

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

One of the main obstacles is the fear of researchers and clinicians about the extra vulnerability of children and their tendency to shy away from difficult ethical decisions. This includes some ethics committees.

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.)**

Cannot give one answer. Depends on circumstances – age and mental capacity of child (and physical condition). Also, subject and type of research – degree of additional intervention required, and any extra risks of research proposed.

Ideally, a joint decision between child and parent/carer but this also has risks (see 4 below).

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

Yes, it is a useful 'halfway house' to taking full adult responsibility.

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?**

Sounds good but could just end up as coercion by one of the parties. Could there be a role for an outside mediator? That begs a further question – who?

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?**

Whatever changes are made, there will always be differing views and difficult decisions. It is important not to be put off, knowing it will never be easy to obtain consensus.

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?**

A voucher for the child for me is an acceptable form of ‘thank you’.

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

This terms is not very helpful as it can be taken to mean the best interests of the child taking part in research (in the here and now) or it could mean the best interests of future generations of children who may benefit from the research. These may very well not be synonymous. See 8 below.

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)?**

In this context, I think the use of the word ‘balance’ is wrong. It implied some sort of equality between the two groups which may be far from the reality. It should be more about ‘protection’ of the two groups from untoward risks/outcomes. (This would include outcomes from not doing the research as well as outcomes from doing the research). Protection for all in a particular study may not amount to a perceived ‘balance’.

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.**

When there is minimal discomfort/risk to child – e.g. extra data from care which child is receiving anyway – medication, physio, urine specimens, weight and height monitoring, temp, pulse, resp readings. Extra blood samples when ‘line’ is already in.

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?**

Usually NO.

Possibly terminal illness, if parents and young people want to go ahead with participation.

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?**

Some ethics committees are still too nervous about paediatric research. Need to allow studies in children as it can be just as unethical to prevent such studies taking place.

If approved by ECs, parents and children can still refuse if unhappy.

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?**

Allow PPI to become more involved in these decisions.

As a generalisation – where there would be greatest gains in benefits to future children – severe conditions and/or common conditions. Rare conditions should not be excluded just on the grounds of being rare as this excludes them in the long term from advances in treatment. Should not be exclusively common conditions for the above reason.

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

To do otherwise is to act unethically – causes waste of valuable resources.

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

To disseminate findings by publication, to participants and families, clinicians, etc.

In the case of medication which is no longer being funded by local services, the researchers could write to and disseminate findings to *local clinicians* and *commissioners of services* to encourage local funding of the relevant medication for the individual child.

