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Technology: Uncertainty surrounding privacy and consent issues for biospecimens

Department of Health and Human Services requests public comment on how to regulate human subjects research

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In 2009, TIME Magazine named the National Cancer Institute's effort to develop a national biobank housing tissue samples, tumor samples, DNA and blood one of the "Top 10 Ideas Changing the World Right Now." A 2010 report from the Tufts Center for the Study of Drug Development summarizing a survey of drug companies noted that half of all clinical trials now collect DNA from participants to help find biomarkers that correlate with a drug's effectiveness or safety. As noted in the TIME article, however, the challenge in developing biobanks is to maintain the privacy of the genetic data and to ensure that people are comfortable with sharing their DNA.

Currently, no comprehensive regulatory scheme exists for the collection and use of biospecimens and the laws that do apply, which vary among states and federal agencies, are confusing and sometimes conflicting. For example, regulations governing federally-funded research permit identifiable biospecimens to be used, in certain circumstances, for future unspecified research with the general consent of the individual. In contrast, the HIPAA Privacy Rule requires that authorizations for use of identifiable biospecimens be study-specific, though interpretation and application of this requirement have varied widely. Further, some states, such as Alaska and Texas, have enacted or have considered laws that give individuals exclusive rights to their own DNA samples, and it is unclear how these laws affect consent for research use of biospecimens.

In July 2011, the federal Department of Health and Human Services (HHS), which regulates federally-funded research, released an advance notice of proposed rulemaking to request public comment on how regulations pertaining to human subjects research, which have been in place for 20 years, might be modernized and improved to better protect research subjects. The topics covered by the advance notice are remarkably wide-ranging, from streamlining review of research by institutional review boards and the information included in research informed consent forms to overhauling data privacy protections and the rules for using biospecimens in future research. Notably, the advance notice proposes extending the scope of the federal regulations to apply to all research that is conducted at U.S. institutions that receive any federal funding from certain agencies for research with human subjects, regardless of funding source.

With regard to biospecimens, the advance notice proposes that general written consent, using a brief standard form, would be required for future research use of any biospecimens collected for clinical or research purposes and could cover all future research and even all biospecimens collected at any time by an institution. The advance notice also provides, however, that this general consent would likely include some more specific categories of biospecimen uses that might raise concerns for a significant segment of the general public, such as creating cell lines or reproductive research, for which the individuals could separately give or decline consent.

The commentary accompanying the general proposal regarding biospecimens highlights the difficulty in finding a realistic, workable approach to consent for use of biospecimens that both adequately protects the autonomy and privacy of the individuals who provide the samples and enables important research. On the one hand, HHS recognizes that some, including potential and former research subjects, object to research performed on biospecimens without consent, yet on the other hand, it acknowledges researchers' worries about consent requirements that create unmanageable logistical demands and make research impossible. HHS notes that promoting use of existing specimens is an efficient mechanism for conducting research without presenting additional risks to individuals.

Given the complexity surrounding this issue, which is just one of many addressed in the advance notice, and the varied stakeholders who have an interest in revisions to the regulations, it may be years until revised regulations become final. However, as use of biospecimens and the genetic data they contain becomes more and more important to researchers, continuing under the current outdated and confusing regulatory scheme may hamper important advances, such as the development of a national biobank.

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