**COVER LETTER**

Dear Editor,

This is to confirm that the article entitled “**Challenges in the governance of biomedical and health research after new drugs and clinical trial rules**” submitted to the *Indian Journal of Medical Ethics* is original and has been co-authored by the undersigned. All authors have participated in the work sufficiently to meet the ICMJE guidelines for authorship. All have read and approved the manuscript.

The submission is not under consideration for publication in any other journal. We give consent to Dr. Yashashri Shetty to act as the author for correspondence.

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We have read the terms and conditions of authorship of IJME and accept them.

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**Short title**: ***Governance of Biomedical and Health research***