

COVER LETTER

Dear Editor,

This is to confirm that the article entitled “An Audit of Warning letters [WLs] issued to Sponsors, Institutional Review Boards [IRBs] and Investigators by the United States Food and Drug Administration (US FDA) over a six-year period” 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 Nithya Gogtay to act as the author for correspondence.

Details of sponsorship or relevant competing interests, financial or otherwise: None

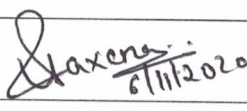

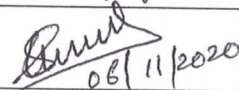


We have read the terms and conditions of authorship of IJME and accept them.

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