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| **Purpose:** The purpose of this application is to request Institutional Review Board (IRB) review for research which may not meet the definition of human subjects research under 45 CFR 46, but still requires IRB review under the Oregon Genetic Privacy Law.  |

**Instructions:** Please complete the following and submit through [Research Administration Portal (RAP)](https://irb.rap.uoregon.edu/) as a new study. Projects that are not human subjects research but involve use of DNA samples, genetic testing or genetic information must be disclosed to the IRB under the Oregon Genetic Privacy Law (see ORS 192.547(c) and ORS 192.*547(2))*. Also see the [UO website for genetic privacy definitions](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions).

If you have any questions, please contact RCS at 541-346-2510 or ResearchCompliance@uoregon.edu.

| **Part I: Determination of *research*** **(**[**45 CFR 46.102**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)**)**  |
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| Human subjects research regulations apply only to activities that meet the federal definition of ***research***, defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Answer questions 1 and 2 below to determine whether or not your project meets this definition of research.1. Is the study a ***systematic*** investigation? ***Systematic*** means having or involving a system, method, or plan.

*Examples of studies that are systematic include, but are not limited to, those which:** Gather data for the purpose of hypothesis building or testing.
* Ask individuals the same sets of questions, or obtain the same kind of information from them.
* Apply the same measures in gathering the data – whether through interaction, observation, or experiment.
* Utilize data collection methods that can be replicated.
 |
| [ ]  Yes [ ]  No **Explain your answer:**       |
| 1. Is the study designed to contribute to ***generalizable knowledge***?
* Your study contributes to generalizable knowledge if you intend for findings from it to be applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the study.
* Note: Activities involving people that are conducted in conjunction with the requirements of a thesis or dissertation generally are research because the purpose of the thesis or dissertation is by definition to make a contribution to general knowledge.
 |
| [ ]  Yes [ ]  No **Explain your answer:**       |

| **Part II: Determination of *human subjects*** **(**[**45 CFR 46.102**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)**)**  |
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| Human subjects protection regulations apply only to research involving ***human subjects***, defined as “living individuals **about whom** an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.” The Oregon Genetic Privacy Law applies to the collection of genetic information for research purposes, regardless of whether the research meets the above described criteria in section I. Please complete the following to determine whether the proposed research meets criteria for human subjects research.1. Does the research involve information about or from ***living individuals***?

Information involving or about an individual includes, but is not limited to, the following:* Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, reflections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.
* Data about living individuals that was gathered by another researcher or source.
* Data about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery.

Note: if all individuals are known to be deceased, please explain and indicate whether all the information/specimens were obtained after the individual(s) were already deceased. |
| [ ]  Yes [ ]  No **Explain your answer:**  |
| 1. Does the research involve obtaining data through ***intervention*** or ***interaction*** with individuals? ***Intervention*** or ***interaction*** includes the following:
* Interaction:
	+ Communication or interpersonal contact between investigator and subject (e.g., a street interview, an online survey, recording posts on a blog or listserv, a mailed questionnaire, etc.).
* Intervention:
* Physical procedures by which data are gathered (e.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.).
* Manipulations of the subject or the subject’s environment that are performed for research purposes.
 |
| [ ]  Yes [ ]  No **Explain your answer:**  |
| 1. Will you obtain information that is both **individually identifiable** and ***private*** about any subjects? ***Private information*** is explained as follows:
* Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
* Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, emails, certain listserv communications, class papers and exams, etc.).
* Private information must be ***individually identifiable***, meaning:
* the identity of the subject is or may readily be ascertained by the investigator, ***or***
* the identity of the subject is or can be associated with the information directly or through links to identifiable information.
 |
| [ ]  Yes [ ]  No **Explain your answer:**  |

** Directions for Next Steps:**

* If you answered “Yes” to *both* questions in Part I, “Yes” to question 3 in Part II, and “Yes” to questions 4 and/or 5 in Part II, your project involves human subjects and you must complete an IRB application rather than this form. Stop completing this form and submit a complete IRB project through the RAP. In addition to completing and submitting materials for IRB review (see [RCS Forms](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) and [Guidance Library](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-research-guidance-library) pages for directions on what to submit and how), also complete and attach [Appendix E](https://research.uoregon.edu/files/2020-12/rap_appendix_e-genetic_information_and_tests.docx) if your research involves genetic information/tests.

