**Research Involving  
genetic Information/Tests**

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| **Purpose:**  This form is designed to provide information to the IRB for human subjects research involving genetic information/tests. |

**Instructions:** Complete only if your research activities will include the collection or testing of genetic material.

* Respond to every question on this application. Incomplete applications will be returned, and will result in a delay of your study being reviewed.
* This form and must be uploaded when submitting a Research Plan for a New Study or Modification activity through the IRB Module of the Research Administration Portal (RAP).
* Save this form to your computer before proceeding.

**General information for investigator’s reference (optional):**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal  Investigator (PI): |  | Faculty Advisor: |  |
| Study Title: |  | | |

| 1. Genetic Information/Tests Details | | | |
| --- | --- | --- | --- |
| * 1. Indicate the genetic information collected and/or genetic tests conducted (select all that apply); | | | |
| **Genetic Tests:** The term ***genetic test*** includes an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes in an individual or the individual’s blood relatives in order to diagnose or determine a genetic characteristic. | | | |
| **Genetic Information:** The term ***genetic information*** means information about a genetic characteristic of an individual or an individual's blood relative derived from a genetic test. | | | |
| **Genetic Counseling:** including obtaining, interpreting, or assessing genetic information. | | | |
| **Other:** Please describe below: | | | |
|  | | | |
| **Note:** Provide a justification or explanation for the collection of genetic information or tests in the Research Plan. | | | |
| * 1. Will the genetic testing or information collected include any of the following; (select all that apply): | | | |
| Genetic information that may be linked to a participant’s health status, such as genetic markers for cancer, heart disease, etc. | | | |
| Information normally recorded in a participant’s medical record, the disclosure of which could reasonably lead to stigmatization or discrimination. | | | |
| Information that, if released, could reasonably damage an individual’s financial standing, employability, or reputation within the community. | | | |
| None of the above applies. | | | |
| * 1. Will the collection or testing of the genetic information take place outside of the State of Oregon and/or the United States of America? | | | |
| Yes  No | | | If "yes", specify the location(s) where this collection and/or testing will occur, e.g., at an institution in the State of Washington, at subjects’ homes in the country of Canada, etc.: |
|  | | | |
| * 1. Will genetic materials be obtained from a repository, for example, a tissue bank? | | | |
| Yes  No | | | If “yes,” please specify the repository: |
|  | | | |
| * 1. Does the research include “*anonymous genetic research*”? | | | |
| Yes  No | | | If yes, please specify the repository: |
|  | | | |
|  | * If “yes,” please note under current federal and state law, genetic research may only be ***anonymous*** only if it meets all of the following requirements: | | |
|  | * There is no possibility that the individuals providing the samples could be identified or located; ***AND*** | | |
|  | * The investigator may not hold a code to the samples that could allow a sample to be linked to the individual who provided it. | | |
|  | | **Does the research meet these requirements?** | |
|  | | Yes  No | |
| * 1. Does the research include “*coded genetic research*”? | | | |
| Yes  No | | | If “yes,” please specify the repository: |
|  | | | |
|  | * Please note under current federal and state law, genetic research may only be considered “coded” if it meets certain requirements; | | |
|  | * The code is not derived from individual identifiers; | | |
|  | * The code key is kept securely and separately from the specimens and information; ***and*** | | |
|  | * The code key is not accessible to the investigator (unless specifically approved by the IRB, please contact RCS if this is the case). | | |
|  | | **Does the research meet these requirements?** | |
|  | | Yes  No | |