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Ethics of research in children

How should children be recruited to clinical research?

This will vary by context, for example whether the study is disease-based (eg recruiting patients) or community based (eg recruiting for a cohort study). The initial approach should be to the parents. Full information should be given – what the research is for, what it will achieve, why it is needed, what it will entail, what are the risks/benefits to the child and family, what will the child/family gain/not gain from participating. They should know their rights – able to withdraw at any time without having to explain and without prejudice to their treatment. The child should be involved in the decision as much as possible, given their age, and if they are capable of refusing to take part, this should be honoured. The study should be explained to parents and children in ways that they can understand. Parental informed consent and the child's informed assent should be obtained wherever possible – there is a useful distinction. There should be no inducements offered, but expenses of participation should be covered, and in a developing country setting where poor families are involved this should include parental loss of earnings for the time involved. I think it's OK for the child to get a voucher or small gift for participating.

What research proposals should be regarded as ethically acceptable?

It should be important, valuable research that will benefit current or future medical practice, be well carried out, scientifically and methodologically sound, and carried out by people trained/qualified to do any procedures safely and to a high quality. It should have been considered by a properly constituted ethics review board. Children should only be recruited if this research is not possible in adults (eg diseases specific to children, studies of development or the relationship between development and later disease, pharmacokinetic studies). Unless the research is of direct benefit to the child, any procedures included should carry minimal risk – I do not think studies that carry higher risk can be ethical, even if parents and children appear willing to take part. Minimal risk procedures can include venesection with proper attention to local anaesthesia and avoidance of introducing infection. It can include low radiation exposure eg DXA. It can include subjecting children to challenging/stressful experiences (eg public speaking, mental arithmetic tests) as long as they know they can stop at any time if they find it too distressing. There will be many situations where the research will not benefit the child (eg many randomised trials, birth cohort studies) and this is justified if parents and child are informed.

How should research in children be encouraged?

Make people in general and school children aware of the benefits of research, and the fact that research is a way that they can contribute to society. Generate trust – trust that research is needed, trust that their wellbeing is paramount and that the research will not harm them, trust that data will be handled confidentially. Current regulations seem OK.

What should happen when the research is over?

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At a minimum, parents and children should be told the results of the research in general terms. People should be told at the beginning what they will and will not gain from the research. If their own data does not have clinical relevance to them, and/or if they will not get their own results/data, they should know this. If, as would usually be the case, it is not feasible to offer the continuation of a successful intervention, or to provide medical services beyond the duration of a study, this must be made clear at the start. Regulations that place open-ended/unpredictable responsibilities on the researchers/funders will discourage research, which will be detrimental in the long run.

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27th Sept 2013