Title: Informed Consent process:

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| --- |
| a challenging issue of health research in India |

Importance of the paper  
  
           It address issues relevant to the fields of medical ethics and bioethics in India and the developing countries?  
  
Is it topical?  
  
           It can influence practice or policy?  
  
  
Originality  
  
           There is no originality

Conclusions  
           The article contains loose generalisations.  
  
           

Recommendation  
  
Accept with modifications –ie if they answer all the queries raised

**Introduction:**

* The first sentence is grammatically not correct .
* The focus now, however, is on “negligence and the failure”, the author is confused and there is disconnect between sentences . What negligence and failure we are discussing here and how anybody can tape this unless monitor the informed consent process.
* How does the consenting process or cultural different population result in restricting sample size or delay in the study. According to the population, such measures to consent or such consents has to prepared or IEC should insist on it or on the other hand 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:**

* Interview guide was prepared to explore researchers’ experiences. Was the interview material validated? In the methods and result section , nothing about this is mentioned
* Instead of the word ‘regulated’. can the authors use the word ‘regulatory’ ..
* 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 )

**Observations :**

1. the process (ii) time span, (iii) barriers and influences and (iii) any suggestion on improvement.

* On physician perspectives: On the time, duration and place: 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 .
* 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 in the article

**Discussion:**

* 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 , we prefer that the consent is executed by a third person (eg post graduate student)
* 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 has not been spelled out in the results

**Conclusion**:

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 – which is not acceptable . Conclude based on the study findings and no referencing is required . ICMR guidelines is totally based on western data is not an absolute truth . The author can recommend something for improvement in ICMR guidelines

**Abstract:**

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.

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.