NEWS

U.S. aims to overhaul ethics rules for research with people

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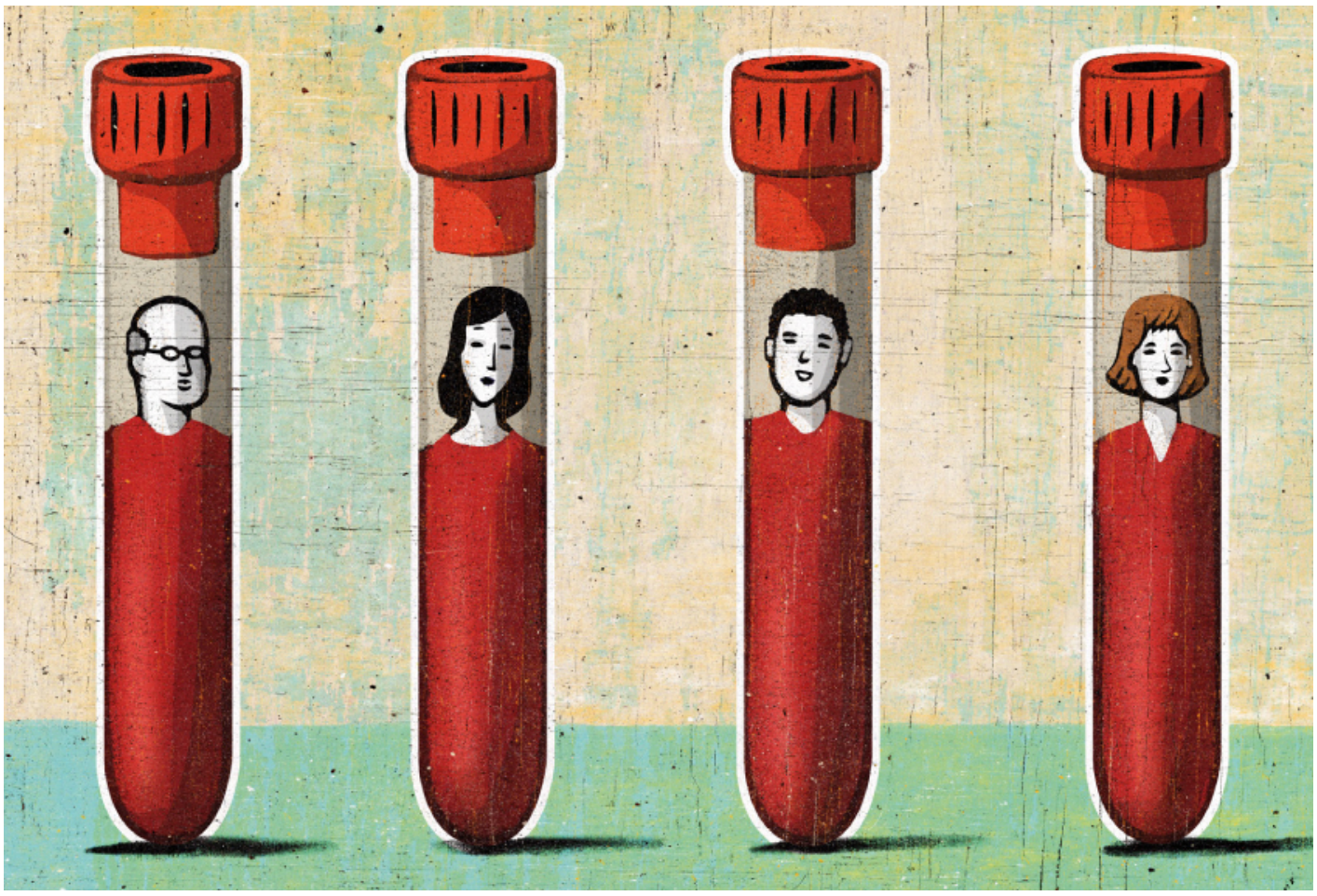

Signing up for a research study may feel like a short-term commitment. A blood draw or a cheek swab and it's done. But those specimens and the data they yield last much longer, and might end up in studies that did not even exist when the participants first gave their consent.

“Maybe I consented to the study that I initially participated in, but you’re now using my sample for a study I don’t believe in — one I never would have consented to,” says **Karen Rommelfanger**, director of neuroethics at Emory University in Atlanta, Georgia. “There wasn’t an opportunity for me to say, ‘Hey, I don’t want my blood used for this research.’”

