Ministry of Health and Sports

Ethical Considerations for Human Research Participant Protection: *Informed Consent*

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What is informed consent?

- a **communication process** between the researcher and the participant.
- starts **before** the research is initiated and **continues throughout** the duration of the study.
- consent given by a **competent** individual
- **understood** the necessary information
- without having undue **influence** or **inducement**, or **intimidation**
- after having **decided** (given enough time)

What is informed consent?

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate

ICH GCP .1.28

3 Fundamental Aspects of Informed consent

Voluntariness

- not be influenced by anyone

Comprehension

- Individuals must have the mental or decisional capacity to understand the information

Disclosure

- provides necessary information in order to make an informed decision

CONSENT
IS NOT:

Assumed Coerced

Implied Convinced

CONSENT

Freely Given
Reversible
Informed
Enthusiastic
Specific

Informed Consent Form has two parts:

Part I - Information Sheet

to give information about the research

Part II - Certificate of Consent

for participant to sign if agree to take part

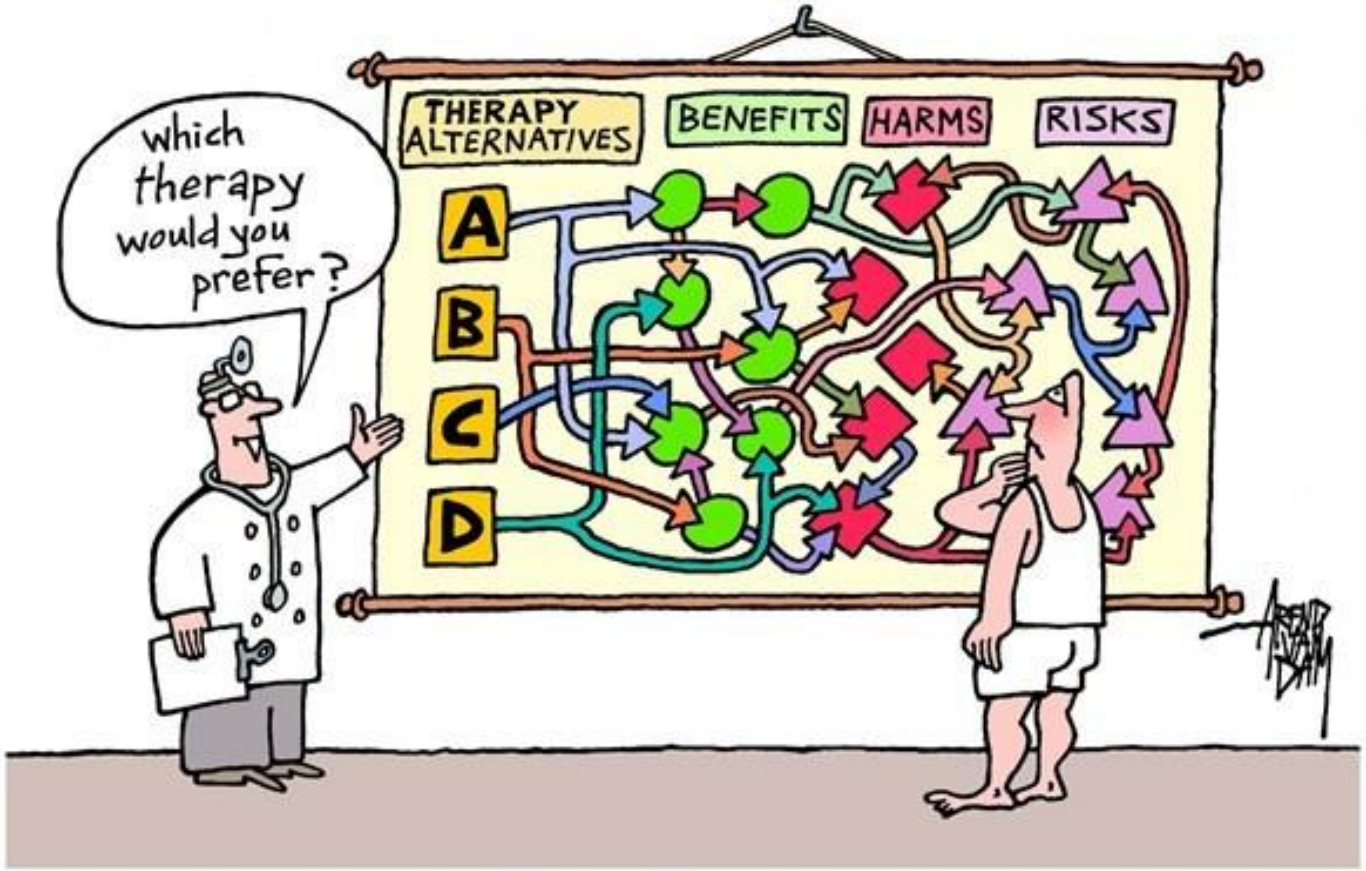
Informed Consent :

- *and any other written information to be provided to participants; any revised written informed consent document and written information should receive the IRB's approval in advance of use;*
- *should not contain language that causes the participant to waive any legal rights, or release the investigator, institution or sponsor from liability for negligence;*
- *language used during the informed consent process should be as non-technical as practical.*

- *Prior to participation in a trial , the written informed consent document should be signed and personally dated by the participant, or their legally acceptable representative, and also by whoever conducted the informed consent discussion.*

Part - I Information Sheet

(1) Introduction
(2) Purpose
(3) Type of Research Intervention
(4) Participant Selection
(5) Voluntary Participation
(6) Procedures
(7) Risks & Discomforts
(8) Benefits
(9) Incentives
(10) Confidentiality
(11) Sharing the Results
(12) Right to Refuse or Withdraw
(13) Alternatives to Participating
(14) Who to Contact



informed consent

CONSENT CAN BE WITHDRAWN AT ANY TIME.

YES YESTERDAY DOESN'T MEAN YES TODAY.

Waiver of Signed Informed Consent

1.That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality.

2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

Even documentation requirement is waived, the investigator must provide participants with a written statement regarding the research

Alter or Waive some or all of the elements of consent

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

WHO

When

Where

Questions, Comments and Suggestions would be greatly appreciated !