

New Subject Privacy Rules in California

By Norman M. Goldfarb

California Senate Bill 13, effective January 1, 2006, requires researchers to obtain approval from the State's Committee for the Protection of Human Subjects (CPHS) before obtaining any personal information from another state agency. Only researchers at the University of California and other non-profit educational institutions may obtain data that identifies individuals. The University of California (including its hospitals) is an agency of the State.^{1,2,3,4}

The bill amends section 1798.24 of the California Civil Code, Information Practices Act. The new law adds another hurdle for conducting some clinical research studies in California. Even HIPAA requires review of clinical research by a privacy board (usually an institutional review board) only in unusual circumstances. CPHS, an internal institutional review board (IRB) for the State of California, has the right to delegate its authority to other IRBs.

State Senator Debra Bowen introduced Senate Bill 13 in response to a computer-hacking incident in 2004. A UC Berkeley researcher requested a 4-county random sample of In-Home Supportive Services (IHSS) provider wages and benefits. The Department of Social Services (DSS) accidentally provided the entire database. An unknown computer hacker obtained entry to the computer that stored the database. There is no evidence that the hacker accessed the database or even knew of its existence.⁵

According to Senator Bowen, the goal "isn't to make it harder for researchers to do their work, it's to stop the state from using a person's Social Security number as a default identifier."¹ Ellen R. Auriti, Executive Director of Research Policy and Legislation for the University of California system, said that CPHS has had this authority for some time, although it is not clear if all researchers were aware of and complied with the approval requirement. According to Auriti, the original bill as introduced would have been a lot worse.

Clinical research and healthcare professionals in California are justifiably sensitive to restrictive legislation. For example, because one nurse in San Jose was caught reusing syringes to draw blood (ugh), the state passed a law in 2003 imposing various requirements such as 20 hours of classroom training for the minimum credential to draw blood.⁶

References

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