limit the protected health information to the “minimum necessary” in order to accomplish the intended purpose of the use, disclosure or request. Explain why the | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | health information collected is the minimum necessary to meet the research objectives: | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **30.** | | | | Will other institutions be ‘engaged’ in this research project? If yes, specify below. These institutions may be required to file a federal wide assurance (FWA) with the Office for Human Research Protections before they can participate in the research.  Yes  No   |  |  | | --- | --- | |  | [OHRP Guidance on Engagement of Institutions in Human Subjects Research](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) |   **INSTITUTIONS ENGAGED (and their FWA #’s):** | | | | | | | | | | | | | | | | | | |  | | | | | |  | | | |
|  | | | | *Note: Don’t know the FWA #? Ask the institution’s IRB.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **31.** | | | | The following items must be submitted in addition to this questionnaire:   * If external, OHA/PHD or MCHD Sponsorship via the “Scientific Merit Pre-IRB Review Tool” or relevant Advisory Committee or PRT review and determination documentation. * HHS application or proposal, if applicable * Research protocol * Recruitment brochures/flyers/letters/scripts etc. * Consent forms/scripts and Authorization form, if applicable * Interview tools/scripts, assessment instruments, surveys, questionnaires, etc. * Letters of collaboration/support, if applicable * CV’s for the P.I. and Co-I’s and proof of HSR training for all personnel * Relevant COI documentation, if applicable, as explained on pg. 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **PRINCIPAL INVESTIGATOR ASSURANCE** | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
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| As principal investigator for this study: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I certify that the information provided in this application is complete and accurate; | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I will conduct this study in compliance with the protocol as reviewed and approved by the IRB; | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I will promptly notify the Public Health IRB of any proposed changes to the project and understand | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | that no changes can be implemented prior to IRB review and approval; | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I agree to promptly report to the PH IRB any unanticipated problems or adverse events which become apparent during the course or as a result of the research and the actions taken as a result. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I will promptly respond to all requests made by the Public Health IRB for review of this activity; | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I assure that identifiable information or biospecimen will be protected from improper use and disclosure; | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ● | I will be responsible for the ethical conduct of this project and for protecting the rights and welfare | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | of subjects and their data in the research. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Signature | | | | | | | | | | |  | | Date | |  | | | | | | | | | | | | | | | | | |

**Send one electronic copy of the application and all other material to:** [**alayna.n.forrest@state.or.us**](mailto:alayna.n.forrest@state.or.us)**.**

**IMPORTANT: For your own records, save MS Word versions of all material and a PDF version of signed documents as throughout the duration of your study, revisions may be needed.**

**Information may also be mailed to:**

Public Health IRB Coordinator

OHA – Public Health Division

800 NE Oregon Street, Suite 930

Portland OR 97232

**Phone:** (971) 673-1221

**Fax:**  (971) 673-1299

[Application deadlines (for protocols needing a Full Board review) can be found here.](http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/INSTITUTIONALREVIEWBOARD/Pages/mtgdates.aspx)

**APPENDIX A: DEFINITIONS per 45 CFR 46.102**

1. ***Clinical trial****:* a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
2. ***Department or agency head:*** the head of any Federal department or agency (e.g. the Secretary of HHS) and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.
3. ***Federal department or agency***: a federal department or agency (the dept. or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulations (e.g. HHS, Dept. of Defense, the CIA)
4. ***Human subject***: a living individual about whom an investigator conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens OR obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
5. ***Intervention:*** includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
6. ***Interaction:*** communication or interpersonal contact between investigator and subject.
7. ***Private information:*** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
8. ***Identifiable private information:*** information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information
9. ***Identifiable biospecimen:*** a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
10. ***Institution***: any public or private entity, or department or agency (including federal, state, and other agencies).
11. ***IRB:*** an institutional review board established in accord with and for the purposes expressed in this policy
12. ***IRB approval:*** the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints stet forth by the IRB and by other institutional and federal requirements.
13. ***Legally authorized representative***: an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
14. ***Minimal risk***: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
15. ***Public health authority:*** an agency or authority of the U.S., a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
16. ***Research***: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. (e.g., some demonstration and service programs may include research activities).

