

# Summary of report

## Children and clinical research: ethical issues

Published Thursday 14 May 2015

Well-conducted clinical research with children and young people is essential if we are to improve our understanding of childhood disease, and provide healthcare based on the best possible evidence. However, professionals and parents often feel uneasy about asking children to take part in research because of potential risks or burdens.

This Nuffield Council on Bioethics report looks at the ethics of involving children in research, and at the roles and responsibilities of children, parents/guardians and researchers. Central to the report is the idea that from a young age, children have a role in determining their own lives and should be seen as active participants in research. The assumption that all children are necessarily vulnerable may prevent worthwhile research from going ahead. The risk of children being placed in vulnerable situations can be minimised by ensuring that researchers engage with children's and parents' views and experiences in the prioritisation, design and review of research and that research is subject to appropriate scrutiny and governance. Children and parents should be confident that an invitation to take part in research is a 'fair offer' where the value of the research and its risks and benefits, have been independently assessed.

### Developing and reviewing research proposals

- Research ethics committees (RECs) should require researchers to involve children and parents in the development of their studies, unless there are good reasons not to. INVOLVE, the NIHR Design Service and the Medicines & Healthcare products Regulatory Agency should explore how the design and scrutiny of clinical trials can better take into account the experiences of children and their families.
- Young Persons' Advisory Groups (YPAGs) are often asked to review researchers' proposals and information sheets. Industry partners should contribute to the costs of running YPAGs without undermining their independence.
- RECs should have access to relevant expertise when making decisions about research involving children. The National Research Ethics Service, Royal Colleges and professional bodies should establish a database of experts who can fulfil this role.
- The UK Departments of Health, NHS and Universities UK should protect the time needed for experts in children's healthcare to contribute to RECs.

### Shared decision making: partnerships between children, parents and researchers

- Wherever possible, decisions about research should be shared decisions by children and their parents. Children should be as involved in decisions as they wish, and are able to be.
- Where children and young people have sufficient maturity and understanding, but are not yet treated legally as adults, professionals should seek consent both from children and from their parents. Exceptionally, RECs may be asked to agree that parental consent is not needed.
- In the case of looked-after children, the UK children's research networks should work with Cafcass to develop good practice guidance for social services departments and researchers to ensure this group is not excluded from research.

### Promoting clinical research in children and young people

- The European Medicines Agency should review the class waiver system to ensure that where a medicine's mechanism of action is potentially relevant for children, research with children goes ahead. Research sponsors should choose to include children in trials if the mechanism of action may be relevant for them, even if a class waiver applies.

### Making research part of everyday life and increasing awareness

- The All Party Parliamentary Group on Medical Research should work with others to explore ways of increasing general public awareness of clinical research, including the benefits for children's health and healthcare.



# Points to consider when carrying out clinical research with children and young people

The report's recommendations represent a significant shift in current practice, meaning that additional guidance will be needed for researchers and those responsible for the scrutiny of research. The following prompts should assist in the development of any research involving children and young people:

- Have you involved children, young people and parents in the development of your study?
  - in the design of the study itself? (e.g. the number of appointments or interventions required)
  - in the development of easy-to-understand information about the study?
- Does your study represent a fair offer to prospective participants? Are you confident that the value of the study, and its likely risks, burdens and benefits, have been carefully weighed up from the perspective of potential participants? Have children, young people and parents been involved in identifying possible benefits, risks and burdens?
- Is expertise in a particular area of children's healthcare important in order for the REC to understand the approach taken in this study? Has this been communicated to the REC, so that it is well placed to obtain advice if necessary?
- Are you able to demonstrate how you will communicate, and discuss, information about the study appropriately and sensitively with potential participants and their parents, so that they are able to make free and informed choices about whether to take part? Does everyone in your team who will be interacting with children, young people and parents have the necessary communication skills?
- Good assent practice is about the *process* of involving children and young people meaningfully in decisions about research. Are the particular methods you have chosen for involving children and young people in decisions about taking part the most appropriate ones?
- Children and young people who have the capacity and maturity to make their own decision about your study should be invited to give consent (not assent), even if the law additionally requires parental consent. Does your consent process and documentation allow for this?
- Decisions about research participation should, wherever possible, represent a shared decision between parents and children/young people. How will you encourage shared decision-making?
- Is the subject matter of your research such that it may be appropriate or necessary to recruit children and young people *without* the involvement of their parents? If so, can you justify the approach you have chosen?
- What arrangements have you made to support children and young people who do not have a parent, or another adult exercising a parental role, so that they are not excluded from your study?
- Will clinicians be responsible for recruiting children and young people, for whom they are providing care, to take part in research? If so, is this the most appropriate approach? Have you considered alternative approaches?
- Does the information provided for children, young people and parents explain how and when they can find out about the outcomes of the research? Will those outcomes also be explained in accessible language?

To access the full report and for further information, please see:  
[www.nuffieldbioethics.org/children](http://www.nuffieldbioethics.org/children)

