

Informed Consent in Biomedical Research: Sounds simple but difficult to comprehend

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Informed Consent for Clinical Trials: a Comparative Study of Standard Versus Simplified Forms

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Background: A high level of reading skill and comprehension is necessary to understand and complete most consent forms that are required for participation in clinical research studies. This study was conducted to test the hypothesis that a simplified consent form would be less intimidating and more easily understood by individuals with low-to-marginal reading skills.....

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Background

ICMR

- **Informed Consent of Participants :** For all biomedical research involving human participants, the investigator must obtain the informed consent of the prospective participant.
- **In the case of an individual who is not capable of giving informed consent, the consent of a legal guardian.**
- **Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not.**
- **Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant/ Patient Information Sheet.**

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- **ICF should have following components as may be applicable :**
- **1. Nature and purpose of study stating it as research**
- **2. Duration of participation with number of participants**
- **3. Procedures to be followed**
- **4. Investigations, if any, to be performed**
- **5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk**
- **6. Benefits to participant, community or medical profession as may be applicable**
- **7. Policy on compensation**
- **8. Availability of medical treatment for such injuries or risk management**
- **9. Alternative treatments if available**

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- **Waiver of consent**
- **Voluntary informed consent is always a requirement for every research proposal.**
- **However, this can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations.**

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- **ICF (WHO)**
- **Part I: Information Sheet**
- **Introduction, Purpose of the research , Type of Research Intervention, Participant Selection, Voluntary Participation, Procedures, Duration , Risks , Benefits , Reimbursements,**
- **Confidentiality, Sharing the Results , Right to Refuse or Withdraw , Who to Contact**
- **Part II: Certificate of Consent**
- **The certificate is an integral part of the informed consent and not a stand-alone document.**
- **I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**
- **A copy of this ICF has been provided to the participant.**

Objectives

- **To find out the shortcomings of ICF of studies conducted compared to the standard ICF .**
- **To find out understanding of ICF among the participants by field experiences.**

Methodology

- **By retrieving details of ICF submitted along with the protocol.**
- **To locate shortcomings compared to standard ICF of ICMR.**
- **To relate understanding of ICF among the participants of field studies.**

Observation

- **ICF reviewed and compared.**
- **Participants were asked (in the field) about understanding of ICF.**
- **About 420 languages and dialects of different languages families are used in a complex and wide ranging ethno and socio-linguistic configuration in north-east India.**

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- ▣ A language in conjunction with culture, religion and history is an important component of nationality formation. Language plays a very important role in different transitional phases.
- ▣ Assam: Four different dialects in Assamese depending geographical location of the state. About 8 other languages of different origin
- ▣ Arunachal Pradesh: Dafla, Adi, Gallong Mishri, Nocte, Monpa, Aka, Khamti, Nishi, Wancho and Tagin
- ▣ Manipur: Meithei and other 5 languages.
- ▣ Nagaland: Nagas speak 60 different dialects belonging to the Sino-Tibetan family of languages. Nagamese and Lotha.
- ▣ Mizoram: Lusei, Mara, Fanai and Changte .
- ▣ Tripura: Bengali, Chakma , Tripuri
- ▣ Meghalaya: Khasi, Garo and Jaintia.
- ▣ Sikkim: Nepali, Bhatia, Lepcha and other at least 10 major dialects.

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- **Lack of proper information.**
- **Unable to understand the content of ICF due to poor education /social background.**
- **Unable to find difference in treatment and research.**

Items	Yes (%)	No (%)
Adequate Information ICF	67	33
Translation of ICF in Language of the people	27	73
Is the information given to the participants was adequate	50	50 25 Not clear

Conclusion

- **Investigators are not adhering to the standard procedure for developing ICF.**
- **Translation of ICF in local language(s) is complex as often experts of the languages are not available.**
- **Participants often do not differentiate between treatment and research.**
- **PIs communication of information to the participants are not adequate.**

