



Informed Consent Document and BLOOPERS

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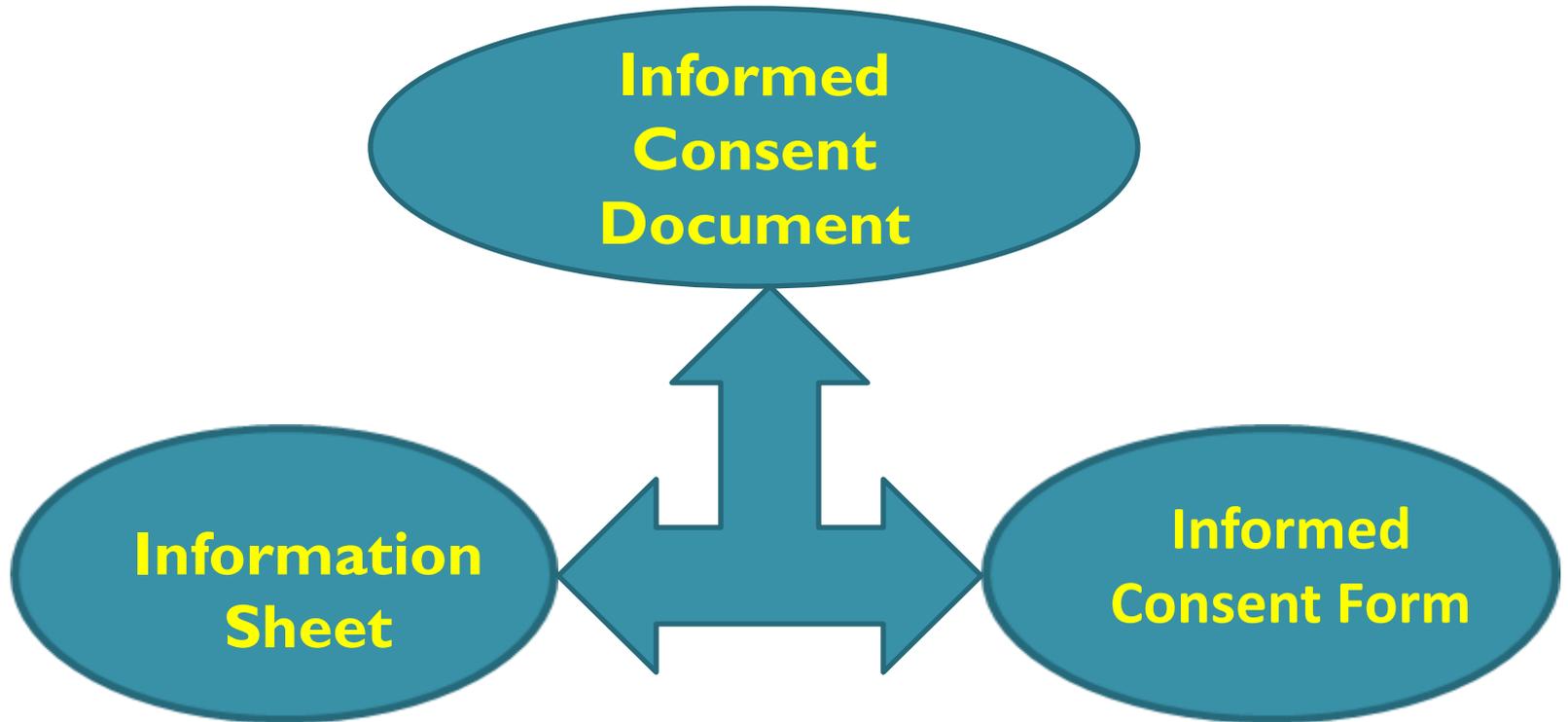
What I am going to talk?

- Introduction to Informed Consent Document (ICD)
- What are the Bloopers or glaring errors seen in the ICD
- What care needs to be taken while drafting ICD
- Conclusion/Opinion

What are the Bloopers or glaring errors seen in the ICD?

- Definitions related bloopers
- Science related blooper
- Language related bloopers

Definitions Related Bloopers?



Science Related Bloopers

- Subject Vs Patient
- Researcher Vs Investigator (PI/Col/SubI)

Language Related Bloopers

- WHO on its site states that language used throughout Informed Consent Form should be at the level of a local student of class 6th/8th
- The ICD is generally referred to as the document which should explain a layman in simple and lucid language everything that a person needs to know about the clinical trial he/she is taking part in.

Language Related Bloopers

- **Study Title** - The title of the study is generally 'as submitted to the DCGI' and as such technical in nature and difficult to translate. The wordings are slightly complex to explain, for eg. "A randomized double-blind multi-centre study". This is translated as "यह एक यादृच्छित बहुकेन्द्रीय अध्ययन है जिसमे दोनो ही अन्धे होते हैं". This can simply be translated as "यह एक अकमित बहुकेन्द्रीय दोहरा अज्ञात अध्ययन है"
- **Procedures** - The study may involve various procedures and all the procedures should be mentioned in the ICD and translated in a way that the subject is able to understand.

Language Related Bloopers

- These procedures could be technical which need to be simplified for the benefit of the subject and care needs to be taken not to use any medical jargon, such as HRCT (High Resolution Computed Tomography), Placebo, ECG, etc. These procedures needs to be explained and not merely mentioned in the ICD.
- I have seen that tubectomy is often translated as “नसबंदी” which actually means vasectomy, correct word for tubectomy is “नलबंदी”.

Language Related Bloopers

- Language in ICD needs to have correct punctuation marks, otherwise it could lead to difficult situation, for eg. Dr. Abdul Narayan D'Souza, **PSYCHOTHERAPIST** could be translated as
Dr. Abdul Narayan D'Souza
PSYCHO THE RAPIST
- Transdermal patch was translated as “त्वचा के पार का पैबंद” which is a literal meaning of trans— के पार, dermal—त्वचा, patch — पैबंद and same is translated in Marathi as “त्वचेच्या पलिकडचे ठिगळ”. This should have been translated as “अंतरत्वचीय पट्टी” in both Hindi and Marathi.

What care needs to be taken while drafting ICD

- Legally accepted representative (कानूनी रूप से स्वीकार्य प्रतिनिधी) is often written as legal representative which literally means representation by a legally qualified person (e.g. a lawyer) and is translated as “कानूनी प्रतिनिधी”.
- In Hindi Guardian is often translated as “पालक” which is incorrect because unlike Marathi where it means guardian, in Hindi पालक means only a leafy vegetable. Guardian in Hindi should be translated as “अभिभावक”.
- Instead of “Signature/Thumb impression” needs to be written as Signature/Left hand thumb impression. This is because in medical language hands have thumbs and feet have toes but in English language hand and feet both have fingers.

Conclusion/Opinion

- Researcher needs to convey WHO requirement of lucidness of translation to the translator
- The ICD is a document that goes to the subject, therefore it needs to be in a language which is easily understood by him/her.
- All possible medical jargons should be avoided
- All glaring mistakes or bloopers needs to be weeded out before the ICD is approved and goes to the subject