

FACT SHEET: Chaptered Legislation

Senate Bill 13 (Bowen) Personal Information Signed into law 9/22/2005: Chapter 241

SB 13 requires that the Committee for the Protection of Human Subjects at the Health and Human Services Agency approve scientific research proposals before state agencies are permitted to disclose personal information to researchers.

I. WHO AT THE UNIVERSITY OF CALIFORNIA SHOULD KNOW ABOUT SB 13?

- Researchers who seek personally identifiable data from California state agencies;
- UC officials who work with researchers on data security and confidentiality issues;
- UC officials responsible for responding to requests from non-UC researchers for personally identifiable UC data;
- UC Institutional Review Board staff and members.

II. WHAT DOES SB 13 DO?

- SB 13 places new restrictions on the circumstances under which state agencies are permitted to disclose personally identifiable information to researchers conducting scientific research at the University of California and at other requesting nonprofit educational institutions. It does this by significantly amending the previously existing research exemption in the state Information Practices Act (“IPA”), a law that generally prohibits state agency release of personally identifiable information. The revised exemption is codified as Civil Code Section 1798.24(t).
- Under the new law, a state agency can release personally identifiable information (e.g., names, addresses, Social Security Numbers) to UC and other educational institutions conducting scientific research **only if** the request for information is approved by the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency (HHS). The CPHS is the Institutional Review Board (IRB) for HHS.
- SB 13 sets out a number of specific criteria that must be met in order for the CPHS to approve a state agency’s release of personally identifiable information to a researcher. Specifically, CPHS must determine that the following criteria have been satisfied:
 - The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical and technical safeguards to protect personal information from reasonably anticipated threats to the security or confidentiality of the information.
 - The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the

research project and has provided a long-term plan sufficient to protect the confidentiality of the information.

- The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.
- SB 13 requires CPHS to include certain minimum elements as part of its requirements for approval of a research project in order to protect personal information held in state agency databases. Specifically, SB 13 requires CPHS to:
 - Determine whether the requested information is needed to conduct the research;
 - Permit access to personal information only if it is needed for the research project;
 - Permit access only to the minimum necessary personal information needed for the research project;
 - Require the assignment of unique subject codes that are not derived from personal information in lieu of Social Security Numbers if the research can still be conducted without SSNs.
 - If feasible, and if cost, time and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.
- SB 13 provides that the agency may bill the researcher for reasonable costs to the agency associated with the agency's process for protecting personal information under the conditions of CPHS approval. Costs that may be billed include the agency's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or securing personal information, or assigning subject codes.
- SB 13 specifies that it does not prohibit CPHS from using its existing authority to enter into written agreements to enable other institutional review boards to approve projects or classes of projects for the CPHS, provided that the data security requirements set forth in the law are satisfied. This is codified as Civil Code Section 1798.24(t)(4).
 - *This provision would allow (but not require) CPHS to authorize a UC IRB to approve projects on behalf of CPHS on a case-by-case basis, as long as the UC IRB determines that the specific data security requirements set out by SB 13 are met. It would also allow CPHS to enter into a written agreement allowing a UC IRB to approve certain classes of projects on behalf of CPHS (e.g., projects involving data in UC custody; projects involving release of agency data to a UC researcher). **We may wish to explore whether and to what extent UC should seek to enter into such an arrangement with HHS.** This requires consideration not only of whether it would facilitate research, but also whether UC IRBs have the staff and expertise to make the determinations required by law and whether UC would be willing to assume responsibility for assuring the state that data security requirements have been met.*

- SB 13 leaves intact a number of existing exemptions to the IPA's general prohibition on state agency release of personally identifiable information. Agencies can still release personal information if the disclosure meets the requirements of one of the other exemption categories on Civil Code Section 1798.24 (e.g., if written consent is obtained from the individual no more than 30 days before the disclosure).
- SB 13 takes effect January 1, 2006, though some state agencies have already begun to enhance their review and approval process prior to releasing personally identifiable information, in response to concerns about security breaches.

III. BACKGROUND

- Senator Bowen introduced SB 13 in response to concern about a data security breach that occurred in 2004 at a UC campus involving a hacker obtaining access to personally identifiable state social services data in the possession of a visiting faculty researcher. Although UC advised the author of steps that had been taken to enhance campus data security practices, the author wanted to change state law to enhance the required review and approval process for protecting personal information in state agency databases.
- The final version of SB 13 is significantly improved from the initial version. As introduced, SB 13 would have completely prohibited state agencies from giving university researchers access to personally identifiable data. UC and other concerned stakeholders worked hard to obtain amendments to mitigate the bill's deleterious impact on research, eventually convincing the author that a complete ban would impede a great deal of important research that relies on agency data. Although the final version of SB 13 does impose new requirements that may raise concerns among some about slowing down the research process, it is much improved, and it is our hope that its implementation will not prove to be a significant impediment.

IV. WHAT DOES SB 13 MEAN FOR UC RESEARCHERS AND IRBs?

- Researchers who need personally identifiable information from state agency databases should build time into their research plan to obtain the necessary review and approval from the state Health and Human Services Agency IRB. Information about the HHS IRB can be found at: <http://www.oshpd.cahwnet.gov/CPHS/index.htm>. For researchers seeking data from state agencies that fall under HHS jurisdiction (e.g., Social Services), this is not a new requirement, but the requirement may not have been uniformly enforced prior to passage of SB 13.
- Researchers should review the criteria in SB 13 along with any specific criteria set out by the agency from which they plan to seek data, and should be prepared to articulate their need for personally identifiable data and their plan for protecting it. Researchers may wish to seek advice from their campus information technology offices and offices of research in developing adequate data security management plans.
- UC researchers conducting human subjects research with personally identifiable information still need to seek review by their own campus Institutional Review Board.

- SB 13 applies to release of data by all state agencies, including UC. Thus, after January 1, 2006, before the University of California can release personally identifiable data in UC custody to researchers at other educational institutions, UC must seek approval from the California Health and Human Services Agency's IRB, unless we enter into a written agreement with the HHS IRB that allows UC IRBs to review and approve requests for data in UC custody.
- As specified above, SB 13 allows the Committee for the Protection of Human Subjects (CPHS) of the California Health and Human Services Agency (HHS) to use its existing authority to enter into written agreements with other IRBs to approve projects or classes of projects on behalf of CPHS, as long as the data security requirements set forth by SB 13 are satisfied. **UC needs to determine whether and to what extent we should seek to have the HHS CPHS authorize UC IRBs to approve projects or classes of projects.** The Office of Research will seek input on this matter from relevant UCOP and campus offices.

V. TEXT OF SENATE BILL 13:

The full text of SB 13 is available at the following url:

http://www.leginfo.ca.gov/pub/bill/sen/sb_0001-0050/sb_13_bill_20050922_chaptered.pdf