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

In my experience a major difficulty lies with the need to delegate identification of the children to the healthcare team, which is usually a busy team with little time for such activities and at risk of forgetting about the various studies going on. I understand the need for this delegation: however, constant reminders to busy clinicians can prove irritating to them and it is difficult to get the balance right.

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.)**

I think the views of the child can be taken on board at all ages in that if a study is clearly generating excessive distress, however indicated by the patient, this should be taken into account. The health professional and the researcher have a duty to protect the child and may have to mediate on behalf of the child where there is disagreement.

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

In the absence of a right to express dissent, assent is a meaningless concept. However, I am a firm believer in providing as much age-appropriate information and explanation as possible to the child/young person.

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?**

Where the child is able to express a view this is the most appropriate approach.

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?**

This can be a very difficult issue – in particular where information regarding diagnosis and prognosis has been withheld from the child or young person. In the first instance professionals often need to work with parents to explain why it may help to start to provide more information to their child over time.

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?**

Certificates and stickers are generally appreciated by younger children. I think a small gift or voucher is appropriate as a token of thanks/memento as long as the receipt of such a gift is not the reason for taking part. So, for example, if the child and family did not know in advance that they would receive anything, this would be acceptable.

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

The concept of best interests of the child is helpful in thinking about what study designs to exclude. In my opinion this concept renders a placebo-controlled trial problematic as it is not usually in the child's best interests to receive placebo. A trial of a plausible new treatment versus current best practice treatment would be more acceptable. Children in a clinical trial will often undergo investigations which would otherwise not be undertaken. This is not in their best interests and therefore the burden of such investigations needs to be carefully considered.

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)?**

Children and their families should be allowed to be altruistic if they wish to, where ethics committees see these as appropriate and in the context of excellent information-sharing and low/controlled risk.

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.**

As per 8.

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?**

For children with debilitating life-limiting conditions for which there is currently no known treatment, it may be appropriate to try an experimental treatment. However, this requires extreme caution and constant consideration of the individual's risk benefit ratio.

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?**

There is scope to increase involvement of young people in decisions about their own participation.

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?**

This is an almost unanswerable question. Common conditions, extremely debilitating conditions (even if rare) and conditions where for some reason it is likely that there may be a research breakthrough are all sensible targets. It's not always known where the breakthroughs will occur though. The public should be more involved than they currently are, but this is most helpful only where the public are adequately informed by an unbiased source.

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

Stakeholder groups can help ensure that the right questions are addressed. Researchers and funders have a duty to produce outputs from high quality, ethical studies in areas of need. Avoidance of duplication and promotion of collaborative efforts are both important.