



## ASIP Public Affairs

### 1997 ASIP Position: Human Tissues in Genetic Research

#### **ASIP Position: Formulation of Policy that Regulates the Use of Human Tissues in Genetic Research**

Regulatory policy needs to protect the individual rights of research subjects while safeguarding the societal benefits that accrue from research with human tissues.

The formulation of policy to regulate the use of human tissue in genetic research must have broad-based scientific input beyond that provided by legal, bioethical and clinical perspectives.

Regulatory policy needs to ensure that the privacy of a research subject's genetic information is protected and that severe sanctions are imposed on violators.

Because research using human tissues yields enormous societal benefits regulatory policy should not have the effect of imposing barriers that impede the progress of this research.

Recognizing the widespread research use of molecular genetic technology, regulatory policy needs to precisely define terms such as genetic testing in order to avoid unintended consequences.

Regulatory policy needs to distinguish between genetic tests performed for research purposes and genetic tests performed for clinical purposes recognizing that the boundary separating them is indistinct and constantly moving.

Regulatory policy needs to distinguish between genetic changes that are of somatic origin and genetic changes that are present in germline DNA.

From a research perspective, genetic studies are not qualitatively different from other types of human research. Regulatory policy must neither create artificial distinctions nor unintentionally impede use of archival tissues.