

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

Practical i.e. studies of conditions present at birth-emotions surrounding this time or unexpected nature of the condition might preclude recruitment.

Time off from school. Overcome by planning and scheduling

Risk parents understandably do not want to expose their children to risk. Overcome by defining what risk is acceptable and communicating this transparently

Ethical in the face of incompletely developed autonomy and no convincing case that participation is in the best interests of the child, who gives consent? Consensus required on appropriate source of consent at each age and consideration of interests e.g. are these served by a therapeutic trial for a condition which the child suffers from, are their broader moral education benefits to involvement?

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.)

Final decision when disagreement – proceed if decision to participate is made by a parent and child does not oppose this. Special cases such as where non-accidental injury is suspected could be considered on a case by case basis. It is possible that a proxy such as local authority may give consent however if the parents retain parental responsibility I feel this would infringe their integrity as a family. Health professional/researchers responsibility is not to proceed if child appears to dissent.

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

Assent essentially describes the process of absence of dissent that I have described above. It is not dissimilar to the way in which decisions are made every day within families. EG Mummy has decided that you will go to nursery and that you will go to this nursery, a child may not be involved in these decisions explicitly but implicitly they may be asked OK/ Ready to go? And if severely distressed by the situation it is likely that their opinion would be heard and included in the parental decision making. Formalising assent however as something which has to be sought is confusing and places the responsibility of consent upon children which is inappropriate. Consent represents are you happy with this decision (in which case will need to be informed and valid); assent means are you happy that this decision has been made for you.

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?

A shared approach sounds appealing and may describe to some extent the consideration of the child's views in the largely parent led model that I describe above. I am concerned however about how this would be implemented.

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 depends on the value of participating in research as at best researchers would be in equipoise about the medical benefit of a therapeutic trial one cannot argue from a physician's area of expertise that a child should participate or would be best served by participating. Equally, would a child be harmed by not participating? In this sense I can't see a moral reason to usurp parental decision making. Professionals should uphold the model of parental consent and lack of dissent from the child even in cultures where children are not generally involved in decision making this scheme can be applied as the children need not be overtly asked, their dissent can be inferred from their behaviour. If a professional felt unclear that the child was happy to participate they should not proceed.

Whether this model serves children as a whole is questionable. For example should groups of parents keen to allow their children to participate in research be allowed to restrict scientific development for the good of all children? I cannot think of an area of parenting/care of children where one child is expected to take a greater risk than others for all to benefit. The closest parallel I can think of is where all children take the possible risk of a vaccine reaction for the good of all achieved by herd immunity following vaccination. In this case each child has a risk of adverse reaction (although not suffer a reaction) and each child also benefits.

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?

Rewards reinforce the sense that children have done the right thing by participating this might contribute to their social education. So long as children are not the prime consenters to research this cannot be said to be coercive. One cannot argue however that payment to cover costs in the same that it is for an adult who has taken time off work for example to participate. I think small book token type rewards not mentioned at the time of recruitment reinforces the child's participation as an individual which may be an important way of compensating for the fact that the decision to participate was not entirely theirs.

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

Best interests are helpful when a child has an obvious need. Does a particular child 'need' to participate in research? Certainly all children need research to be done. In many ways considering children's best interests against a backdrop of research is more informative than considering interests in the context of therapeutic intervention. Here the answer is often simpler but only because health interests assume overriding importance. This has perhaps restricted our consideration of children's interests. Growth and development of autonomy is one such interest. Some might consider research participation under the guise of parentally supported decision-making an arena in which autonomy might develop.

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)?

I have struggled to express this previously with my analogy of vaccination. I find it easiest to balance rights in terms of a best interests model i.e. if there is no personal gain only minimal risk research is permissible.

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.

This overlaps with 8, I would permit minimal risk but would argue that it is impossible to say that there is no benefit to that child. At a trivial level they may be very grateful to miss a day of school for example! Indulging this child like reasoning is permissible in my view if the research itself is of minimal risk.

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?

I am unclear whether this refers to interventional therapeutic research. Potentially in a very poor prognosis situation where a new treatment is being developed it would seem unfair to restrict a perhaps Gillick competent mature child the chance for participation if under similar circumstances this would be allowed of adults but I would support participation under these circumstances only if there was a chance of personal gain.

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 think current regulations are weighted far too heavily in view of clinical drug trials and as such reflect a reliance on parental consent and do not adequately address the question of the child's voice and how it should be heard.

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?

If resources are limited no matter how distasteful resources should be at the centre of decision making. The most promising research to alleviate the greatest suffering should be supported. That does not mean that the decision should be purely economic as there is room for consultation with parents and children regarding what is the greatest suffering. Ideally a balance between the most severe and most prevalent conditions should be struck. This will require medical, scientific personal and economic sources of expertise.

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

Co-ordination is exceptionally important to answer the requirement above that the most effective research is funded. However with much charitable funding it is important that the likely impact of research is well funded. Coordination could be integral to research governance for example via compulsory publication of negative findings.

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

Once a study is over the findings should be communicated to participants in a manner in which they understand as this will inform their likely participation in the future. Feedback from participants can also be used to improve accessibility and relevance of future research.