Public prefers limited informed consent process for biobanks

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Biobanks are repositories for tissue samples, usually in the form of blood or saliva or leftover tissue from surgical procedures. These samples are collected and used for future research, including genetic research. They may be linked to personal health information regarding the sample donor. People who are eligible to donate these samples and researchers who want to use them face important questions with respect to whether and how informed consent should be obtained for sample and health information collection and use.

A team of University of Iowa researchers led by Christian Simon, Ph.D., associate professor of bioethics and humanities in the Department of Internal Medicine at the UI Roy J. and Lucille A. Carver College of Medicine, conducted a study to determine people's preferences with respect to informed consent for biobanking. The study, "Active choice but not too active: Public perspectives on biobank consent models," was published ahead of print in last month's online edition of the journal, *Genetics in Medicine*. The study involved 751 telephone surveys and seven focus groups with English-speaking members of the public who were randomly sampled from counties across Iowa. Over half the study participants were female.

Most study participants had not heard of a "biobank" before, but when it was explained to them what biobanks were and that they could help advance research on genetic and nongenetic aspects of disease, most study participants were enthusiastic.

The majority (95 percent) of survey participants rejected the idea of deriving and banking samples without first informing and asking patients for their permission—obtaining their informed consent.

"This speaks to the premium many people place on being informed and having a choice about participating in research," Simon said.

Participants were also asked whether they would prefer to opt in or out of biobank participation.

"This distinction is important because opt-in consent typically involves more detail, more time and a more active decision on research participation when compared to an opt-out process," Simon explained.

Sixty-seven percent of those surveyed and 63 percent of those who participated in the focus groups said they would prefer an opt-in consent process.

"Nonetheless," Simon said, "a substantial minority -- 18 percent in the surveys and 25 percent in the focus groups -- said they would prefer an opt-out process, primarily because they felt it provided at least some level of choice, involved less time for potential donors and fewer resources for the biobank, and would help with sample accrual and therefore also medical research and progress."

Study participants were then asked to consider whether they would prefer a broad description of how their samples and health information might be used in future research, whether they wanted to control what research their samples and health information are used in via "menu-type" consent forms, or whether they wanted to be contacted for their permission every time their samples and health information became eligible for research.

"Broad consent was preferred by more people when compared to either the menu or study-specific types of consent," Simon said. "However, if you were to lump together the people who said they preferred the menu and study-specific types of consent on the grounds that both these approaches promote more control over sample use than broad consent, the margin is not so impressive."

Forty-one percent of people surveyed – and 54 percent of those in focus groups – were in favor of the broad approach to providing consent.

Simon noted that some experts have suggested that more than one consent approach should be offered to people to allow for a diversity of consent preferences.

"Of course, there may be significant cost and logistic implications to creating such multiple options," Simon said.

He said the study findings will provide a starting point for discussions about consenting patients to a new comprehensive tissue biobank at UI Hospitals and Clinics, which will house thousands of tissue samples for future research purposes. The tissue will be accessed for DNA as well as RNA, Simon said.

"Biobanks are going to be – already are – dependent on public support and participation," Simon said. "Putting into place an informed consent process that meets formal requirements and standards and that works for people by taking their values and preferences into account is one way that we can reach out and build public support and trust for biobanks."

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