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Selling access to human specimens: Survey reveals public attitudes

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The almost 5 million people who paid to get their DNA analyzed by the company 23andMe recently found out that their genetic data and related health information might have been sold to a major drug company.

That's because 23andMe made a $300 million deal with pharmaceutical giant Glaxo SmithKline, to let it tap that genetic goldmine to help it develop new medicines. If 23andMe customers consented to allow their DNA samples to be used for research when they sent them in, their data can be sold in this way.

Millions more people have samples sitting in very different kinds of biobanks: at universities and major teaching hospitals. When patients have surgery, biopsies, or blood draws at hospitals, those specimens may be kept for future research.

A new University of Michigan survey documents public attitudes toward potential commercial use of these samples.

A new survey reveals what members of the public think about such deals, and what they would want to know if their specimen were part of one, even if it didn't have their name attached. The results are published in a new paper in the August issue of the journal *Health Affairs*, by a team of U-M bioethics researchers from the Medical School and School of Public Health.

Only one in four of the 886 people surveyed nationally said they'd be

comfortable with companies getting access to their leftover specimens from a university or hospital biobank.

Two thirds of the survey respondents said that if such a deal happened, they'd want to know. If the specimens in academic biobanks don't include patients' identifying information, researchers don't need informed consent from the patient in order to keep them for research. However, as Andrew Shuman, M.D., a head and neck surgeon and co-chief of the Clinical Ethics Service of the Center for Bioethics & Social Sciences in Medicine points out, "there are compelling reasons to ask for patient consent before we collect specimens for research—whether or not their identifiable health information is included."

Nonprofit institutions, like academic medical centers, usually use these samples for research. But often they need to look elsewhere for funding to support the upkeep of the biobank—and may sell access to private companies through a process called commercialization.

"That's a big part of the business model of the direct-to-consumer genetic testing companies" points out U-M faculty member and co-author Michele Gornick, Ph.D., but it was not the driving force behind the creation of academic biobanks.

As more academic institutions seek to commercialize their biobanks, the U-M team asked survey respondents what universities and hospitals should do with the money they might get from such deals.

Sixty-two percent said they should plow those funds back into more research. The U-M researchers argue in the new article that these findings demonstrate that when researchers are asking for informed consent to biobank donation, they should also disclose what the money will be used for in the future.

The findings have real-world implications, says Jody Platt, Ph.D., the study's senior author and assistant professor in the Medical School. Under the new regulations, public biobanks will often be required to disclose to patients if specimens will be commercialized in the future.

"We found that if you disclose commercial interests, people are less likely to participate," says Platt. "But if you also tell them that the money will be reinvested in research, this will reengage trust and encourage participation."

Their findings suggest that institutions should go above and beyond what the law requires, under the newly revised Federal Policy for the Protection of Human Subjects, or "Common Rule," that takes effect in January.

The survey, done as part of a larger one led by co-author Sharon Kardia, Ph.D. of the U-M School of Public Health, and also with U-M medical school faculty Raymond De Vries, Ph.D., included a nationally representative sample of adults who were presented a scenario about biobanking and commercialization, and then answered questions online.

"The new disclosure laws are supposed to be a floor, not a ceiling," says lead author Kayte Spector-Bagdady, J.D, MBE, who is Chief of the Research Ethics Service at CBSSM. "But it may be counter-intuitive for biobanks to disclose more information than legally required. Here we found that they should be doing just that."

Spector-Bagdady, Platt, Shuman and Gornick are members of the U-M Institute for Healthcare Policy and Innovation.

More information: Kayte Spector-Bagdady et al, Encouraging Participation And Transparency In Biobank Research, *Health Affairs* (2018). DOI: 10.1377/hlthaff.2018.0159