OHSU Policy

I. Policy

A. All genetic research conducted with biological specimens or an individual’s health 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.

Effective: 4/21/2008