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

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**Review Comments**

**Reviewer 1**

Abstract –

1. The analysis is directly referred in the abstract regarding regulatory study and questionnaire based study. This is not seen in the result section as well as in discussion. Please rewrite and try to explain in full.
2. “The issue of informed consent in research done in India is a challenge due to various complexities of culture, level of education and demographics.” This sentence appears disconnected, as this is not been analysed in the result section. Please rewrite the abstract.

Introduction –

1. When the authors say ‘The focus now, however, is on “negligence and the failure”’, it appears confused and there is disconnect between sentences. What negligence and failure is being discussed here and how can anybody tape this unless the informed consent process is monitored.
2. How does the consenting process or culturally different population result in restricting sample size or delay in the study. According to the population, such measures to consent have to be prepared or IEC should insist on it or else because of backwardness, it’s easy to fool people as they never question or doubt your character. Is there any reference for such a statement?

Methodology –

1. The Interview guide was prepared to explore researchers’ experiences. Was the interview tool validated? In the methods and result section, nothing about this is mentioned.
2. It is stated that - The study interviewed four groups of researchers who were involved in various types of research study namely (1) regulated and (2) non-regulated clinical trials, (3) funded (but not trial related) and (4) non-funded research projects. What is the difference between non-regulated and funded trial. There is a 4th category described as ‘non–funded’ , no study can be conducted without funding , such studies are called ‘self–funded’ studies (the funding will be minimal but without a budget, studies cannot happen even, for e.g, retrospective analysis).

Observation and Discussion –

1. On physician perspectives on the time, duration and place: It says ‘as the investigators don't have time, place for consenting’ - how can IEC give permission for such sites where the investigator doesn't have time or place? They need to specify which type of study they are referring to here; because now there are four categories, accordingly the impact will be different. The results should comment on the investigator's perspective in four different types of study, as there can be an overlap.
2. On patient perspectives: ‘this is evident in epidemiological studies.’ - What about patients' feelings in other types of studies? AV consent can be an issue only in regulatory studies. Please clarify this in the article.
3. It says, “Such refusals are observed more when post graduate students are involved in the consent process than in the case of the treating clinicians”. Is there any reference for such statement, because for reducing therapeutic misconception, IECs may prefer that the consent is executed by a third person (eg. post graduate student)
4. “Refusal to consent is found maximally in questionnaire based studies” - this is discussed, but how many were questionnaire based studies and what did the investigator feel about this? This has not been spelled out in the results.

Conclusions –

1. The paper concludes “The regulations of Indian Council of Medical Research are based on the western guidelines. do not necessarily address the requirements of Indian population being culturally and socially different from western world” and a reference is quoted – Such a conclusion is not acceptable. Conclude based on the study findings and no referencing is required. That ICMR guidelines are totally based on western data is not an absolute truth. The author may recommend something for improvement in ICMR guidelines.

**Reviewers 2**

1. 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.
2. 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.
3. 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.
4. Tables –
   1. 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.
   2. 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.
5. Methodology - 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.
6. 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.
7. Conclusions - 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.
8. 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.