

This response was submitted to the evidence call issued by the Nuffield Council on Bioethics' Working Party on *Children and clinical research: ethical issues*. Responses were gathered from 7 August to 31 October 2013. The views expressed are solely those of the respondent(s) and not those of the Council.

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

The culture of contemporary clinical practice is subject to a hypo-narration of the relationship between clinical interventions and therapeutic research. This subsequently creates an illusory dividing-line, with the role of research for clinical medicine becoming marginalized as an area of scientific medicine that occupies a different space to treatment. When research is proposed, therefore, especially in the context of research in children, there is a lack of understanding by the parents about their child's status as a research subject. The cases where this becomes the exception is when the research occupies the role of compassionate use of treatment, thereby becoming likened to a clinical intervention more than being recognised as or acknowledged as a research proposal.

The impact of this disparity between clinical treatment and research is reflected through the lack of rules applying to children and the subsequent obstacle of not being able to obtain consent for research. By further elaborating on the role of research in clinical medicine, this obstacle could be overcome and the values of research will increase in their transparency. This may be particularly beneficial in cases where research on children who are otherwise healthy but may at risk of or susceptible due to their genetic make-up or family history to certain conditions in the future.

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.)*

Following the consent of a child to participate, by virtue of the concept of consent, the child can withdraw at any time. If it is not the case where the child is refusing to participate, then there is a further clause as to who should make the final decision. For example, in cases where the researcher is also the child's clinician, I consider it important for the final decision to be made by an external figure or body such as an ethics committee.

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

Assent, for a child, is equivalent to consent in a phenomenological sense. The process whereby information is shared albeit according to the child's level of understanding is an indication that the child's view is valued and that the child has a certain form of agency over his or her body. In this case, although consent requires a further robust and structured validation, the distinguishing between assent and consent is not very useful. The usefulness for the distinguishing of consent from non-assent, however, is greater in the sense that there is greater potential to avoid any violation of the child.

- 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?**

The UK, or indeed, the Western paradigm of scientific and clinical medicine, is premised on the concept of autonomy. However, arguably, this standard of autonomy has difficulties in being defined and applied across all of medical practice. Thus, it is essential that the shared or collaborative decision-making approach is provided and recognized as such for a child. A child may be able to provide certain forms of consent, but a child is not yet an individual body and as such, the decisions of the child will reflect the environment and familial relationships that he or she is accustomed to. The approach, therefore, is a necessary approach. The problems that this model might encounter such as differing of perspectives and monopolization of a central voice can be aided by a strong facilitator who is neutral from the group.

- 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?**

Different parenting approaches will inevitably lead to varying and conflicting conclusions. Rather than the emphasis being placed on the outcomes of the approaches, greater understanding is required in how the development of these approaches is related to a wider spectrum of narratives such as culture and religion. The balancing of values and negotiation of certain values to prioritize will be an important step-forward in the mediation of different voices. There needs to be a greater understanding of intentions and motivations towards certain decisions and what the inherent meanings within these processes are. This is not to say that a good intention surpasses the outcome. Rather, the focus should be on prevention of conflict of different approaches. This will harvest a greater relationship between parents, the law and professionals.

- 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?**

A reward that benefits the child, rather than as being vulnerable as a motivating incentive for the parents, is a permissible act of recognizing that the child has endured certain experiences. The balancing between appreciation and coercion must be strictly managed, but in such cases where a reward is acceptable, forms of gratitude could be arranged in terms of educational or health promotion formats.