

6. Redman 210913

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

Concerns from parents/the public – however, if the principle of equipoise is fully explained and the benefits of the research are explained, then perhaps it will be viewed in a more positive manner.

Communication with children - this has to be appropriate and not above/below their level.

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.)

It depends a lot on the age/maturity. I feel that where a child is assessed for capacity for making treatment decisions, they should be assessed for capacity of making decisions about research (as often the two are interlinked). However, it is important to discuss with the child and parents/family as it may/probably will directly affect them also, and I would expect the rate of completion of involvement in the research will be highly dependent on the parents/guardians of the child.

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

As a term, it is potentially quite confusing and just more jargon, especially when the terms are so closely linked.

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?

I think that that is the best approach where there is a 'functioning' family. Often parents know and want what's best for their child, and many children may alter their reactions depending on their parents view. Therefore it is ideal to think of the child as a unit with the relevant family members involved. Depending on what the research involves, it may also have a direct effect on them and therefore it is important that they are happy with it.

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?

Respect to parents needs to be given, especially when it is clear that they have their child's best interests at heart.

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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?

I think it is fine to give it to the child, but not the parent, especially if the parent is involved in the decision making.

A small toy/gift voucher would be acceptable, but expensive gifts would not be appropriate as they would likely (even if inadvertently) become a form of bribery/incentive to take part.

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

It is a helpful concept but as healthcare professionals we use the term quite frequently and we need to make sure we communicate its true meaning to patients.

Best interests - would be making a decision that aims to provide the best possible outcome for the child.

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)?

It is a very difficult decision and perhaps one that should be made by the ethics committee and determined on a case-by-case basis. Minimised risks, with appropriate factors in place, e.g. cold spray for taking blood, seems acceptable by my understanding, but it is a flexible term and must not be subject to abuse. Also the parent/child should have a say in what is acceptable by them.

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.

Yes, where they know it will benefit others, where the risks to them are minimal (again by my understanding, e.g. extra blood tests).

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?

This would have to be done on a case by case basis, assessing merits and risk, and also the psychological status of the parents/young people.

11. Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and

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involving children in decisions about their own participation? What (if anything) would you like to change?

It's really difficult and as a student I don't feel I have enough research experience to comment.

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?

Who to be involved – researchers, clinical and/or academic paediatricians, children's nurses, children/young people, parents, some form of management who understands budgeting, market system etc

How to decide – group decisions to achieve the fairest solution

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

Responsibility of communication internally and externally, appropriate advertisement, information dissemination.

There should be an individual/small number of people with responsibility for coordination, to avoid confusion.