ASCP STRONGERTOGETHER

Informed Consent and Research

(Policy Number 96-01)

Policy Statement

ASCP believes that scientific advances in disease research should maintain a proper balance between patient confidentiality (e.g., informed consent) and the needs of the scientific community to access stored human blood, body fluid and tissue samples (herein referred to as "human samples").

Background and Rationale

I. Introduction

The ability of scientific researchers to obtain stored human samples for research purposes has been the cornerstone of conventional disease research and diagnosis for more than a century.[1] Without continued access to stored human samples, new and rapid advances in the understanding of cancer, heart disease, HIV and other diseases could suffer significantly.

ASCP recognizes that medical information derived from laboratory testing and stored human samples pose benefits and risks to the public and the individual. Adequate safeguards must be implemented to protect against the misuse of patient information, without sacrificing the advancement of disease research.

II. Patient Privacy and Confidentiality

ASCP supports the principles of patient privacy and confidentiality concerning all medical information. Protecting the privacy and confidentiality of a patient's health information is paramount in the field of pathology. Identifiable patient profiles have the potential to seriously impact an individual's ability to obtain health insurance or employment. There are two separate federal regulations designed to protect the privacy of patients. One policy is specific to human research subjects and the other is specific to patient privacy.

A. The Protection of Human Research Subjects (45 CFR 46)

The Department of Health and Human Service's policy on human research subjects (45 CFR 46) outlines regulations for obtaining informed consent in various situations. This regulation states that the use of identifiable private information or identifiable specimens for research purposes constitutes human subjects research and must be approved by an Internal Review Board (IRB).[2] Research involving only coded specimens is not considered to be human subjects research if the following conditions are met:

- The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals and
- The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.[3]

Therefore, informed consent must be obtained when specimens are collected specifically for research. However, many studies rely on excess specimens that had been stored after all laboratory work necessary for a patient's care had been completed.[4]

B. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The HIPAA Privacy Rule is a set of national standards for protecting personal health information. A major goal of this legislation is to ensure that individual's health information is properly protected while allowing the flow of health information needed to provide and promote quality health care and to protect the public's health and well being.[5] These regulations require written authorization for release of identifiable health information.

The HIPAA Privacy Rule defines three categories of health information: identifiable information to which the rule of obtaining authorization applies; de-identified information which is exempt from HIPAA regulations; and a limited data set, to which some parts of the rule apply.[6] HIPAA has the potential to have a serious impact on research involving stored human specimens, which often have coded identifiers and could possibly be linked back to an individual if the identifiers are not properly maintained.

III. Balancing Informed Consent and Disease Research

ASCP believes strongly in a patient's right to privacy, extending strict informed consent policies to the use of stored human samples could limit the progress of future disease research. Advances in genetic testing have highlighted a variety of ethical, legal and social issues. Those issues include proposals to strengthen patient confidentiality policies as they relate to the use of patients' genetic data.

ASCP, in accordance with the National Bioethics Advisory Commission[7], believes that research involving anonymous specimens should not be considered human subjects research. Currently, most stored human sample research involves investigators working with a variety of unlinked or coded materials. If properly maintained, these samples are impossible for researchers to link back to the patient.[7] A strict informed consent policy for the use of all stored human samples could create an extensive administrative accounting process that may decrease anonymity of those samples.

Furthermore, the creation of an overly detailed informed consent process may deter patients from engaging in medical research because of the overly burdensome paperwork requirements. Many patients will likely not have the desire or time to monitor and approve all future uses and activities involving their anonymous stored human samples. Since research specimens are typically stored and studied for years or even decades, it is likely that the specimens could outlive the patient. If a stricter informed consent policy is implemented, it could deplete the overall supply of medical specimens for disease research. Such a situation could pose serious threats to human health that far outweigh attempts to strengthen patient privacy and confidentiality measures.

IV. Recommendations

In order to allow the optimal use of stored human samples while advancing disease research and protecting patient privacy and confidentiality, ASCP recommends the following:

- Research using anonymous or coded stored human samples should be exempt from obtaining IRB approval or informed consent.
- Keys for decoding stored human specimens should be destroyed once research is completed and the identifying information should never be given to the researchers.

V. Conclusion

It is important for medical researchers to obtain and use stored human samples in order to treat disease. While informed consent is necessary when dealing with human subjects, preventative measures are taken with stored human specimens so that they are unable to be linked back to the patient. Requiring researchers to obtain informed consent to use stored specimens would create an enormous burden on both the patient and the researcher and could have a negative effect on the future of disease research.

References

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[3] United States Department of Health and Human Services, Office for Human Research Protections. Guidance on Research Involving Coded Private Information or Biological Specimens, 2004. Available at: www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf. Accessed September 7, 2005.

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[5] United States Department of Health and Human Services, Office for Civil Rights. Summary of the HIPAA Privacy Rule. Available at: http://www.hhs.gov/ocr/privacysummary.pdf. Accessed September 7, 2005.

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