39. Hector Velarde, MD, Mexico 311013

How should children be recruited to clinical research?	**What research proposals should be regarded as ethically acceptable?**
Inclusion and exclusion criteria must be clear and specific, without leaving them up to the investigator or the parents. Efforts must ensure that the participant is a COMPLETELY health child, without any other known risk, with the exception of the disease to be treated.	Proposals that do not place the children's lives at risk, that have been previously demonstrated in adults and adolescents, and that force the investigator to provide detailed clinical care, not simply to provide care related to the study hypotheses.
How should research in children be encouraged?	**What should happen when the research is over?**
By ensuring complete medical care by specialized pediatricians and not simply offering study medications.	Follow-up of the participant should be conducted until they turn 24 years old to guarantee that no side effect is present. In case of medications that result effective, medication should continue to be provided.

1. **What do you consider to be the main obstacles to recruiting children to research? How might these be overcome?**

The main obstacles are related to the following two issues:

i. The legal capacity to consent
ii. The clinical capacity of a research physician to suggest a child.These obstacles may be overcome through the use of specific and clear inclusion-exclusion criteria, without leaving this up to the judgment of the research physician or the parents. Efforts must be made to ensure that the child participant is COMPLETELY healthy, with the exception of the pathology or condition to be treated. The research physician should conduct the interview in a good professional manner, without leading the prospective participant, and should strive to provide and receive the corresponding information, clearly and without doubts, using language which is understandable to all in regards to the risks and benefits of the proposed research.

2. **Who should make the final decision as to whether a child participates, or continues to participate, in clinical research when parent and child disagree? What responsibilities do health professionals or researchers have in such cases? (You may wish to distinguish between children at different stages of development and/or the different ways in which disagreement may arise or be expressed.)**

In all cases involving minors under 16 years of age, the decision shall be made by the parents or duly appointed guardian, and the assent of the minor. In case of parental discrepancy, the decision shall be not to intervene. In minors older tan 16, there should be a consensual agreement between the minor and the parents. Any discrepancy will lead to a negative decision.

3. **How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?**

In all cases of minors under 16, the assent of the minor is required but the legally appointed representative must consent. In case of shared custody, there must be a consensus between the adults.

4. **A 'shared' or 'collaborative' decision-making model is often advocated for decisions about a child's research involvement, involving the child, relevant family members and professionals. Is this a helpful approach? How might any problems arising in this model be overcome?**

In all cases, the decision shall be made by the parents or by the legally appointed guardian, but the assent of the minor is required. In case of paternal discrepancy, the decision will be not to intervene. Minors have rights and one of those rights is to have parents who protect their best and fair interests. Collaborative decision requires the agreement of all parties involved.

5. **Parents' views on whether (and how) children should be involved in decisions vary enormously both within and beyond the UK. How should the law and professionals take account of such different parenting approaches?**

In all cases of minors under 16, the assent of the minor is required but the legally appointed representative must consent. In case of shared custody, there must be a consensus between the adults.

6. **Rewards (such as vouchers) for children participating in research may be welcomed as an appropriate way of saying 'thank you', or criticised as a form of undue incentive (to either child or parent). What forms of compensation/reward/expression of gratitude for research involvement do you think acceptable, and why?**

Compensation for minors undergoing a clinical research procedure must be the same as compensation offered to adults in the same situation. Since the parents are legally responsible, they should come to an agreement with their children so that the compensation does not go to the parents.

7. **How helpful is the notion of the best interests of the child participant? How would you define 'best interests'?**

Best interest of the children is when there is no possibility of benefit for the child who is a research subject, and this child will die anyway, but his/her participation may

enable the identification of treatment for future siblings or children with the same condition.

The best interests of the child may lead to approve the participation of a minor in a research study as long as the child is terminally ill and that there is not risk of lowering the quality of life or shortening the life span of the minor in question.

8. **How can the rights and interests of individual children (potential participants in research) be balanced against the rights and interests of all children (potential beneficiaries of the knowledge gained by the research)?**

Participants have rights and these are not renounceable, not even in the benefit of probably beneficiaries.

9. **Are there any situations in which you think it would be acceptable for a child to be invited to participate in clinical research when there will not be *any* personal benefit to them? If so, please give examples.**

No, there are not. No minor should be exposed to risks to their health without the prospect of benefit to their health.

10. **Are there any circumstances where it would be right for a research ethics committee to approve research involving risks they would usually regard as too high, if parents and young people had clearly expressed their willingness to accept these?**

Only in cases where there is no possibility of cure for the research subject and there is the certainty that his/her participation will benefit other children in the future, as long as it does not affect their quality of life or shorten their life span.

11. **Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and involving children in decisions about their own participation? What (if anything) would you like to change?**

I would change nothing about renouncing to children's rights to a healthy life, to a life without risks and the mandate for the adults to preserve these children's rights.

12. **With limited resources, how would you decide which childhood conditions should be the priorities for research? Who should be involved in making these decisions?**

Priority shall be divided into 2: frequent and costly chronic degenerative diseases and neglected diseases.

13. **What responsibilities do funders, researchers and stakeholder groups have to encourage the coordination of children's clinical research?**

Funders have responsibilities to cover the same 2 groups indicated in 12 above, but keeping in mind children's rights, their right to a healthy and quality of life, without unnecessary risks.

14. **What responsibilities do researchers have towards child participants and parents when the study is over?**

Researchers should follow-up study subjects until they turn 24 years old to guarantee identification of any possible risk to their health. In case of successful products, they have the obligation to continue to provide them until their commercialization.

Any other comments?

Please highlight any relevant areas you think we have omitted, or any other views you would like to express about the ethical issues arising in clinical research involving children.

Children should not be considered as CASES, but as patients and the commitment of the research team should be to provide integral medical care to include permanent overview of vital signs, weight and height, hormonal, enzymatic, liver, renal and mental tests.
The term children includes all minors under 14 and teen agers until 18.