Ethics & informed consent in research

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Ethics & informed consent in research

- address the need for ethical considerations in research
- highlight the importance of informed consent in research
- review challenges surrounding informed consent
- informed consent in reproductive health research

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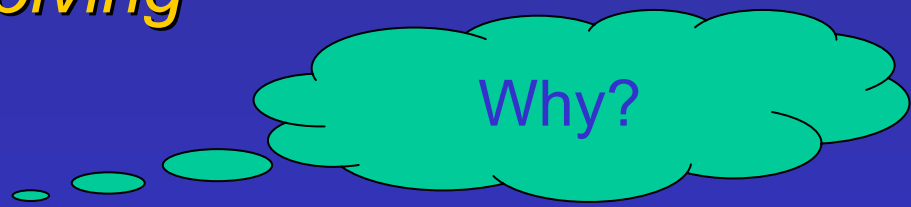
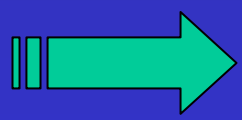
- *Ethics in research involving human subjects*





Protect against abuses

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- *Nazi experiments*

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Nuremberg Trial

the Nuremberg code
issued in 1947

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- *Tuskegee syphilis experiment : 1932-1972*

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- 1964 Declaration of Helsinki the fundamental document in the field of ethics & biomedical research

principles

- *Respect for persons*
- *Beneficence*
- *Justice*

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1966

The International Covenant on Civil and Political Rights

Article 7: No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjcted without his free consent to medical or scientific experimentation"

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- 1964 Declaration of Helsinki the fundamental document in the field of ethics & biomedical research

principles

Respect for persons

Beneficence

Justice

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- *Declaration of Helsinki*
  - *respect for persons*

Respect for autonomy

Protection of persons with impaired or diminished autonomy

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- International ethical guidelines for biomedical research involving human subjects CIOMS 1982

- revised by CIOMS-WHO 1993

International guidelines for ethical conduct in scientific research identify the requirement for <u>informed consent</u>

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- *CIOMS Guidelines:*

Guideline 1

"For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorised representative"

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- *CIOMS Guidelines:*

Guideline 1

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What should be included in the consent form?

- *purpose of the research*
- *procedures*
- *risks & discomforts*
- *benefits (to you & to others)*
- *compensation*
- *alternatives to participation*
- *confidentiality*
- *statement that participation is voluntary & the subject can withdraw at any time*
- *additional items*

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- *In a signed form concluding paragraph states:*

  "I have the read the foregoing information, or it has been read to me. I had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my further medical care."

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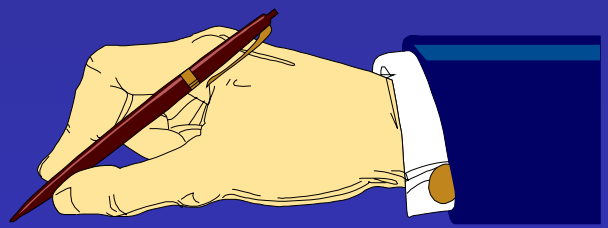
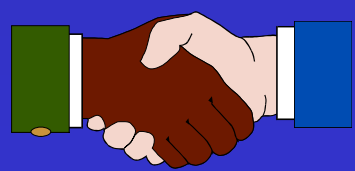
From a signature...



for legal coverage

To accurate and adequate information

for free decision-making



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Is obtaining informed consent simple?

- comprehension of information
- language barriers
- autonomy and locus of decision-making authority
- confidentiality and disclosure of information

Social & cultural context

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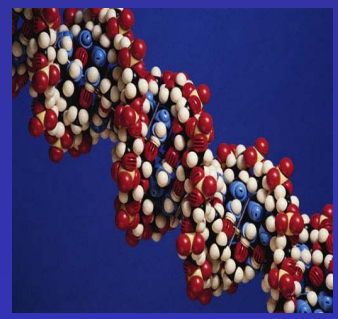
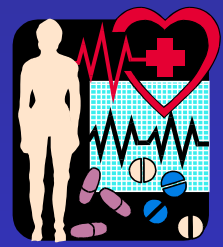
comprehension of information

- Sophisticated scientific concepts





- Level of literacy or illiteracy

- Fear of signature

- Disease aetiology

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language barriers

Choice of words

Concepts

Translators interpreters

Cultural norms in the structure of the discourse

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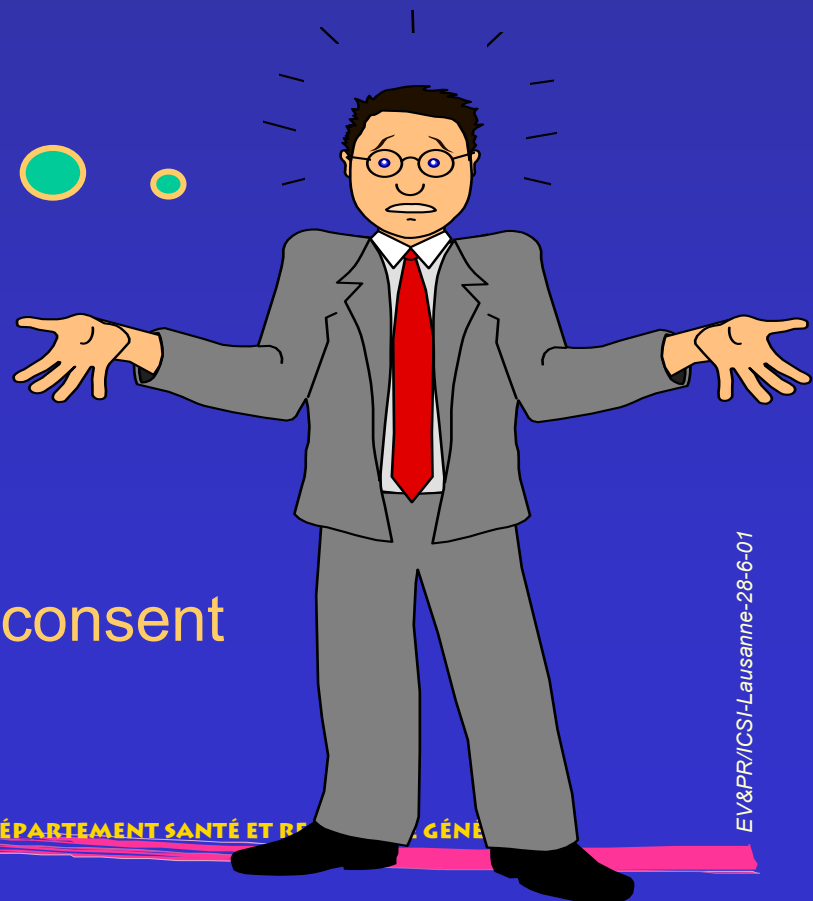
- autonomy and locus of decision-making authority

Who is making the decision?



- notion of personhood
- person versus community
- individual consent versus community consent
- women

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- confidentiality and disclosure of information

Stigmatisation

Discrimination

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Is informed consent different in reproductive health research?

Contraception

Pregnancy

Fetus

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Questions:

What is your experience
with obtaining informed consent?

What are your views on international guidelines on ethics given the various cultural environments?