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

Adult gatekeepers are usually the biggest obstacle in recruitment and often make decisions about whether or not a child should participate and whether or not it is in the child's best interest without discussing with the child first. This prevents the child making her own decision about whether or not to participate. This combined with a lack of recognition or respect for children's capacity or agency to understand and to contribute an opinion often limits children's choices. Overly paternalistic attitudes towards children, particularly very young, sick or disabled children perpetuates the concept that 'adults know best' rather than respecting and valuing children's ability to be experts in their own lives.

**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.)**

As the child herself is the research participant the final decision should rest with the child. The concept of Gillick competence is important. Where a child has sufficient understanding she should be able to make an informed decision about whether or not to participate or continue to participate in a research project. Good practice suggests that wherever possible parental/carer's consent should also be obtained. It is unethical for research to continue if the child disagrees. If the parent disagrees on behalf of a child who has the capacity to decide for herself the child should be able to voice their own views about continued participation independently. Similarly if the child wishes to end their involvement but the parent wishes to continue this should not be permitted. Where there is a dispute the health professionals and or researchers should provide as much information and support to all interested parties as is possible but ultimately it should remain the choice of the child herself.

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

The concept of assent is very useful in understanding the importance of the child's understanding of what they are being asked to agree to and what the implications/consequences of this may be. Continuing assent is useful as this may alter during the process. At all times a child should be given the opportunity to withdraw from the research process.

**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 collaborative approach is a useful model but there may be a range of diverse views. Parent/carers may have a very different perspective about the concept of 'best interests' and may also have additional information and or personal experience

that is impacting on their views. Parents themselves may also have conflicting views and there may be additional cultural or faith based issues to address. Ultimately this is a rights issue and the importance of retaining a rights perspective may be helpful. As the research participant, the child has rights to protection, participation etc. that must be upheld. The adults have a responsibility to address other issues such as safeguarding, good practice etc. but should consider first and foremost their responsibility to the child.

**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?**

As above if this is seen from a rights perspective the UNCRC and EHRC apply in the UK and elsewhere. There will be local variations that are affected by culture, faith, class, age etc. and which impact on approached to parenting. The conflict between parental rights and children's rights is a complex one. Children have a right to protection, and also have a right to participate and no distinction is made in human rights legislation between children and adults. Gillick competence is relevant and, at all times adults (health professionals and researchers) must be mindful of safeguarding issues and the dangers of exploitation. This should not prevent children from participating in research projects where they fully understand and are choosing to take part.

**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?**

Payment/rewards should always be offered to participants in order to recognise and value their time and expertise. Our experience is that the best way to recognise children's involvement should be discussed at the outset with children and they will decide how they will be reimbursed or rewarded for taking part.

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

The best interests of the child are fairly clearly defined within UNCRC and are often then incorporated into domestic legislation within countries that are signatories (although not in the UK). The concept that the child's best interests should be of paramount consideration are set out explicitly. What is complicated is who defines 'best interests'? is it parents, professionals etc. and what about the child's own perspective? Is the child recognised as having an idea of what is in her own best interests?

We have found it useful to consider that adults don't always know best but they often know different, i.e. they have access to additional information and greater experience by virtue of having been here longer, their perspective is, therefore, important in determining what is in the best interest of their child. But an equally important view,

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also enshrined in the UNCRC, is the child's right to express their views freely including their views about what is best.

**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)?**

The importance is in ensuring that upholding one persons' rights do not exclude or interfere with any other individuals' rights.

**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.**

Children are often very realistic about the outcomes of research and fully aware that there may be no improvements for them personally but that things might improve for other young people or future generations. Children often have an ability to be altruistic and this quality can be useful. There is a delicate balance with the possibility of exploiting children who are vulnerable but, as long as children are properly informed and supportive they may well, have the capacity to agree to participate to research that does not have a direct benefit to them but may help to improve things in the future. There may be children who are living with life limiting conditions or who are terminally ill and for whom there is limited benefit to personally. However there benefits to them personally for the process of participating may be important and beneficial even if the outcomes ultimately cannot be.

**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?**

The role of the ethics committee should be to ascertain that there are no unnecessary or unreasonable risks or consequences. If the possible risks have been identified and every effort has been made to predict, address or reduce these and both parents and the child have been fully informed, the child should be able to agree to participate.

The concept of working to an agreed set of ethical principles (mutual respect, democratic participation, equality and inclusion, making a difference, personal integrity, active learning, collective action) may be helpful. Ethical approval should be about issues other than solely about risk.

Having patients/service users on the ethics committee may help to generate informed discussions and debates about how to manage the process to allow innovate research to take place.

**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?**

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The current regulations are confusing and do not make clear the relevance of international rights legislation. There is insufficient understanding of the status of the UNCRC, ECHR and confusing. The concept of ethical approval, in the UK, is grounded in medical research which gives it a very narrow and risk averse perspective. It should encompass a broader rights framework which covers more ground and allows for a more inclusive approach that respects children's right to participate and to express their views on all matters that affect them.

**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?**

In the first instance children themselves should be involved in helping to make such decisions. A partnership approach to decision making will help to shape more balanced decisions and ensure that issues/conditions which children themselves think are important are researched as well as those identified by adults.

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

It is important that children are not over researched i.e. that they are not continually asked the same questions without any possibility that the information they provide leads to any improvements for them or impact on services. This means that co-ordinating research is crucial and adults, academic and research institutions should try wherever possible not to duplicate research activities

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

Researchers have a duty to ensure that all participants are informed of the research outcomes, have access to the research reports in a format that is accessible to them, and also that research should be transformative i.e. that it has a purpose at improving organisations, services, processes, treatments wherever possible.