*Comments on the paper*

Title: **Informed consent process: a challenging issue of health research in India**

**I. Importance of the paper**1.  Does it address issues relevant to the fields of medical ethics and bioethics in India and the developing countries?

Yes, it addresses a very important issue in research ethics which is applicable to India and in the developing world.   
  
2. Is it topical? – Yes, it is topical  
  
a. Is the issue discussed from another country's/culture perspective?

No, the results of the study have not been discussed from another country/cultures’ perspective. In fact, although the authors have mentioned more than once about the unique social and cultural milieu of India that makes the informed consent process a particularly complex one in the country, they have not discussed their findings in a way that will allow this point to be justified.  
  
b. Will it influence practice or policy?

Although the paper is dealing with an important and topical issue, the way the findings have been presented and discussed does not allow for any new or relevant contribution to practice or policy changes. The findings need further clarification and hence do not present any entry points to make meaningful recommendations to policy or practice.  
  
c. Is it too specialized for the journal?

No, it is not too specialized for IJME.  
  
  
**II. Originality**

 Is the information /comment new?

The area is not a well researched one in the country, but the paper hardly brings out any new and relevant information that will add to the existing knowledge base. The fact that informed consent process is a very complex one, fraught with many challenges in the country is not new information. The aim of the paper was to explore the perception of researcher’s on the challenges of informed consent process. If the paper had really achieved this aim, then it would have succeeded in adding some new information to the area. This is primarily due to the way the authors have communicated their findings.

Table 1 is not clear. The title says it is about the researchers’ feedback on challenges during the IC process.. The table is not self explanatory and it is really not clear what the authors meant by the column names “areas of semi-structured interviews” and “topic guide”. It obviously needs a more detailed description in text.

Tables 2 & 3 discuss the interpretations pertaining to researchers’ challenges and their feedback on challenges from patients’ perspective during informed consent process. Since a thematic framework approach was used for analysis, the authors could have explicitly mentioned that the analytical framework they decided upon included three components namely – challenges in comprehension, challenges related to time, place and duration and pertaining to other issues. It would have greatly aided our understanding if they gave some more insight into their process of development of the framework (for instance, was it inductive or deductive or did they use a mixed approach, why did they decide upon this particular framework and so on). It would also have been better if these were justified using a few verbatim quotes to give us an insight into how and why did the researchers came up with the interpretations.

The authors have commented on the communication skills of researchers and also mentioned about verbatim quotes by research subjects. However, it is also not clear whether the authors observed the researchers interacting with research participants or interviewed research participants separately or watched the video recordings.

**III Conclusions**1. Is the interpretation warranted, unwarranted, well developed?

Since the authors have mentioned very sparingly about their analysis (except that they have used a thematic framework approach) and have not really placed their findings in a way that will allow the readers to make any kind of correlation with their interpretations, we were unable to decide if the interpretations were warranted and well developed.   
  
2. Does the article contain loose generalizations?

The discussion part of the paper speaks about the need for adequate information to be provided and the need for researchers to have good communication skills. However, these generalizations do not seem to be grounded on the findings that they have presented as part of this study. Similarly, in the discussion, under the sub heading, “comprehension”, the authors have mentioned, “It was noted that the way of posing questions by the investigators and thereby the answers from the patients lacked a normal flow or spontaneity—both investigator and patient appeared very self-conscious on the recording”. The authors have not mentioned anywhere in their methodology that they have used the video recordings as a source of data.

3. Other comments

The methodology is incomplete and ambiguous. Results section lack clarity; more information is need to make sense of the findings presented in the results section. The process of coding, the development of the working analytic framework etc are not mentioned and is vital to understand the interpretations of the researchers. Discussion part is too general and does not seem to emerge from the findings of the study.

**IV. Recommendation**  
  
Accept with modifications (specify)  
  
- Rework the methodology, results and discussion. Strengthen the results and provide a proper link between the results and discussion. Justify generalizations like poor communication skills of researchers and “ethical principles of western countries may not be applicable in Indian system, which is culturally and socially different from the western world” and so on.

-Needs thorough spell check, grammar check and copy editing  
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would prefer it not be disclosed.