OR

* If you answered “No” to all questions in Part I and either “No” to question 3 in Part II or “No” to *both* questions 4 and 5 in Part II, continue to Part III below.

| Part III: Genetic Materials |
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|  |
| * 1. Please indicate the genetic information collected and/or genetic tests conducted (select all that apply);
 |
|  | [ ]  | * + 1. 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.
 |
|  | [ ]  | * + 1. 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.
 |
|  | [ ]  | * + 1. Genetic Counseling: including obtaining, interpreting, or assessing genetic information.
 |
|  | [ ]  | * + 1. Other: Please describe
 |
|  |
| * 1. Describe the proposed use of DNA samples, genetic testing, and/or genetic information;
 |
|  |       |
|  |
| * 1. Will the subjects whose DNA samples or genetic information is used in this project (or the subjects’ physicians) be recontacted using project information that is identifiable or coded?
 |
|  | [ ]  Yes | [ ]  No  |
| **If Yes, explain your answer:**  |
| * 1. Please select at least one of the following regarding subject consent to use of their DNA sample and/or genetic information for this project (select all that apply);
 |
|  | [ ] [ ]  | * + 1. The DNA samples or genetic information that will be used in this research was or will be obtained with [specific informed consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions) for this project. Please attach a copy of the consent or permission form that was or will be used.
		2. The DNA samples or genetic information that will be used in this project were obtained with [blanket informed consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions) prior to June 25, 2001. Please attach a copy of the consent or permission form that was used.
 |
|  | [ ]  | * + 1. The DNA samples or genetic information that will be used in this project were obtained without [*specific* informed consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions), were derived from a biological specimen or clinical individually identifiable health information for [*anonymous research*](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions) *or* [*coded research*](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions) *AND meet the criteria described below*.
 |
|  |  | * *If selecting this option, please explain how this research meets all of the following requirements and provide supporting documentation if necessary;*
 |
|  |  | [ ]  | * + - 1. Waiver of the consent requirements under the Federal Policy for the Protection of Human Subjects are met;
* *The research involves no more than minimal risk to the subjects;*
* *The research could not practicably be carried out without the requested waiver;*
* *The research either does not involve collecting identifiable private information/specimens or if the research does involve using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;*
* *The waiver or alteration will not adversely affect the rights and welfare of the subjects; and*
* *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. If not appropriate, explain why.*
 |
|  |  | Please explain how all the above waiver of consent criteria apply:       |
|  |  | ***AND*** |
|  |  | [ ]  | * + - 1. HIPAA is either not applicable or HIPAA applies but qualifies for a waiver of authorization pursuant to the federal Health Insurance Portability and Accountability Act (HIPAA) privacy regulations under 45 C.F.R. parts 160 and 164 is applicable.

