

42. Professor Jane C. Davies 011113

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

A lack of protected research time for most paediatric clinicians hinders their involvement and prevents their patients having access to clinical research - there appears often to be reluctance of health care teams to 'burden' families with requests for participation
- concern over painful or uncomfortable procedures, many of which are technically more challenging in children such as venepuncture, and which are not required for clinical purposes

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 baby or young child: parent/ carer

- child who is any older (not just 'Gillick competent') I would be extremely concerned about including A child who consistently expressed the wish not to participate unless the research had the potential to provide clinical benefit to that child itself (eg. an open label safety trial of A new drug with clear clinical benefits in older populations)
- we need to ensure, preferably before we ask for consent/ assent, that the family unit knows where we stand on this issue. Parents need to account for the wishes of their older children in my opinion, at least morally if not legally

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

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 do think so, as it reflects my answer to the Q above.

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?

I don't know if I would find this difficult area any easier to navigate if there was a clearer legal position.

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 do think 'thank you's' are acceptable. They need to be of relatively small monetary value, but something that is appreciated by the child eg. I-tunes vouchers, but not a new iPad. Certificates and badges can make children feel proud to be involved and are less likely to attract criticism. One can avoid the perception of an 'incentive' by raising the issue only once consent/ assent has been obtained.

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

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)?

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.

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?

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?

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?

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

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