



# **Informed consent Draft position paper discussion**

**Policy Working Group meeting  
27th – 30th March 2008**

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PWG  
Informed consent  
draft position paper

- **Background and Scope**
- **Rationale**
- **Recommendations**
- **How to proceed**



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Background and Scope

- To sought, respected and referred to a person autonomy - capability of making good and right decisions, independently of any third party person - in *all biomedical or non biomedical intervention* (clinical trials, treatments, and other interventions) concerning the health or well-being of any person



clinical trials



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Special cases

Research/ clinical trials  
Organ donation  
Pre-taken decisions  
Decisions by representatives  
Exemption of consent

Clinical trails  
    Research vs treatment  
    Recruitment bias



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### Informed consent Clinical trials special situations

- Minors, permanent or temporary non capable adults (including diagnosis related emotional stress situations)
  - Can the same information be obtained enrolling only capable adults?
  - Information must be adapted to the assumed level of understanding of the minor or non capable adult, and his or her decision considered and respected.
- Consent from parents, tutors, proxies or other representatives, legally in charge, should be based on the same rules and with the same content as in the case of capable adults.



## PWG Informed consent special situations

- Specific ethical issues
- Specific technical issues – language, level of understanding, etc.



capable autonomous participants



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Rationale

- **Why ?**

Ethical and legal relevance

Universal application (*almost*)

- **Issues to understand and address**

History

Practice and problems

Typology



# PWG

## Informed consent

### History

Philosophical, medical and juridical origins

Traditional medical ethics

Hippocratic deontology

respect for the master

experience, respect for life and duty of secrecy (sigil)

pledge of honour

*beneficium* - dedication to the good of the patient

*non maleficium* - duty of at least do not do any harm

Plato Aristotle virtue (*areté*)

technical and moral



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History

Traditional medical ethics

professional intern system, paternalistic and asymmetric

Modern philosophy

a new naturalism distinguishing public and private areas,

private moral ... deontology  
public moral ...responsibility

Bioethics

*Beneficium, non maleficium, autonomy and justice*  
first came the *person* and the *citizen*



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History

Traditional medical ethics

Duty of *beneficium*

“every men has the right to speak when his health and life is at stake”

“ to inform is a primary duty of clinicians”

Legal and juridical origins

Duty to inform based on the person autonomy

i.e.

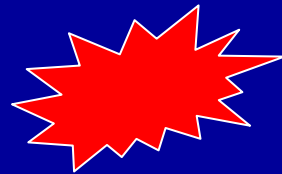
the medical profession accepted autonomy only through the *juridical practice/imposition*



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History

Legal origin  IC as liability waiver

“it is very helpful and efficient to make patients sign a document stating that they have understand the kind of treatment proposed, the risks involved, the possibility of a partial failure and the residual defects it will produce in case of success!”



Clinical research *per accidens*

This attitude goes against the ethical requirements to respect participants/patient's autonomy and to protect participants/patients, as well as the principle of justice



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Bioethics approach

Informed Consent - a juridical object and an ethical concept  
implying:

to seek and respect participant's autonomous will and  
decision

respect and understand the person values' system

Autonomy

Knowledge

Information (truth and right information)

Free decision (deliberation)

*Autonomy as the right NOT to know*

*The truth wherever you want it or not*



## PWG Informed consent

It's a process of information sharing, communication, and clarification of data with the objective of capacitate the participant/patient to freely take and express his/her decision in the context of his/her own system of values and believes

process

information

communication

free decision

system of values



## PWG

### Informed consent

#### Individual requirements

- intentional action
- informed and knowledgeable decision
- free from any external or outside
- without intervention of any element of force, fraud, deceit, duress, overreaching, or ulterior form of constrain or coercion
- authentic

#### Main issues

- understanding the information
- amount and detail of the information given
- independent discussion and clarification of the information



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Informed consent  
Understanding the information

Understanding the information

- Common, lay, clear and easily understood language.
- Technical, scientific and medical language is not acceptable.
- Information on rights, responsibilities, protection against damages or potential benefits also in lay language.

Addressing and understanding problems and difficulties

- Patient and professionals cultural perceptions
- Organizational and individual obstacles
- Illiteracy
- Translation errors

IC based on information that has not been understood properly violates logical and ethical requirements



## PWG

### Informed consent discussion and clarification of the information

#### Investigator obligations

- Verbal explanations in an understandable language.
- Time for reading and understanding.
- Encouragement to discuss with anyone before taking a decision.
- Revision and clarification of any question.

#### Some essential points about informed consent

- does not waive the participants' legal or medical rights, and researchers remain liable for damages due to negligence.
- is not a contract, and participants may discontinue the participation in a trial at any time for any reason without having to provide any explanation or having to suffer any consequences.
- sponsors, promoters or researchers have the obligation to inform participants (and seek for a renewed informed consent) when there are changes in the study design, new safety data or new information about the experimental agent or other new agents.



## PWG

Informed consent  
amount and detail of information

### Information to patients

- Transparent, comprehensive, effective and of quality
- Layers of detail
- Adequacy to patient expectations
- Adequacy - comprehensive, inclusive, clear, explicit, intelligible information and extension - to the complexity of the intervention, its weakness, irreversibility and capacity to induce mutilation, suffering and discomfort

### Improving information quality

- Patients' involvement
- Frameworks for interaction of patients (patients groups) with
  - regulatory agencies – regional and national
  - pharmaceutical companies



## PWG

### Informed consent amount and detail of information

- Identification of the study - title or name, registration, regulatory and ethics approval details
- Short description of the study and its objectives
- Study results publication policy
- Identification of the research centres
- Identification of the sponsor, promoter, principal investigator, local investigators
- Research centres' and researcher's compensation
- Brief explanation of study procedures; treatment procedures; understandable chart of study phases, visits and visits procedures and monitoring tests
- If and when the study includes a control group, brief explanation of allocation of participants between active and control, treatment (if any) received by control group and justification
- Duration and number of participants.



## PWG

### Informed consent amount and detail of information

- Study restrictions and participant's responsibilities
- Voluntary participation, discontinuation conditions and right to leave the study
- Confidentiality and personal data protection; who may access the personal information; relation with the participant GP
- Short description of the experimental intervention or drug (if applicable); what is already known from earlier studies; existence of alternative treatments
- Drug supply (experimental and/or others) and drug circuit; packaging
- Description of possible adverse effects, risks and discomforts; secondary effects; effects in fertile or breastfeeding women
- Long-term follow-up and drug availability after the end of the trial.
- Participants' legal and medical rights; compensation for damages and insurance
- Possible benefits; direct benefits of the treatment; payments or costs compensation to participants



## PWG Informed consent Format

Expressed - oral or written – by the patient or by proxy vs.  
Non expressed - tacit, implicit, presumed

Universal and uniform vs.  
Adjusted to individual information needs and casuistic decision

Intervention specific

Written format

Extension

Language tested, revised and approved by patients  
(RECs and regulatory agencies)



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Informed consent  
sources and references

## Philosophical

Plato, Aristotle, Boecio, Suarez, J. Locke, E. Kant, ...

## Medical

Hippocrates, John Gregory, Benjamin Rush, F. Cotton

## Juridical

British Courts jurisprudence, Prussian legislation on research on Humans (1900), *Richtlinien* Law (1931), Nuremberg Code, United Nations Declaration of Universal Human Rights, 1948, World Medical Association Declaration of Helsinki, 1964, Council of Europe Convention on Human Rights and Fundamental Freedoms, 1950

## Bioethics

J. Childress & T. Beauchamp, Claire Foster



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