MedicalXpress

Genetic research using human samples requires new types of informed consent

September 16 2008

Genetic studies involving the long term storage and study of human samples hold great promise for medical research—but they also pose new threats to individuals such as uninsurability, unemployability, and discrimination, say a team of researchers in this week's *PLoS Medicine*.

Matthias Wjst (Institute of Genetic Medicine, Bozen, Italy) and colleagues argue that the traditional informed consent process—in which the researcher counsels potential study participants about the risks and benefits of taking part in a study—may no longer be appropriate when dealing with long-term studies using biological materials.

"In current practice," say the authors, "the only moment when a person is really able to make a choice about participating in clinical research is when they sign the informed consent form." But they argue that there is a major problem with asking participants to sign this form as a "once-and-for-all decision"—a biological sample collected from a study participant for one study today might feasibly be of use in a future study several years down the line. New genetic information that is obtained from these later studies, if released, could lead to "uninsurability, unemployability, discrimination, and the breakdown of family relationships by unintentionally demonstrating missing or unknown relatedness."

"Informed consent should be seen as an ongoing process between researcher and participant, and not just as a once-and- for-all decision," say Wjst and colleagues.

They argue that any research following the initial storage of samples needs to be explained to the participants so that they can give their feedback. The authors suggest that such communications could involve both conventional channels—face-to face meetings, group meetings, and letters—as well as newer electronic communications—such as e-mail alerts, online chat rooms, and blogs.

Citation: Mascalzoni D, Hicks A, Pramstaller P, Wjst M (2008) Informed consent in the genomics era. *PLoS Med* 5(9): e192. doi:10.1371/journal.pmed.0050192
medicine.plosjournals.org/perl … journal.pmed.0050192

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