What’s Changed?

1. The revision changes the types of research that can be done without informed consent using an individual’s (a) biological specimen, or (b) health information.
2. Beginning July 1, 2006, health care providers must notify their patients that any specimens or health information collected will be available for anonymous\(^2\) or coded\(^3\) genetic research unless the person “opts out.”
3. A patient “opts out” by completing an opt-out form in writing and submitting it to their health care provider.
4. If a patient opts-out of coded or anonymous genetic research a health care provider must inform any indirect provider (e.g., lab or radiologist) he/she sends the patient’s specimens or health information to of such opt-out.

Implementation at OHSU?

1. In most areas, Admitting and Patient Registration staff will be providing patients with OHSU’s Genetic Notice.
2. Patients can opt-out of future anonymous or coded genetic research by completing OHSU’s Genetic Notice opt-out section and returning the form to OHSU.
3. Opt-outs will be documented in Epic (Prelude) and A2K.
4. If a specimen or health information is sent to a non-OHSU indirect provider (e.g., lab or x-ray facility) and a patient has opted-out of coded or anonymous genetic research, then such opt-out must be communicated to the non-OHSU indirect provider.
   a. In most areas, the opt-out will automatically be included on printed order requisition forms.
   b. Areas not using order requisition forms will need to look up the patient’s status in the patient’s record or run an opt-out report using Crystal Reports.

OHSU Ancillaries (Indirect Providers) Who Receive Specimens or Health Information from non-OHSU Providers and are Informed of a Patient Opt-out

If an opt-out is received from a non-OHSU provider with a patient’s specimen or health information, such opt-out must be communicated to HIS using the form found at [http://ozone.ohsu.edu/cc/forms/gen_optout.pdf](http://ozone.ohsu.edu/cc/forms/gen_optout.pdf).

If you have questions about the new law or whether the procedures outlined above apply to your area, please contact the OHSU Integrity Office at 4-8849 or oips@ohsu.edu.

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1 “Indirect provider” is a health care provider having a relationship with a patient in which: A) Health care is delivered to the patient based on orders of another health care provider; and B) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the patient.

2 “Anonymous” means that the no one can identify the patient from whom the biological specimen or health information was obtained.

3 “Coded” means that the patient from whom a biological specimen or health information was obtained cannot be identified without using a code or other encryption that is kept separately from the specimen or information.