

# Comprehension & How to Write an Informed Consent Document Including Need for Translations

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# Five Building Blocks for Informed Consent

## 1. Competence

- capacity for autonomous choice
- ability to understand relevant information & appreciate consequences of decisions taken based on the information given

## 2. Disclosure

- provision of relevant information & its comprehension by the recipient

# Five Building Blocks for Informed Consent

## **3. Understanding**

- ability to understand and process information given

## **4. Voluntariness**

- coming to a decision freely without force, coercion or manipulation

## **5. Consent**

- a voluntary decision and an authorization to proceed

# Five Building Blocks for Informed Consent

“one gives an informed consent to an intervention if one is ***competent*** to act, receives a thorough ***disclosure***, ***comprehends*** the disclosure, acts ***voluntarily*** and ***consents*** to the intervention”

# Factors that Limit Comprehension

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- Illness
- Poverty
- Illiteracy or low level of education

# Factors that Limit Comprehension

- Unfamiliarity with conduct of medical research
- Unorthodox views about disease causality
- Immaturity
- Irrationality

# Enhancing Comprehension of Consent Information/Documents

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- Provision of information at the educational level of the individual participant

# Enhancing Comprehension of Consent Information/Documents

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- Language and design of consent forms should enhance comprehensibility & recall of pertinent information

# Enhancing Comprehension of Consent Information/Documents

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- Using local illustrations to explain research goals, risks, benefits and probabilities

# Enhancing Comprehension of Consent Information/Documents

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- Multiple sessions of interaction between investigator and prospective participants

# Enhancing Comprehension of Consent Information/Documents

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- Re-consenting during the course of research where appropriate

# Enhancing Comprehension of Consent Information/Documents

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- Use of aids to understanding: literature, pictures, photographs, audiovisuals, etc.

# Enhancing Comprehension of Consent Information/Documents

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- Provision of supplementary information sheets where indicated

# Enhancing Comprehension of Consent Information/Documents

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- Use of counselors, trained communicators, etc. in place of clinician/investigator

# Enhancing Comprehension of Consent Information/Documents

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- Routine formal assessment of research participants' comprehension of the consent form

# Enhancing Comprehension of Consent Information/Documents

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- Translation of consent forms into local languages

# Resources and Further Reading

- National Code of Health Research Ethics, Federal Ministry of Health, Abuja, Nigeria, 2007
- Fitzgerald DW, Marotte C, Verdier RI, Johnson Jr WD, Pape JW. Comprehension during informed consent in a less-developed country. *Lancet* 2002; 360: 1301–02
- Agulanna C. Informed Consent in Sub-Saharan African Communal Culture: The “Multi-step” Approach. 2008 Master’s Thesis in Applied Ethics Centre for Applied Ethics, Linköpings Universitet