BALANCING RESEARCH PROGRESS AND INFORMED CONSENT

The American Society for Investigative Pathology has adopted the following position:

"The American Society for Investigative Pathology believes that the principles of utilization of stored human tissues must continue to ensure patient privacy and confidentiality, but emphasizes that any guidelines on the ethical, legal and social impact of such use must also preserve and protect the accessibility of residual human material for research that leads to the understanding of the mechanisms of disease and the development of new diagnostic and therapeutic modalities for human diseases."

Background:

The Human Genome Project’s Ethical, Legal and Social Implications (ELSI) Working Group contracted with the Health Law Department of Boston University School of Public Health to develop guidelines for protecting privacy of information stored in genetic data banks. The final report of this contract is in the form of a document entitled "The Genetic Privacy Act and Commentary" and includes proposed wording for federal legislation. This final report has been discussed within the ELSI Working Group, but has not been formally proposed as government policy. The report has also been circulated to interested individuals, including those who wish to pursue implementation at the state level.

This report and its proposal argue not only for genetic privacy but also for very specific requirements for informed consent for the use of residual human tissue, including anonymous samples, in research studies. Advocates for this proposal contend that it is virtually impossible to totally maintain patient confidentiality and anonymity. They propose that to adequately respect and protect patient privacy, a patient or his/her heirs must be kept fully informed of each specific use of residual tissue and must be provided with the opportunity to approve, on an ongoing basis, all studies planned for that tissue; use of the tissue for research purposes could be revoked at any time.

The American Society for Investigative Pathology believes that implementation of such practices would seriously undermine the research advances of biomedical scientists who (1) use anonymous samples for basic research on the fundamental mechanisms and molecular genetics of human diseases, including cancer and infectious diseases; (2) perform epidemiologic studies on incidence and verification of certain kinds of diseases; (3) develop effective diagnostic and prognostic test procedures; and (4) study new and promising therapies. The process as proposed is so detailed and cumbersome that patients may be discouraged from their otherwise willing altruistic participation as a biomedical research subject and research scientists will be unable to pursue such studies without additional financial resources to support such an administrative burden.
October 20, 1995

Lori Andrews, Esq.
Chicago-Kent College of Law
Illinois Institute of Technology
565 West Adams Street
Chicago IL 60611

Dear Ms. Andrews:

The American Society for Investigative Pathology represents more than 2,000 basic scientists who study the mechanisms of disease. We write to express our concern about some of the concepts presented in the final report of ELSI’s contract with Boston University School of Public Health, entitled "The Genetic Privacy Act and Commentary". We understand that this is simply a final report and that it has not been proposed as public policy, but that the report has been discussed by the ELSI Working Group and that some individual members of the ELSI Working Group strongly support the report, perhaps to the level of public advocacy within their own groups and communities.

As research scientists, we feel that the report and its advocates present a perspective that needs some balance with views from other quarters. Many of our members are indeed practicing pathologists and are quite familiar with issues of privacy and confidentiality, but they are also experienced in understanding the value of archived tissue for opening new insights into human health and disease without jeopardizing individual research subjects.

The purpose of this letter is two-fold. First, we wish to convey our support for the concept and need for privacy and confidentiality of individual patient data and to advocate the continued use of anonymous archived tissues for research purposes.

Second, we request official standing as a participating organization in the working group to assure that the concerns of basic scientists like ours are not overlooked in the deliberations and recommendations of the committee. The implementation of the measures proposed in the...
document "The Genetic Privacy Act and Commentary" could have a devastating effect on biomedical research, whether enacted at a state, local, or federal level. We feel that the issues raised in this report should be fully discussed by all groups with an interest at stake so that a balanced perspective can be achieved.

We recognize that the ELSI Working Group is confronting some very difficult issues and we look forward to contributing positively to those efforts so that appropriate balance is achieved.

Sincerely yours,

Richard G. Lynch, M.D., President
Chair, Department of Pathology
University of Iowa College of Medicine

Enclosure: ASIP Position Statement

cc: Dr. Francis Collins