Workshop on the use of biospecimens calls for broad initial consent with oversight

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Credit: National Cancer Institute

(Medical Xpress)—In the recent edition of the *American Journal of Bioethics*, the target article, authored by a consortium of participants of a workshop hosted by the National Institutes of Health Clinical Center's Department of Bioethics, discussed broad consent with oversight as an ethically appropriate response to the changing nature of research with biospecimens.

Biological specimens are tissues that have been collected from people in the clinical or research setting, such as tumor that was removed or cells collected to test for disease or research. Under provisions specified in the current Common Rule, these tissues may be saved and stored for future research without obtaining the consent of the patient who provided the tissue, as long as identifiers are removed. However, with the changing landscape in how research is conducted as well as increased interest in biobanking, including as part of the U.S. Precision Medicine Initiative, and in proposed changes to the Common Rule, some form of initial patient consent is likely to be required, that would allow for future, sometimes unforeseen research on donated biospecimens.

Grady et al. propose an initial broad consent strategy in which patients and donors provide broad consent to use their tissues for research purposes at the time that the tissue is collected. Broad consent means that the patient consents to future research with few specified limitations. However, this broad initial consent, the authors believe, should be coupled with oversight and a way to communicate how the biospecimens are being used.

They specify five reasons why consent is necessary: It respects donors; it allows donors to have control over whether their samples are used for research purposes; it allows donors to decide whether the risks and burdens of research are acceptable to them; it allows donors to decide whether they want to contribute to the goals of the research as opposed to only using their samples for particular areas of interest; and it promotes transparency and public trust.

The workshop was held almost two years ago, but the article was published during a time when the federal government is soliciting commentary on proposed revisions to the Common Rule. The Common Rule is a set of regulations for the protection of human subjects in medical research. However, these regulations were last revised in 1991

which means they do not account well for current technology which can identify the donor of "anonymized" biospecimens, as well as current research trends in which trials are conducted at multiple institutions. Currently the Common Rule does not require consent for the secondary use of de-identified biospecimens in research.

As part of their argument for broad initial consent with oversight and communication, Grady, et al. cite empirical studies in which persons were asked about their preferences for consent. In surveys of more than 100,000 individuals from around the world, most respondents wanted to have a say in whether their tissues were used for research, but they were less concerned with the specific research being done, except in some cases of controversial research, such as cloning or commercial research, and sometimes for research with indigenous populations.

The authors state that specific limitations could be built into broad consent based on empirical surveys of what research certain populations might find objectionable. Ensuring that the secondary research is consistent with what the broad consent allows would be part of the role of the overseeing bodies. Oversight bodies would ensure that the research would not conflict with the values of the donors and that reasonable decisions are made on the donor's behalf.

The authors propose a two-step oversight process that would streamline this process without being prohibitively expensive or burdensome. Additionally, oversight bodies that are already in place, such as IRBs, could be involved in certain cases. Notably, this type of oversight goes above and beyond the current Common Rule provisions.

Communication with the donors, the authors suggest, could be done via a website that allows donors to keep up with research, make comments, and opt out, if necessary. When asked why the workshop participants believe donors should not only have an opportunity to consent to the use

of their biospecimens, but also to know how their biospecimens are being used, lead author, Christine Grady, said, "Based on respect, donors should have a say in whether their biospecimens can be saved and used for research, and when feasible, should have access to information about how their samples are used over time."

The authors believe additional research is needed understand what kinds of research donors would find troubling or might wish to make an exception for in the research use of their tissue. The authors propose more empirical studies to understand what information donors want when consenting to research. Additionally, more research is needed in implementing this process as well as interacting with the global community.

More information: "Broad consent for research with biological samples: workshop conclusions" *American Journal of Bioethics*, DOI: 10.1080/15265161.2015.1062162

Abstract
Different types of consent are used to obtain human biospecimens for future research. This variation has resulted in confusion regarding what research is permitted, inadvertent constraints on future research, and research proceeding without consent. The National Institutes of Health (NIH) Clinical Center's Department of Bioethics held a workshop to consider the ethical acceptability of addressing these concerns by using broad consent for future research on stored biospecimens. Multiple bioethics scholars, who have written on these issues, discussed the reasons for consent, the range of consent strategies, and gaps in our understanding, and concluded with a proposal for broad initial consent coupled with oversight and, when feasible, ongoing provision of information to donors. This article describes areas of agreement and areas that need more research and dialogue. Given recent proposed changes to the Common Rule, and new guidance regarding storing and

sharing data and samples, this is an important and timely topic.