

BMJ editorial: India's research participant protection policy

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In an editorial published online today in *BMJ*, Johns Hopkins bioethicist Jeremy Sugarman and other experts warn that action is urgently needed to deal with possible unintended consequences of India's new policy protecting research participants.

Passed earlier this year, the Drugs and Cosmetics Act (First Amendment) Rules, was meant to mitigate [ethical concerns](#) with potential serious consequences for public health, as well as India's viability as a continued global leader in clinical research. However, Sugarman and his co-authors highlight specific concerns that could lead to the policy having the opposite effect, including a table of the policy's "Conditions attributable to clinical trial injury or death." One of these is "use of placebo in a placebo controlled trial," to which the authors respond that "placebos are not necessarily harmful. Indeed the use of a placebo is often the only way of truly assessing whether the agent under study is associated with undue risk or significant benefit."

Among the authors other concerns is the policy's call to compensate research participants for injury for "failure of investigational product to provide intended [therapeutic benefit](#)," arguing that the purpose of the trial is to determine just that.

The authors give short and anticipated long-term ramifications of the policy, noting that at least 35 collaborative research projects funded by the US National Institutes of Health have been suspended since March 2013, most investigating large scale public health problems. They also

note that India is the main supplier of [antiretrovirals](#) to donor supported HIV treatment programs in developing countries, and the dramatic fall in clinical trial applications that is already taking place could have a ripple effect on the availability of registered drugs.

"It is essential that the unintended consequences of the new policy are dealt with effectively but rapidly," the authors write. "The relevance, impact, and quality of [global health](#) research have been greatly strengthened by engagement of Indian scientists and participation of Indian research volunteers. Advances in health research need India's leadership and participation."

More information: www.bmj.com/content/347/bmj.f4841

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