BIOMEDICAL RESEARCH

Controversy over clinical-trial rules

Finalized regulations by US agency stoke privacy concerns.

BY SARA REARDON

In a blow to patient-privacy advocates, the US government has abandoned a plan that required scientists to obtain the consent of people who donate biological samples before using the material in subsequent studies, even if those specimens cannot be identified.

The US Department of Health and Human Services (HHS) proposed the change in September 2015 as part of an overhaul of the Common Rule, a set of regulations that govern clinical trials and patient consent in research. But the final version, released on 18 January, did not include the provision.

Most of the changes are intended to lessen regulatory burdens on researchers. They drop requirements that scientists obtain separate approval from ethics boards at every institution where a study will be performed, for instance. This allows government agencies to decide whether a study needs multiple approvals.

The US National Academies of Sciences, Engineering and Medicine blasted the proposed changes in a June 2016 report. It said that the government's plan was "marred by omissions and a lack of clarity" and recommended that the plan be withdrawn.

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The final version of the Common Rule shows that the government listened to scientists' fears about increased research burdens, says Ellen Clayton, a bioethicist at Vanderbilt University in Nashville, Tennessee. "I went into my chair's office and did a happy dance, I'm thrilled."

The updated rules still require that participants be informed if the research might include whole-genome sequencing, which could make the specimens they donate identifiable.

But the decision to drop the consent requirement is a disappointment to Twila Brase, president of the Citizens' Council for Health Freedom in St Paul, Minnesota. The council has campaigned to classify blood spots used in infant disease screenings as human subjects, and to require consent for using the spots in research.

The final version does call for a description of each study, along with the risks and benefits, on the patient consent forms. There is also a requirement to post those forms online for some federally funded trials. But the rules do not extend to trials that are not federally funded.

Applying the Common Rule to non-federally funded trials would be an unnecessary burden, says Jerry Menikoff, director of the HHS Office for Human Research Protections. Most institutions that receive federal money apply the regulations to all of their trials regardless of who funds them, he says.

That decision is unfortunate, says Michael Carome, director of health research at consumer-advocacy group Public Citizen in Washington DC. "We think human subjects deserve protection whether or not they're in a federally funded trial." ■