**Title: The new Indian National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: an opportunity to translate benefit sharing into practice**

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**Reviewer Comments:**

1. The paper lacks sufficient critical analysis and tends to focus heavily on ‘benefit sharing’.

2. A critical engagement with the Guidelines could have resulted in flagging the absence of a meaningful definition of 'community' for the purpose of sharing activities (2.10 is pretty much vacuous). Invariably this is followed by an admonition to 'engage', and sometimes agree 'a priori' to a deal, but how that would actually occur is uncertain, given that ‘community’ isn’t clearly defined.

3. There is other vacuous content in the Guidelines such as the admonition to balance risks and benefits. While that bravely repeats what every other guideline stipulates, it remains silent on ‘how to’, which in any case is difficult. Besides, as you have also noted, the force of the benefit sharing paradigm is seriously weakened by those ubiquitous qualifiers ('whenever relevant' etc).

4. This manuscript is of fairly limited interest, because, like the Guidelines on these issues, it skates around the issues that actually matter in the real world.

**Editor comments:**

1. Will be helpful for authors to situate the revised ICMR guidelines with reference to the other research ethics guidelines or guidelines of research involving human participants with reference to the central theme of ‘benefit sharing’ that authors have chosen.

2. Will also be helpful if authors compare the revised guidelines to the earlier version at least to some extent. For example, it is not clear to the readers if the earlier version of the ICMR guidelines referred to ‘benefit sharing’ at all, or they did but only marginally and the revised version has honoured it with a more prominent place compared to the earlier version.

3. It would also be essential to mention implementational challenges going beyond training of the EC members.

4. Revision along these lines will be help strengthen the piece.