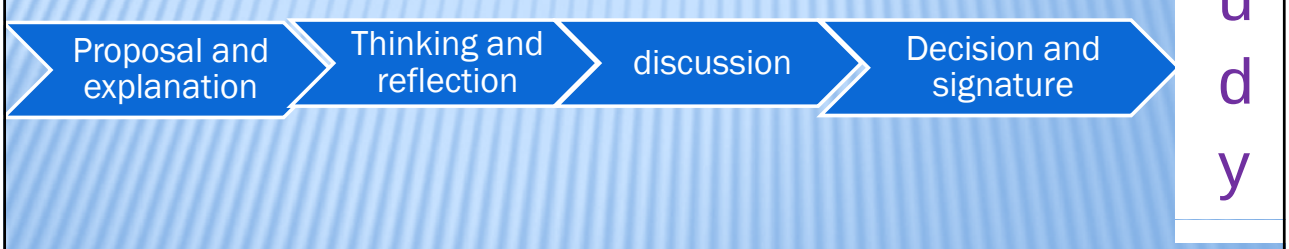
Informed Consent

A very delicate time in the relationship with the patient ……..

……..the discussion of the informed consent

Today, everybody underscores the the informed consent is a PROCESS.



The information to be mandatorily included in the informet consent is describet by GCP
(§ 4.8.10)

The different pieces of information are:

1. That it ‘s a research
2. Aim of the research, foreseen treatments and probability to be assigned to one of them
3. All procedures foreseen by the study including the invasive ones
4. Responsibilities of the subject, study experimental aspects, risks or troubles foreseeable for the subject, the embryo, the fetus and nursing infant
5. The reasonably expected benefit; if there are not, the subject must be aware of it
6. Treatments or procedures available as an alternative with related risks and benefits
7. The compensation and/or treatment available to the subject in the event of trial related injury

The information to be mandatorily included in the informet consent is described by GCP (§ 4.8.10)

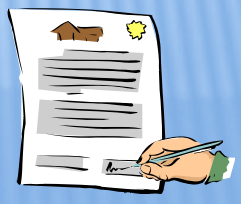
8. The anticipated prorated payment, if any, to the subject for participating in the trial.
9. The anticipated expenses, if any, to the subject for participating in the trial.
10. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
11. That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
12. That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential.

The information to be mandatorily included in the informet consent is described by GCP (§ 4.8.10)

13. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
14. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
15. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
16. The expected duration of the subject's participation in the trial.
17. The approximate number of subjects involved in the trial.

Responsibilities of the Ethics Committee (EC)

- The text of the Informed Consnt (IC) must be submitted to the Ethics Committee for approval. The same is applicable for whichever piece of written information to be presented to the patients.
- The EC must approve unusual procedures for collecting consent



The collection of the IC

- The investigator or his/her delegate must give to the subject the time for reflection and the possibility to ask questions.§4.8.7
- The consent must be signed and dated personallly by both the subject and the investigator before the admission to the clinical trial §4.8.8

The collection of the IC

- The patient must receive a copy of the signed consent and of whichever other written information before entering the study §4.8.11
- All signed ICs must be kept at site and their confidentiality must be assured §2.11, 8.3.11

In the case of a child or minor .....

The investigator must:

- obtain the consent of both parents or from the tutor

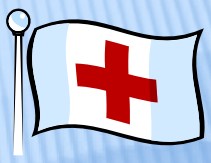
- obtain the assent of the child/minor too

Vulnerable subjects: definition

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

An EC should safeguards the rights, safety, and well-being of all trial subjects. **Special attention should be paid to trials that may include vulnerable subjects.**

The informed consent in emergency or uncosciouss subjects



It should be asked to the legal representative of the subject § 4.8.15.

If unavailable,the specific measures described by the protocol and/or other documents approved by the Ethics Committee to protect the subject § 3.1.7, 4.8.15

As soon as possible, the subject must be informed about the study and his/her consent to go on with the study must be asked § 4.8.15

Consent in subject unable to read

- An impartial witness is needed §1.26, 4.8.9
- The subject (or his/her legal representative) after the explanation of the study must give the verbal consent in front of the witness, who will sign and date the consent form §4.8.9

The signature of the impartial witness is the confirmation that the collection of the consent has been impllemented in the correct way § 4.8.9

All possibilities of asking the consent in special conditions should be described in the protocol and should be approved by the Ethics Committee (EC). Generally, the text of the informed consent is attached to the protocol and is submitted to the EC, who defines in the approval which version (number and/or date) has been accepted.

You can understand now that it is important that the consent form be a good, complete and easily-understood document ...

… it is unfortunately common that such is not the case.

MAJOR PROBLEMS WITH IC FORMS

- **IC are written by and screened by highly educated people, often with "help" from lawyers: they may be impenetrable to laypeople**

THE MOST IMPORTANT THING ABOUT IC

- **A consent form is an important aid, documentation and information source for obtaining informed consent**
- **But it is NO substitute for a genuine consent *dialogue*, with someone who is knowledgeable about the study, knowledgeable about informed consent, and skilled at layspeak**

THE PROCESS OF INFORMED CONSENT
ANOTHER INFORMATIONAL ISSUE:

- **Language commonly used in consent forms and consent discussions may be understood differently by laypeople.**
- **Information may therefore be "understood," but not in a way that helps make consent effective.**

THAT TRULY RESPONSIBLE INVESTIGATOR WILL:

- Design experiments that minimize risk;
- Make sure that the information is available for the subject to make a sound decision about participation;
- Make sure that information is presented in a way that maximizes understanding;

THAT TRULY RESPONSIBLE INVESTIGATOR WILL:

- Make sure that the information is presented in genuine dialogue, both testing understanding and affording opportunities for questions;
- If possible, give the subject time for reflection and consultation before a decision is required;

THAT TRULY RESPONSIBLE INVESTIGATOR WILL:

- Make sure that the decision, when it is made, is made under the least coercive conditions that can be arranged;
- Make sure that the decision will be honored, even if contrary to the investigator's wishes;

THAT TRULY RESPONSIBLE INVESTIGATOR WILL:

Perhaps most important of all --

- **Continue the consent dialogue for the duration of study participation, so that:**
  - **new questions are addressed;**
  - **new information is shared;**
  - **continued presence of consent is assured;**
  - **opportunity to withdraw is genuine**

THAT TRULY RESPONSIBLE INVESTIGATOR WILL *ALSO*:

- **Conduct the research in a responsible manner, so that the consent granted by the subject is given in support of research that is both ethically and scientifically sound.**