

 <b>OHSU Research Integrity Office</b>	<b>Policies &amp; Procedures</b>	
<b>Title: Policy for Accessing Tissue Specimens or Information at OHSU for Anonymous or Coded Genetic Research</b>	Date Effective  4/21/2008	Supersedes P&P dated:
	Identification	Page 1 of 4

## Background

The Oregon Genetic Privacy law (ORS 192.531-192.549) requires that individuals be notified that their specimens or clinical individually identifiable health information could be used for anonymous or coded genetic research and that they have the ability to opt out of such research. The Institutional Review Board (IRB) may approve anonymous or coded genetic research performed without consent only if all specimens or information to be used are obtained from individuals who have been provided a notice and did not opt out. Certain exceptions apply as described below. The Oregon Genetic Privacy law also requires that all genetic research, even if completely anonymous, be reviewed by the IRB.

### I. Scope

This policy applies to biological specimens or health information from OHSU patients or subjects that will be used for coded or anonymous genetic research without consent.

### II. Responsible Parties

- A. Principal Investigators (PIs)
- B. OHSU Institutional Review Board (IRB)
- C. OHSU Integrity Office/Privacy Officer
- D. OHSU clinical department/ repository guardian

### III. Policy

- A. All genetic research conducted with biological specimens or an individual's health information (information) from OHSU patients or subjects will be conducted per the requirements of the Oregon Genetic Privacy law.
- B. Investigators proposing to conduct coded or anonymous genetic research must submit the project for review by the IRB.
- C. When an investigator wishes to conduct genetic research using biological specimens or information from OHSU patients or subjects and does not have informed consent for the use of anonymous or coded biological specimens or information in the specific genetic research project, the following requirements must be met:
  1. The individual(s) from whom the biological specimens(s) or information will be or has been obtained must have been provided with the "Notice of Your Right to Refuse Participation in Future Anonymous and/or Coded Genetic Research" and did not exercise his/her right to refuse to participate in coded or anonymous genetic research (opt out), as verified by appropriate genetic opt out review; or
  2. The individual(s) from whom the biological specimen(s) or information will be or has been obtained has granted consent for genetic research generally; or
  3. The individual(s) from whom biological specimen(s) or information will be obtained is deceased (or specimen or information was obtained in emergency circumstances but the individual died before receiving opt out notice); or
  4. The biological specimen(s) or information was obtained prior to July 29, 2005.

5. If the specimen(s) or information are coded, the following additional requirements apply:
- a) The code is:
    - (i) Not derived from individual identifiers;
    - (ii) Kept securely and separately from the specimens and information; and
    - (iii) Not accessible to the investigator unless specifically approved by the IRB.
  - b) The information is stored securely in password protected electronic files or by other means with access limited to authorized personnel.
  - c) The information is limited to elements required for analysis and meets the criteria in 45 C.F.R 164.514(e) for a limited data set.

**D.** Consent for genetic research is required for use of fully identified specimens/information in genetic research.

## **IV. Procedure**

### **A. IRB Approval**

1. Many studies involving anonymous and coded genetic research may not meet the definition of research involving a human subject, per 45 CFR 46 102(f) and would not require IRB review. However, under the Oregon Genetic Privacy Law, all genetic research projects must be submitted for review by the IRB.
2. The PI must submit the proposed research to the IRB via the eIRB. The submission must contain a plan for obtaining specimen(s) or information in compliance with section III.C of this policy.
3. Research may only commence once IRB approval and waiver of consent and authorization (if applicable) are granted and appropriate genetic opt out review has occurred.

### **B. Requirements for Checking Opt Out**

1. Requesting Specimens and/or information
  - a) The research team contacts the clinical department or repository guardian and requests specimens or information.
  - b) The research team provides a copy of the IRB approval to clinical department or repository guardian.
2. Genetic Opt Out Review
  - a) The clinical department or repository guardian compiles list of specimens or, for information, the list of patients and visit dates, and submits the list with the dates of collection and two of the following types of identifiers to the Privacy Officer or designee for genetic opt out review:
    - Name
    - Medical Record Number (MRN)
    - Date of Birth (DOB)
  - b) The Privacy Officer or designee checks the list of specimens or patients and visit dates against the genetic opt out report:
    - If the specimen or information was collected prior to 7/29/05, the clinical department, or repository guardian will be notified if the patient from which the specimen or information was collected has opted out of anonymous or coded genetic research.
    - If the specimen or information was collected on or after 7/29/05, the clinical department or repository guardian will be notified if 1) The patient from which the specimen or information was collected has opted out of anonymous or coded genetic research or 2) There is no record that they received a Notice of Right to Refuse Participation in

Future Anonymous and/or Coded Genetic Research. In these cases, specimen(s) or information may not be released for genetic research.

3. Release of specimens or information
    - a) Once the clinical department or repository guardian has verified IRB approval and received genetic opt out review, the specimens or information may be released to the PI.
    - b) For studies where all components of the research involve genetic research, the clinical department or repository guardian will exclude all specimens and information for patients that the Privacy Officer or designee has indicated should not be used for genetic research.
    - c) For studies that have genetic and non-genetic components, the clinical department or repository guardian will flag all specimens and information for patients that the Privacy Officer or designee has indicated should not be used for the genetic research component.
  4. Anonymous specimens or information held in a research repository may be used for genetic research without a genetic opt out review:
    - a) if obtained prior to July 29, 2005, or
    - b) the investigator has documented that the original consent form included consent for genetic research on those specimens or information
- In no other circumstances can the specimens or information be used for genetic research.

## **I. Authority**

- A.** Oregon Genetic Privacy Law: ORS 192.531-549 and Administrative Rules: 333-025-
- B.** Waiver of Consent: 45 CFR 46.116(d)

## **II. Definitions**

- A.** "Anonymous research" means scientific or medical genetic research conducted in such a manner that any DNA specimen or genetic information used in the research is unidentified. "Anonymous research" does not include research conducted in such a manner that the identity of such an individual, or the identity of the individual's blood relatives, can be determined by use of a code, encryption key or other means of linking the information to a specific individual.
- B.** "Clinical" means relating to or obtained through the actual observation, diagnosis, or treatment of patients and not through research.
- C.** "Coded" means identifiable only through the use of a system of encryption that links a DNA specimen or genetic information to an individual or the individual's blood relative. A coded DNA specimen or genetic information is supplied by a repository to an investigator with a system of encryption.
- D.** "Guardian" means the person who has primary control of information and/or specimens. This may be the PI of the repository or database or a designee
- E.** "Genetic characteristic" includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome, or to identify an individual or a blood relative. "Genetic characteristic" does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.
- F.** "Genetic information" means information about an individual or the individual's blood relatives obtained from a genetic test.
- G.** "Genetic opt out report" means the report from the OHSU database that shows which OHSU patients have chosen to opt out of coded or anonymous genetic research.
- H.** "Genetic research" means research using DNA specimens, genetic testing or genetic information.
- I.** "Genetic test" means a test for determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, including tests of nucleic acids

such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.

**J.** “Health information”, including demographic information collected from an individual, is information that:

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.

**K.** “Limited data set” means protected health information that, in accordance with the Federal Privacy Rule, excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names;
2. Postal address information, other than town or city, State, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

### **III. Additional information**

**A.** links to flow charts

**B.** link to Repository policy

**C.** Information Security and Research Data Resource Guide

[http://ozone.ohsu.edu/cc/sec/isg/res\\_sec.pdf](http://ozone.ohsu.edu/cc/sec/isg/res_sec.pdf)