

## **Impacts of SB 1267 on University of California Research and Health System Operations**

SB 1267, as amended on May 1, 2012, defines genetic information to include not only information obtained from genetic tests of the individual but also information obtained from genetic tests of the individual's family members, and the manifestation of a disease or disorder in family members of the individual. An individual's genetic information could not be obtained, analyzed, retained, or disclosed without specific written authorization. A separate written authorization would be required for each separate disclosure of an individual's genetic information. Each violation of the provisions of SB 1267, even if accidental or no actual risk of harm to the patient exists, would result in a penalty \$1,000 to \$10,000 plus court costs.

The scope of SB 1267 is not limited to research and health services activities that involve collection of DNA samples. Rather, it extends even to activities that do not involve collection of biological samples at all, but that involve obtaining information about the manifestation of diseases or disorders in an individual's family members. Terms such as genetic information are broadly defined and would be inseparable from general health information included in research and medical records. As such, the authorization requirements of the bill would apply to hundreds of UC research studies involving tens of thousands of research participants, as well as all patient medical records. The impact on the University's ability to effectively and efficiently carry out important research and manage patient care and medical center operations is significant.

### **SB 1267 could result in the loss of hundreds of millions of dollars of public and private research funding and will significantly increase central research administration costs.**

The University is seriously concerned that compliance with the provisions of the bill will place it, and other public and private research institutions in California, at a competitive disadvantage when competing nationally for public and private research grants. UC received \$5.4 billion in research awards from public and private funding sources in FY 2011 and is the largest recipient of National Institutes of Health (NIH) grant funding in the nation. NIH funding is increasingly awarded for health sciences research that would likely trigger the authorization requirements. With specific regard to genetic research, the \$3.8 billion spent by the U.S. government to map the human genome has spurred the creation thousands of jobs in California and nationwide and gave rise to an industry that now generates about \$67 billion nationally in annual economic activity.

SB 1267 would require that an individual's genetic information only be used for the specific purpose, by the specific individuals indicated on the authorization form, and that all genetic information be destroyed once the specific purpose is fulfilled. These restrictions are simply not feasible. A single research project may involve many researchers, graduate students, research assistants and others who would need to obtain, analyze, retain and disclose genetic information.

UC's ability to conduct secondary research would be severely limited by SB 1267. Many of the discoveries we have today that were the products of unexpected results that inspired new studies not planned at the onset of a research project. The exploration of these serendipitous discoveries

would be prevented by SB 1267's requirement to obtain authorizations for each subsequent research use. A few examples of discoveries from secondary research use include hormone replacement therapy which resulted from samples collected for other purposes; initial AIDS transmission findings were derived from research on hepatitis; and findings that obese individuals were at a high risk for liver disease. Further, the most powerful genetic research often depends on obtaining data obtained from large numbers of participants. It would be virtually impossible to have to obtain authorizations and reauthorizations needed for the tens of thousands of research participants needed to perform these types of research activities.

UC may simply not be able to participate in federally-funded multi-center research studies of archival or retrospective tissue samples, research that requires data sharing, and other health related activities in areas such as cancer, diabetes, transplant medicine, and personalized medicine. California has been a national leader in health care research such as statewide approval and funding for stem cell research. The requirements of SB 1267 run contrary to advancing research in these areas.

Should UC be unable to compete for even a small percentage of federally or privately funded research because of limitations resulting from SB 1267, UC could lose hundreds of millions of dollars in research funding. As UC researchers become unable to obtain grant funding for their research activities they will likely move to other states. Additionally, UC conservatively estimates that the bill could increase staff costs associated with central research administration alone by at least \$285,000 - \$594,000.

**SB 1267 will adversely impact patient care while significantly increasing hospital administration costs and hindering important medical center operations across the UC Health system.**

SB 1267 will have a detrimental impact on the UC Health system, which is the second largest in the state. In addition to adversely effecting patient care, the bill will significantly increase UC hospital patient record-keeping costs and other administrative costs, and will inhibit many vital health care operation activities. Although UC has not yet calculated the annual cost impact of SB 1267 on this aspect of UC operations, it will likely exceed the above annual cost impact estimated for research administration personnel and would be in the millions of dollars annually.

A patient's medical history contains personal history, past medical history, social history and family history of diseases and conditions. Genetic information as defined by the bill would be included within routine medical history created and reviewed by treating clinicians. Patients at any of UC's medical facilities would be required to sign numerous authorization forms for every disclosure of the genetic information in addition to the numerous privacy notifications and other forms already required by federal and state law. The flow of patient information among healthcare providers for the purposes of diagnosis and treatment will be severely halted and delayed while the proper patient authorizations are obtained. SB 1267 will discourage healthcare providers from consulting with one another about a patient's condition and course of treatment, seeking additional laboratory tests, and otherwise pursuing treatment options.

In addition to the costly burden of obtaining and storing the vast number of paper authorizations that would be required for patient care, the bill would inhibit other important hospital operations such as conducting peer reviews, quality of care and patient safety reviews, coding and billing activities, releasing information requested by health insurance agencies, and reporting to public health agencies such as the California State Cancer Registry, which is mandatory. Separate patient authorizations would be required for all of these activities.

Federal efforts to expand the use of electronic medical records systems and health information exchanges could be significantly delayed or derailed. There would likely be technical challenges associated with segregating genetic information, lab test results, and family medical history information within an electronic medical record from other treating providers. Unless the University decided to revert to the use of paper records, changes to UC's existing systems to meet the requirements of SB 1267, if technically feasible, would greatly increase costs. Additionally, workforce members would need additional training about the various federal and state privacy laws, permitted uses and disclosures.

Further, although the bill requires genetic information to be destroyed once the identified purpose of the use of the genetic information is fulfilled, existing record retention laws require research and medical records to be retained for years after research and patient care activities are completed.

**Research Participant and Patient Privacy is already extensively regulated.**

SB 1267 neither recognizes the vast body of existing federal and state laws and regulations governing the privacy of medical information nor the laws and regulations governing human subject research. The Health Insurance Portability and Accountability Act (HIPAA) and the HIPAA regulations have been in effect for nearly a decade and protect the privacy and security of protected health information, including genetic information. At the state level CMIA also protects this information. However both laws intentionally allow the sharing of information for treatment and other medical center operations without specific authorizations. All human subjects research conducted at UC is subject to the federal Common Rule for human subject research. These federal regulations mandate review by an Institutional Review Board (IRB), which is a critical body of scientific and ethics experts responsible for ensuring that all research involving human subjects meets nationwide ethical and privacy standards.

These laws and regulations already require the University to implement numerous complex administrative procedures that are highly regulated and scrutinized. UC believes that SB 1267 creates an additional costly layer of administrative requirements that will snarl research and healthcare activities throughout the state without providing significant additional protections to patients and research participants.

**Penalty provisions within the bill do not include a risk of harm provision.**

Finally, UC is concerned that the disclosure penalty provisions in the bill could result in costly litigation and fines for accidental or unintentional disclosures of genetic information that are made without authorization during the course of legitimate research and patient care activities. Additionally, SB 1267 requires that the form the patient must sign to authorize each separate disclosure be in a typeface no smaller than 14-point type, include specific language and be a “separate document, not attached to any other document, and shall not be more than one page.” However, the required language will not fit on one page if it is in English in 14-point type. Thus, UC could be subject to fines and penalties should it not obtain authorization on a written form that contains the precise language prescribed by the bill in the specific manner prescribed by the bill.

These provisions could result in millions of dollars of penalties and litigation costs regardless of whether an individual suffered, or reasonably could have suffered, actual harm from the disclosure.