Letter to Editor

Prerequisite of doing clinical trial with drugs in COVID-19 patients: Situational experience

Sir,

We read with great interest an opinion published in perspective in clinical research by Bhatt.[1] Herewith, we have outlined our experience start from the preparation of the documents, through ethics committee (EC) approval, and till the start and conduct of our clinical trial. The EC review process was done online, and we were contacted via phone/email for queries. This not only expedited the process but also aligned with the norms of social distancing. In the current situation, a few deviations from routine practice were approved by the EC. One such change in policy was that the principal investigator was allowed to provide an undertaking on behalf of all the other co-investigators. This is important as multiple departments are normally involved in the working of a clinical trial, especially in a situation such as COVID-19, which include departments ranging far and wide such as radiology to anesthesia. Personally, obtaining original signatures of all the co-investigator was not feasible, due to poor accessibility and availability. It is important to bear in mind that many of the doctors were posted on COVID duty or were in quarantine postduty or were too aged to move about. A leeway should be made in these cases to permit getting their consent over mail, which could be attached to the document. It is also helpful for EC if the principal investigator submits the project as a Fast Tracked Protocol of dynamic nature.

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Conflicts of interest

There are no conflicts of interest.

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