New rules proposed by the U.S. Department of Health and Human Services (HHS) **address this potential ethical lapse**. The rules add privacy protections for participants, streamline the ethical review process for clinical research and redefine ‘human subjects’ to include genetic data and tissue specimens[1].

The revisions would require scientists to destroy biological specimens if they don’t have the explicit consent of the participant for further use.

As onerous as the rules may prove to be, they “may be necessary to ensure the continuing public trust in scientific research,” says **Helen Tager-Flusberg**, director of the Center for Autism Research Excellence at Boston University.

Protecting privacy:

The proposed revisions would revamp the so-called ‘**Common Rule**,’ a collection of guidelines that safeguard the rights of people who participate in research. The rule is ‘common’ because it covers projects funded by 15 government agencies and departments, ranging from the National Institutes of Health to the National Aeronautics and Space Administration.

Despite mammoth advances in biotechnology, the Common Rule has changed minimally since the HHS adopted it in 1981. The proposed update places particular emphasis on biological specimens that researchers collect for big-data initiatives, such as genomics databases. Although these databases include protections for participants’ privacy, researchers have exposed loopholes that could allow hackers to **obtain sensitive information**.

“Today, you cannot take a sample of DNA and use it to determine that it came from me, unless you merely match it to DNA that you already know came from me,” says **Deborah Barnbaum**, author of “The Ethics of Autism” and chair of the philosophy department at Kent State University in Ohio. “But what if, in the future, the databases become so extensive and the science becomes so good that even an anonymous sample can be traced back to a single individual?”

The new rules acknowledge these risks and impose greater limitations on the use of biological specimens such as blood and saliva than currently exist. The revised regulations would also, for the first time, extend beyond government agencies to privately funded studies.

Expiring specimens: New rules would prohibit indefinite storage and use of biological specimens in research.

Simpler system:

The new rules streamline the ethical review process by replacing a lengthy, densely worded informed-consent document with a short, simple form in which most of the study details appear in an appendix. The rules also specify the use of a single form from a designated institution for multisite collaborations. This change skirts complications that often arise from inconsistencies in guidelines among collaborating institutions.

The guidelines also clearly specify which research projects don't require approval from ethics committees, also known as institutional review boards (IRBs). The exempt projects include public health surveys and other efforts that pose little risk to participants. Researchers can also submit grant proposals without first getting an IRB review.

Researchers who run clinical trials generally welcome these simplifications. **Alexander Kolevzon**, who is involved in a clinical trial of **insulin-like growth factor in children with Phelan-McDermid syndrome**, hails the recommended changes as a step toward reducing the burden for families participating in research as well as for researchers who need IRB approval for their work.

One aspect of the proposal is controversial, however. The proposed guidelines reclassify biological specimens as 'human subjects,' suggesting that the genetic information contained in the samples is inextricably linked to personal identity. The rules would require researchers to obtain broad consent from participants who agree to the future, unspecified use of their samples — and to discard these samples after 10 years unless the participants sign a new consent form. In some cases, biological specimens from children may expire even earlier.

Kolevzon and others are concerned about the potential destruction of valuable data, given the difficulty of tracking down participants for new consents.

"The ability to store biospecimens for future analysis will be critical to improve our understanding of the causes and treatment of autism," says Kolevzon, clinical director of the Seaver Autism Center in New York City.

Cultivating trust:

Other researchers, however, say that the change would strengthen the partnership between researchers and families with autism.

Trust is paramount in the field of autism, because the participants are often **actively interested or involved** in the research goals, notes **Rommelfanger**.

In some cases, she says, the participants may disagree with the goals of future studies. "If you're starting research from the basis that we need to cure autism, there may be some people participating in those studies who don't actually believe that should be the goal of the work." In those instances, she says, individuals should be able to opt out.

Rommelfanger says the revamped Common Rule is unlikely to resolve all of the ethical quandaries that dog autism research. Still, she is optimistic about the sea change they represent. "I'm glad there are people who are thinking about how to modernize and improve our human research processes," she says.

The HHS is inviting **comments and feedback** on the proposed changes until 6 January. If approved, the changes will roll out over the next three years.

REFERENCES:

1. Hudson K.L. and F.S. Collins *N. Engl. J. Med*. **373**, 2293-2296 (2015) **PubMed**