**APPENDIX B: EXEMPTIONS**

**Exemption Categories per 45 CFR 46.104(d):**

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

*(i) information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;*

*(ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation, or*

*(iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7) (regarding confidentiality).*

1. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the follow criteria is met:

*A. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.*

*B. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputations; or*

*C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).*

1. Secondary research for which consent is not required: Secondary research uses of identifiable private information (IPI) or identifiable biospecimens (IB), if at least one of the following criteria is met:

*(i) The IPI or IB are publicly available;*

*(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;*

*(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A & E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b)*

*(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates IPI that is or will be maintained on information technology in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501.*

1. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. *Note, each Federal department or agency conducting or supporting the research or demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that they conduct or support under this provision.*
2. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8, relevant to secondary research, include a “limited review” and require “broad consent”. The PH IRB elects not to apply these and will continue to utilize previous pathways to approve secondary research.

**APPENDIX C: INFORMED CONSENT (IFC) REQUIREMENTS per 45 CFR 46.116**

**General requirements (a):**

* Prior to involving a human subject in research, obtain the legally effective IFC of the subject or the subject’s legally authorized representative (LAR);
* Provide sufficient opportunity for the subject or the LAR to discuss and consider whether or not to participate, minimizing the possibility of coercion or undue influence;
* Provide information in a language understandable to the subject or the LAR;
* Provide information that a reasonable person would want to have in order to make an informed decision;
* Begin the form with a concise and focused presentation, one that facilitates comprehension, of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate.
* Provide information in sufficient detail, presented in a way that does not merely provide lists of isolated facts, but rather facilitates understanding of the reasons why one might or might not want to participate.
* Do not include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**Basic elements (b):**

* A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
* A description of any reasonably foreseeable risks or discomforts to the subject;
* A description of any benefits to the subject or to others that may reasonably be expected from the research;
* A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
* A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
* For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
* An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
* A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
* One of the following statements about any research that involves the collection of identifiable private information (IPI) or identifiable biospecimens (IB):
  + Identifiers might be removed from the IPI or IB and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional informed consent from the subject or the LAR, if this might be a possibility; or
  + The subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**Additional Elements (when appropriate) (c):**

* A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
* Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR’s consent;
* Any additional costs to the subject that may result from participation in the research;
* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
* A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
* The approximate number of subjects involved in the study;
* A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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| **APPENDIX D: DEFINITIONS & ELEMENTS OF HIPAA AUTHORIZATION** | | | |
| Protected health information = Individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. | | | |
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| Health information = Any information, whether oral or recorded in any form or medium, that 1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. | | | |
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| Individually identifiable health information = Information that is a subset of health information, including demographic information collected from an individual, and 1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and a) identifies the individual; or b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual. | | | |
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| **A valid authorization must contain the following elements and can be a “stand-alone” authorization or imbedded within the consent form:** | | | |
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| ● | Specific, meaningful description of the PHI to be used or disclosed; | | |
| ● | The name of the person (or classes of persons) authorized to use and disclose the PHI; | | |
| ● | The name of the person (or classes of persons) authorized to receive the PHI; | | |
| ● | A description of each purpose of the use or disclosure, including but not limited to a statement that the use or disclosure is at the request of the individual; | | |
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| ● | An expiration date or an expiration event (e.g. end of research); | | |
| ● | Subject’s signature (or personal representative of the individual) and the date; or documentation that the individual or personal representative of the individual provided verbal authorization and the date verbal authorization took place. If signed by personal representative, a statement of the representative’s authority; and | | |
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| ● | Statements adequate to place the subject on notice of the following: | | |
| **►** | | The subject’s right to revoke the authorization in writing; | |
| **►** | | The exceptions to the right to revoke the authorization; | |
| **►** | | The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization; and | |
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| **►** | | Warning that PHI disclosed to a 3rd party may be re-disclosed by the recipient and no longer protected by HIPAA. | |
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