

# **THE PROCEDURE OF INFORMED CONSENT IN INDIAN CLINICAL RESEARCH**

## **Directions towards Improving the Quality of Provision of Information**



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# Introduction


- ▶ Literature Review Study.
- ▶ A critical assessment of the standard and method in regard to the quality of the IC procedure as practiced in India today and makes fresh proposal for a good model in agreement with the culture and tradition of India.



## Introduction

- ▶ For the large number of patient population, varieties of diseases and availability of English speaking investigators, India is considered by pharmaceutical industry a large privileged area where to perform clinical trials.

## Regulation of Trials in India

- ▶ For the international trials which are conducted in India, the investigator should follow the Good Clinical Practice (GCP) Guidelines.
  - ▶ The Indian GCP guidelines went further than ICH-GCP with provisions to protect the poor and the uneducated patients and providing compensations for drug related adverse events.
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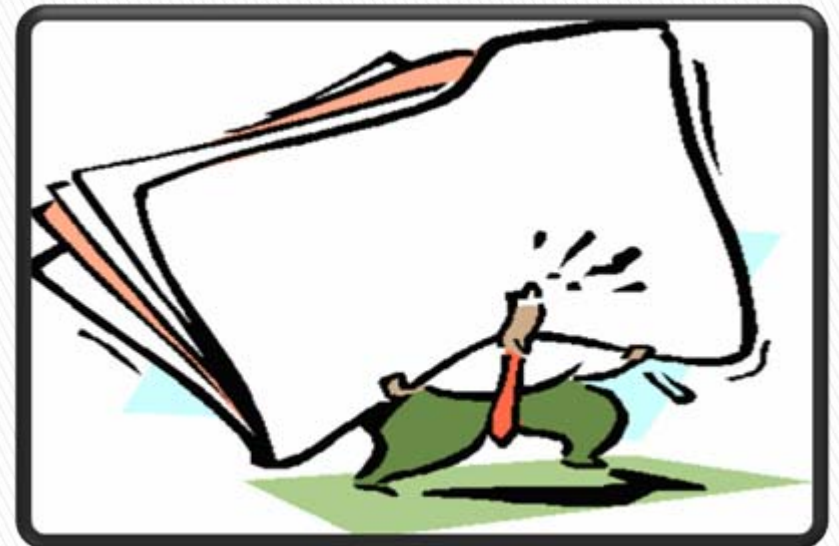
## Current Situation of Informed Consent in India

- ▶ The process of giving informed consent, the desire of information in the consent process, the degree of paternalism in the researcher-trial subject relationship, the role of family and community in the IC procedure are largely influenced by the ethos and values of the nation and culture prevailing in the region.




## Current Situation of Informed Consent in India


- ▶ The illiterate and poor patients will be easily influenced by the benefits and facilities offered by the sponsors and investigators like free hospital/medication, treatment, food, and laboratory check-up.



## Current Situation of Informed Consent in India

- ▶ Schedule Y provides a checklist for informed consent and a revised format for the informed consent form.
  - ▶ These changes when fully implemented will provide better legal protection to patients and protect their right to information about the trial and consent for participation.
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# Main Problems in the Consent Procedure


- ▶ Investigators may not allot all the sufficient time.
  - ▶ Many subjects fail to realize crucial information.
    - Content of the consent form.
    - Randomization.
    - Difference between Clinical trials and Regular Therapy.
  - ▶ Consenting to please their physicians.
  - ▶ Professional struggle to balance patient-care and research activities
  - ▶ Pressure of quick patient recruitment from the sponsor etc.,
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## The main areas need to be changed


- ▶ The format for the informed consent can be modified.
- ▶ Translation to local language in simple format.
- ▶ The physicians should develop communication skills.
- ▶ There is a lack of formal training in bioethics and research methodology for the Researchers.



# Need for Simplification in the Procedure of Informed Consent

- ▶ The informed consent forms usually designed in India are translated and back-translated to ensure that they retain their original meaning. This will meet only the legal format of the process rather than the actual need of the participant to understand the information.
  - ▶ The improvement of the procedure for informed consent depends upon variables like the consent form's reading level, the amount of written details presented, the length of the form, whether the information was presented verbally or in a written form, the age of the subjects, etc.
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## How to improve an IC procedure?

