

The EU Clinical Trial Regulation and children and young people (minors)

Ethical and procedural issues



Hugh Davies, Chair of Oxford “A” Research Ethics
Committee, UK

Just some ideas to start the discussion

General issues (with some bearing on minors)

- Balancing research promotion and protection of participants
- Transparency
- Lay summary
- Waiving consent in emergencies

Issues specific to children and young people

- “Children or adult” debate – “Children are not little adults”
- Minor and parental involvement
- Consent / Assent / Dissent
- Payments
- Nontherapeutic research

Procedures with consequences for children and young people

- (The portal)
- (Part 1 and Part 2)
- Lay representation, patient voices, and expertise

Summary, conclusions and what next?

Balancing research promotion and protection of participants

There is a wish to promote research by making it easier to do

- **Low intervention trials**
- **Facilitating non commercial sponsorship**
- **Recognising the needs of orphan diseases**
- **Promoting further research**

Transparency

(and all that that entails)

Lay summaries of research

Writing for parents **and** children?

Waiving consent in emergencies

(Harmonisation)

What it gives with one hand, with the other tied behind its back (or bound to other legislation).....

1. *“Incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures.”*
2. *Directive 95/46/EC Data Protection Directive (soon to be a Regulation)*

Issues specific to children and young people

- Children vs adult debate
- Minor and parental involvement
- Consent / Assent / Dissent
- Payments
- Nontherapeutic trials

Children vs adult debate

Is it true that “Children are not little adults”? Or is this the plaintive cry of the union of child health care professionals (of which I am one) protecting their turf?

A more sophisticated, realistic debate is needed.

Involvement of children and young people in research

A VERY central part of the Nuffield Council of Bioethics report

<http://nuffieldbioethics.org/project/children-research>

Consent – not much change?

Assent - a legal issue

Dissent - not much help or guidance

Payments to children

Is it ethical to pay adults but not children?

Do we believe parents will put their children into studies for profit (and professionals will collude)?

Non therapeutic clinical trials involving minors

A very difficult issue

Given the conditions placed on this research, the position remains uncertain.

Are we any further on than one piece of guidance in 2000 which concluded “It’s not necessarily unethical”?

Procedures specific to children and young people

- Lay representation, patient voices, and expertise

Lay representation, patient voices, and expertise

Rising expectations but details derogated to member states

<http://nuffieldbioethics.org/project/children-research>

Summary and some conclusions

Regulation and research involving minors

Where we are now.

Let us not expect too much of Regulation.

It's written, published and to be implemented, so
where can we exert influence?

Quo vadis?

- Grasp opportunities when putting the Clinical Trial Regulation into practice (avoiding the street gossip or over interpretation - interpreting it in accordance with its philosophy – courage!).
- Debate the balance for the 21st century (not 19th) freeing ourselves from history.
- Proactive contribute to revision of E11 – “Ethical considerations for clinical trials on medicinal products conducted with the paediatric population”.
- Watch for the Data Protection Regulation
- Plan for the next set of Regulations!

**Promoting research and protecting
ALL children - a never ending balancing
act for every generation**

**and one day they will be grown ups
and see the issue from the other side!**