Subject: New research rules are mixed bag for human subjects

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# HHS Proposal Leaves Many Human Subjects at Risk

## *Statement of Dr. Michael Carome, Director, Public Citizen's Health Research Group*

*Note: Today, the U.S. Department of Health and Human Services (HHS), along with 15 other federal departments and agencies, issued a proposed rule (PDF) that would revise federal requirements for the protection of human subjects in scientific research. Dr. Michael Carome, who served as associate director for regulatory affairs at the U.S. Office for Human Research Protections from 2002 to 2010, is an internationally recognized expert on the protection of human research subjects.*

The long-awaited rule from HHS, which has been under development for more than four years, represents a mixed bag of changes. For example, on the up side, the rule would extend federal protections to all clinical trials conducted by institutions that receive federal funding for human research, regardless of how trials are funded. On the down side, the rule would inappropriately mandate that only one institutional review board (IRB) may review clinical trials conducted at multiple institutions, including trials that involve dozens or hundreds of sites. IRBs review human research to ensure it is ethical and complies with regulations.

HHS appears to be overstating the potential benefits of the rule. HHS misleadingly suggests that the rule will greatly enhance informed consent for research by "imposing stricter new requirements regarding the information that must be given to prospective subjects." In fact, the proposed rule makes few substantive changes to the information that must be disclosed during the consent process.

More broadly, the proposed rule is premised on the dubious assumption that reducing the time and effort IRBs spend reviewing low-risk research will allow them to spend more time and effort reviewing higher risk research, but HHS offers no evidence to back this up. It is far more likely that IRBs – many of which feel overburdened – will spend the same amount of time and effort reviewing moderate- and high-risk research that they currently do, resulting in no enhanced protections for subjects. Without additional, specific requirements for higher risk research, human subjects will continue to remain at risk.

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