- ▶ Research Ethics Committee should approve only the simplified form of the consent and should assess the readability of the consent form.
  - ▶ The sponsor should supply the template in a standard language and in local languages, where the investigator is going to carry out the study.
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# Studies Conducted in the field of Simplification of IC Procedure

- ▶ The population with low levels of literacy needed the help with illustrations, descriptive videos, communication materials. (Paasche-Orlow MK et al.)
- ▶ Measurements in the ongoing studies might be a possible method.
  - Observation by a trained person.
  - Even the research team members can share their experience in IC procedure with others.

(Sugarman J et al)



# Studies Conducted in the field of Simplification of IC Procedure

- ▶ measuring the quality of the IC procedure called the “brief informed consent evaluation protocol (BICEP)”.
- ▶ It is using a telephone interview immediately following consent that has good reliability. (Sugarman et al)
- ▶ One system used by investigators in Western countries to progress the informed consent procedure is called the ‘teaching to goal.’
- ▶ Quizzing the participants after reading a simplified informed consent document.



# Proposal of Informed Consent Quality Assessment Questionnaire (ICQA)

- ▶ Prepared with the help of basic elements of IC.
- ▶ To assess participant understanding about the
  - Nature of the trial
  - All other information relevant to patient safety and security



# Proposal of Informed Consent Quality Assessment Questionnaire (ICQA)

- ▶ Must be a first step to assess the quality of IC undersigned by patients illiterate or inhibited to understand what they are signing.
- ▶ The questionnaire could become part of the normal IC procedure in India, if it will encounter Authorities and manpower appreciation.

## INFORMED CONSENT QUALITY ASSESSMENT QUESTIONNAIRE

Age:


Sex: M/F

Occupation:

Qualification:

1. Do you feel that you have been informed how long your participation in this clinical trial will be?
2. Do you think that all the treatments and procedures that the investigator proposed you are the best for your disease?
3. Did you understand what “randomization” means?
4. Do you know that no direct medical benefit will derive to you from your participation in this clinical trial?
5. Are you sure that participation to the trial does not involve any additional risk or discomfort?
6. Do you know that because you are participating in a clinical trial, it is possible that the study sponsor, various government agencies, or others not directly involved in your health care could have access to your medical records?
7. Do you know that the consent form you signed lists the names of the contact persons, who must answer any of your question or concern about the clinical trials?
8. Do you know that the consent form you signed describes how you will be covered by insurance if you are injured or become ill as a result of participation in the clinical trial?
9. Did you understand that if you do not want to participate in the clinical trial you are free to refuse to sign the consent form
10. Did you understand that you are not obliged to remain in the clinical trials if you decide to withdraw?
11. Try to explain with your words the clinical trial of which you will become the subject

## Discussion

- ▶ There should be more studies focusing the participant's understanding about their trial participation.
  - ▶ Research is needed to determine methods to increase comprehension, especially for participants with inadequate or marginal reading skills.
  - ▶ Long and complicated discussion during the consent process is regarded as a hindrance to research.
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## Discussion


- ▶ Testing the written materials on colleagues who are not part of the clinical trial, and also on some not particularly literate people, an accurate check of ambiguities, missing or hidden information or too difficult sections might be a good method.




# Conclusion

- ▶ The process of obtaining informed consent should follow a framework for better quality.
  - The research team should share the information with the participants.
  - The researchers and potential participants should discuss and interact about the issues related to the study.
- ▶ Researchers and participants should collaborate in both directions: a better relationship, if possible less paternalistic, and a kind of therapeutic alliance for the best results in the clinical research.


## Conclusion

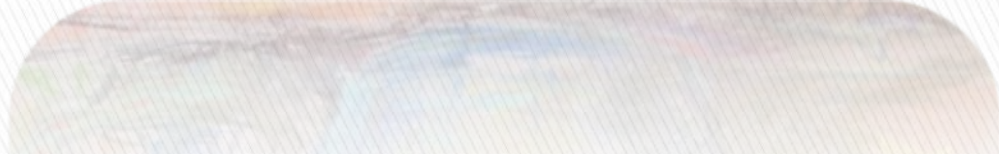
- ▶ If the participant rejected to participate in the study, he must receive in any case the gold-standard treatment.
  - ▶ The researcher should not capture the good will of the participants with money or with any other benefits.
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## Limitations of the Study

- ▶ Shortage of studies concerning the improvement of informed consent quality procedure in India.
  - ▶ Without proper analysis of the issues supported by qualitative studies we can't improve properly the IC procedure.
  - ▶ Interview based studies in both participants and physicians are equally important for the success.
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**Thank You**