**EFGCP Regional Conference on**

**Hot Topics in Clinical Research**

# Optimitzation of Informed Consent in Paediatric trials

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In what ways the informed consent can be improved?

Need of researcher:

written Informed consent

Often the informed consent process is perceived as a bureaucratic process

# Needs of researchers:

- To be sure that **participants understand** what they are consenting to and
- What the the **risks and benefits** of the research are to them.
- To know the characteristics of the particular target population

Who are recruited and give consent are the child's parents

# Reasons for the parents to consent

- Altruistic reasons: the hope that the study would be of help to future infants.
- Attitudes about research: If pushed or if they perceive coertion parents will not consent
- Educational benefit: they want to learn about their children.

  Teaching is not a goal of the clinical research, but parents often consider their own learning in follow up visits as a benefit.

RH Pickler and AT Martin

J Pediatr Health Care 2010; 24:66

# Informed Consent process

**Process of communication**

- Information
- Decision
- Signature of the document

Full disclosure is in fact the cornerstone for informed consent

# Information contents

- Purpose
- Duration of the study
- Procedures that the subject will undergo
- Description of risks and benefits for the subject or others
- Alternative treatments
- Confidentiality of the records
- If there will be any compensation
- The participation is volontary and the subject is free to withdraw at any time

# Improving information

- The information sheets tends to become very long
- Information is more valued than comprehension
- Information to protect researcher or sponsor
- Language is not easy to understand

# Improving information

- **Provide both written and verbal information to parents**.
  - Review the information brochure and the study consent form with them.
  - Encourage them to ask questions.

- **Parents need time**!: Schedule appointments to discuss it and a second to sign.

# Improving information

- **Environment that offers  privacy**:
  - To be able to focus in parents needs
  - Parents are less inhibited in expressing their thougts and concern**.**
- Having someone on site who can **answer questions**

# Improving information

- Plane language, draws, Experimental models, dolls...
- No use of unacceptable exculpatory language
- To take into account the national legal framework and statutory arrangements
- Compensation: expenses, clinical.

# OPTIMIZING CONSENT PROCESS

Information must be presented to enable persons to voluntary decide whether or not to participate as a research subjects or accept their chidren participation.

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# OPTIMIZING CONSENT PROCESS

- Collaboration between researchers and clinicians:
  - The researcher must inform health care members about the research project and try to look for their participation .
- Disagreement father-mother

# OPTIMIZING CONSENT PROCESS: **Assent**

Is one of the principal requirements for pediatric research and often the only requirement to specify when children should have a say in wether they paricipate in clinical research.

Failure to require children's assent when appropriate represents a failure to respect pediatric research participants

**Assent:** “positive agreement” of children who are capable of providing it

When

- 0-7 years parents consent only
- 7-12 + assent (some countries)
- 12-18 + signed assent

At what age children become capable of providing assent?

A child who can understand the risks or the potential benefits of research, but not both, is unlikely to make a good decision

Children may find distressing  to be asked to make decisions abour research they can not understand

Failure to waive the assent requirement when apropriate may block parent’s decisions to enrol their children in potentially beneficial research.

**Waiver** : when there is prospect of direct benefit, no more than minimal risk

**The assent may be waived** :

-The research qualifies for waived informed consent

-The research offers a prospect of direct benefit that is important to the health or wellbeing of the children and is available only in the context of the research.

**Children dissent has to be respected**. Physical resistance can be the manifestation of dissent.

**To be avoided**:

Forcing children to undergo medical procedures against their will. Always remains the concern that the child is being forced to undergo a particular intervention for the good of society.

This concern suggests a child's sustained dissent should be binding in all cases, including research that offers a prospect of direct benefit for the child.

D S Wendler J Med Ethics 2006: 32: 229-234

# Deferral consent in emergency situations

Maitland and al. Trials 2011. 12:90

http://www.trialsjournal.com/content/12/1/90

**Genetic research**

- Confidentiality
- Return of the information

**Biobanks** :

- instrument: service to research
- improve protection of samples and data confidentiality

Informed consent in biobanks:

- Project consent → **Broad consent**
- To be confirmed at 18 years?

# CONCLUSIONS

- To accept informed consent as a process of communication with the family and the child
- To improve facilities for this process
- Institutional Review Boards may propose some Informed Consent document models as a guide to researchers
- Biobanks: samples to be conserved

# Thank you very much