Privacy and Confidentiality Case #4

Clinical-trial patients assist in drug research.¹

This top pharmaceutical firm has built up its human DNA bank over the past four years in hopes of tapping it to get new insights on the ways drugs interact with humans. The elusive but promising goal, which still may be years off, is to zero in on how to "personalize" drugs to make them more effective in treating diseases in more people.

Within a few years, 10,000 patients a year could be donating samples. The pharmaceutical company’s chief pathologist says the percentage of people in clinical trials who agree to give samples to the bank is high, topping 80 percent of those asked. In part because of the well-publicized successes in decoding the humane genome, "We're in an environment where patients want to participate in research," he says.

The Role of the Pharmaceutical Company

Kept under tight security at the firm’s headquarters campus, the iced-down bank of hundreds of thousands of specimens, given by volunteers, forms the latest tool for the company's drug development scientists.

Besides having the responsibility of housing the clinical samples, the pharmaceutical firm must keep track of both the sample and the donor’s clinical records, electronic case report forms, and consent forms, which are held within an electronic data exchange.

The role of the Health Information Exchange

HIE is a non-profit company incorporated in a Midwestern state. It was founded by a unique collaboration of 13 institutions representing hospitals, providers, researchers, public health organizations, and economic development groups.

Privacy concerns

Quoting from Kohane and Altman’s Nov. 10, 2005 New England Journal Article on “health information altruists,” privacy advocates point to However, a recent study by Malin and Sweeney concerning database security has shown that apparently de-identified subjects often can be either unambiguously re-identified or partially identified by means of filtering the data to a very small subgroup of potential matches. (for example, they hey showed that 33 percent of patients with cystic fibrosis could be re-identified from a large data set.)

Questions

- What legal and regulatory hurdles must the pharmaceutical company address?
- What legal and regulatory arrangements must be made by the health care exchange?
- What are other patient’s, pharmaceutical, and health care legislative and policy initiatives that may be applicable either at the federal or state level?
- What are the top five practical issues that must be addressed to create a feasible approach for a pharmaceutical company to address? What can the company do at the federal level to expand this regional project to include the rest of the country?

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