Criteria for HIPAA waiver: * The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
	1. an adequate plan to protect the identifiers from improper use and disclosure;
	2. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
	3. an adequate written assurance that the protected health information will not 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 protected health information would be permitted (i.e., under the HIPAA regulations).
* The research could not practicably be conducted without the waiver; and
* The research could not practicably be conducted without access to or use of the protected health information
 |
|  |  | Please either explain why HIPAA does not apply (e.g., data/specimens are not being obtained from a HIPAA covered entity, none of the [18 HIPAA identifiers](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/protected-health-information) will ever be obtained) or explain how your study qualifies for a HIPAA waiver:       |
|  | [ ]  | * + 1. The DNA samples or genetic information that will be used in this project were obtained without [*specific* informed consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions), were derived from a biological specimen or clinical individually identifiable health information for [*anonymous research*](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions) *or* [*coded research*](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/genetic-privacy-definitions)***AND*** *one of the following applies:*
 |
|  |  | [ ]  | The subjects have consented to genetic research generally (if possible, please attach a copy of the consent or permission form that was used); ***OR*** |
|  |  | [ ]  | All subjects were notified by their health care provider in accordance with [ORS 192.538](https://oregon.public.law/statutes/ors_192.538) that the subjects’ biological specimen or clinical individually identifiable health information may be used for anonymous research or coded research and the subjects did not, at the time of notification, request that the biological specimen or clinical individually identifiable health information not be used for anonymous research or coded research; ***OR*** |
|  |  | [ ]  | Subjects were not notified due to emergency circumstances, in accordance with [ORS 192.538](https://oregon.public.law/statutes/ors_192.538) that the subjects’ biological specimen or clinically individually identifiable health information may be used for anonymous research or coded research and the subjects died before receiving the notice |
|  |
| * 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", please indicate the location 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  | 1. 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:
 |
|  |  |  | * + 1. There is no possibility that the individuals providing the samples could be identified or located; ***AND***
 |
|  |  |  | * + 1. The investigator will not hold a code to the samples that could allow a sample to be linked to the individual who provided it.

Does the project meet these requirements? |
|   | [ ]  Yes | [ ]  No |  |
| If “Yes”, explain:       |
| * 1. Does the research include “*coded genetic research*”?
 |
|  | [ ]  Yes | [ ]  No  | 1. If "Yes", please note under current federal and state law, genetic research may only be considered ***coded*** if it meets certain requirements;
 |
|  |  |  | * + 1. The code is not derived from individual identifiers;
 |
|  |  |  | * + 1. The code key is kept securely and separately from the specimens and information; ***AND***
 |
|  |  |  | * + 1. The code key is not accessible to the investigator (unless specifically approved by the IRB, please contact RCS if this is the case).

(Note: if the University of Oregon researchers will obtain identifiable information because they have access to the code key or other identifiers, a complete IRB submission will likely be needed)Does the research meet these requirements? |
|   | [ ]  Yes | [ ]  No |  |
| If "Yes", also address these items:Describe the risks of coding and include an explanation of how you will minimize the risks associated with a breach of confidentiality:     Do you have DNA samples or are responsible for maintaining the DNA sample(s) from which genetic information is obtained?[ ]  Yes [ ]  NoIf “Yes”, please also describe how the DNA sample will be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless the individual or the individual’s representative directs otherwise by informed consent:      |
|  |
| * 1. Will genetic information or samples be retained and/or stored?
 |
|  | [ ]  Yes | [ ]  No | If yes, please describe how it will be retained/stored. If it will be stored in a repository, also specify the repository:       |
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| 1. Investigator and Faculty Advisor Signatures
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| * The investigator certifies that the above information is correct and accurately reflects the conduct of the proposed genetic research and/or collection of genetic information.
* The investigator agrees to conduct the above describe genetic research and/or collection of genetic information in accordance with the Genetic Information Nondiscrimination Act of 2008 (GINA) and the Oregon Genetic Privacy Law (ORS 192.531 to 192.549).
* The investigator agrees not to begin the genetic research and/or collection of genetic information described above until the Institutional Review Board has issued a determination that the proposed research is exempt from review per the Oregon Genetic Privacy Law.
* The investigator agrees to notify Research Compliance Services and the Institutional Review Board of any proposed changes to the genetic research and/or collection of genetic information/samples described above before such changes are implemented.
 |
|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |
| **Principal Investigator Signature Date** * *Electronic signatures or typed names are acceptable.*
 |
| **REQUIRED FOR STUDENT RESEARCH** * By signing this form, the Faculty Advisor attests that (s) he has reviewed and approves the research and agrees to provide appropriate education, oversight, and supervision of the student investigator above, and share the above investigator responsibilities.
 |
|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |
| **Faculty Advisor Signature Date** * *Electronic signatures or typed names are acceptable.*
 |