What Is Genetic Research?
Specific Scenarios Explained...

**Immunology research**

*Q. I’m just looking at immune response, not looking at DNA, is this genetic?*

*A. Looking at differences in immune response between different individuals could be considered a genetic test. Identifying the cellular and ultimately the genetic cause of the different immune response could indicate who is susceptible to a disease, or who may progress to a more severe disease state.*

**Gene expression**

*Q. I’m comparing different expression patterns from those with or without disease, or between a tumor sample and regular tissue, that’s not genetic is it?*

*A. Looking at differences in gene expression could be considered a genetic test. A certain profile of altered expression could indicate disease susceptibility or prognosis.*

✓ With regard to testing of tumor samples, the OHSU IRB considers somatic alterations to also be covered by the requirements of Oregon’s Genetic Privacy Law.

✓ As noted by the American Society of Clinical Oncology, “Although ASCO supports a more stringent review process for research involving germline DNA (ie, inherited alterations), it is important to recognize that the distinction between studies assessing somatic alterations in abnormal tissue and those evaluating germline genetic variations is somewhat artificial. The examination of certain somatic changes by either direct DNA analysis or other techniques may indicate the presence of a germline predisposition (eg, microsatellite instability, mismatch repair protein expression, gene expression profiles).” (J. Clinical Oncology, Vol 21, No 12 (June 15), 2003).

**Other questions**

*Q. I am doing a genetic test only to find out if a subject qualifies for my study, does this mean the research is genetic research?*

*A. Yes, you are conducting a genetic test for research purposes.*