

CURRENT TOPIC

'Will you help us with our research?'

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A useful part of preparing a paediatric research protocol is to summarise the main points in a leaflet for parents and children. This article reviews the benefits of using such leaflets and then outlines their main contents and style.

The uses of research information leaflets

Medical researchers have to communicate clearly if they are to gain essential support for their work from funding bodies, ethics committees, and the adults and children who might take part in the research. While some of these groups require elaborate protocols, others appreciate clear leaflets.

It is helpful if, during the early planning stages, researchers think about the questions which lay people might ask, such as: What is the point of the project? Whom might the research help and how? The research is more likely to be well received if the protocol design starts from reasonable attempts to answer these questions. One way to do this exercise is to write a clear set of questions and answers. These can be printed in a short leaflet which serves several purposes.

Ethics committee members often glance first at the patient information leaflet to gain an overall view of the project. Leaflets can be sensitive indicators of researchers' attitudes towards the research subjects, such as respect, concern, or indifference. These attitudes are highly likely to affect the informed cooperation on which efficient research depends. The leaflets are the only means through which ethics committees can ensure that people have the minimal information they need to decide whether to take part in the research. Sometimes a leaflet shows up strengths or faults in the research design more clearly than a long protocol does.

Leaflets help to ensure that all the staff affected by a project are informed. Nurses, technicians, and frequently changing junior medical staff may have little idea why they are collecting research samples. Their ignorance, unease, or even resentment can influence patients' attitudes; so too can their informed commitment to the research. Leaflets can also help people to talk over the project with the researchers, and back at home with their relatives or family doctor. Then they can make a more informed choice about whether to take part in research. For those who do consent, a leaflet to keep can help them to recall the agreed details – taking tablets or attending

clinics – and why these matter. When people are well informed in advance, then mistakes, problems, and complaints are less likely to arise, and there is less risk of wasted time and money over failed projects.

Consent to research

One of the hardest tasks for many researchers is to translate medical concepts into lay terms. This difficulty has been used to argue that, as so many adults cannot read consent forms, it 'is both inappropriate and impractical' to request children's consent.¹ However, lawyers argue that most adults can grasp the salient issues,² and that some children have sufficient understanding and discretion to be able to give valid consent.³ Research with children with chronic conditions has found that children with cancer, for example, want to be informed^{4,5}; most children in a study of orthopaedic surgery wanted to share in making decisions about their treatment.⁶ Even greater care is advised to ensure that decisions about research are shared with families.^{7,8} The British Paediatric Association's guidelines advise requesting 'the agreement of school age children'.⁹

Frequently, the problem with consent forms is not lay people's inability to read them, but doctors' inability to write them clearly. One doctor concluded his article on writing leaflets for patients: 'Does all that sound difficult? Time consuming? Expensive? It is, and that's why so much material given to patients is so awful'.¹⁰ Yet time spent writing a research leaflet can later save much trouble and cost. Wording that has been carefully worked out for a leaflet can be used many times over in discussions with families to elicit their informed cooperation.

Parents who are confused by medical and research jargon face two serious questions. How can they possibly decide whether their child should enter the research project? (It is one thing to decide for yourself, and quite another to decide for someone else.) Secondly, how can they explain the research in terms that their child will understand and accept, especially if their child is anxious or resistant? These questions are particularly important in research which might have long term effects, which lasts for weeks such as drug trials, or which involves children who have a stressful disease or disability.

Clinicians who think mainly in terms of 'management' and 'compliance' can find it

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hard to move into consent mode, to offer choice and to respect informed refusal. Yet this respect is the basis of ethical research, as explained over decades in codes, guidelines, and legal rulings. The guidance has been summarised in a booklet for people who write research leaflets.¹¹ Before they can give consent, people have to know that they can take time to decide, can ask questions, negotiate and possibly refuse, without feeling coerced into a decision.

Style

It is efficient to write paediatric research leaflets in terms that children can read for themselves, or their parents can read to them. This approach also helps parents who cannot read much, or who speak little English, and it simplifies translation into other languages. Parents and children could be asked to help with checking and revising the drafts.

Medical research forms are replete with long words and phrases when short ones would do, for example: *participate* instead of 'take part'; *It is now well established that the substance currently under investigation is effective for the duration of a minimum of four hours*, instead of, 'the tablets being tested work for at least four hours'; *assurance that despite declining to participate your routine clinical treatment will in no way be affected and you shall not be interrogated about your motive* for 'You can refuse, or withdraw at any time from the research. You do not have to give a reason, and we shall carry on giving you the best care that we can'. There are useful guides on writing plain English.¹²

While some leaflets have a friendly style, others are bossy: 'You will visit the clinic a total of 7 times. You will inform the doctor about all medication you have taken. You will take none, one or two tablets a day. You will ...' These researchers appear to be confused about who is benefiting whom. Though, as clinicians, they provide treatment which they hope will benefit the child, as researchers they ask children to help them to test new interventions, to act as controls, to provide data, to attend extra clinics, to tolerate the stressful uncertainty which is the basis of clinical research – research is necessary when there are not yet definite and reassuring answers. So requests are more appropriate than commands.

Folding an A4 sheet, to make four small 'pages' makes the leaflet look more user friendly. As newsprint shows, short lines are much easier to read. Subheadings also help. White or light coloured matt paper with large black print helps slow readers and people with poor vision. Diagrams or time charts can replace many words and help younger readers.

Content

The leaflet should explain:

- The nature and purpose of the research
- The hoped for benefits and whether these are likely to benefit the research subject directly
- Possible alternatives to any treatments being tested
- The risks, harms, costs, or inconvenience to subjects
- Assurance that people can freely refuse, or withdraw from a project, and that their other health care will not be affected
- Details about reimbursement and indemnity
- Names of the project sponsors and director/coordinator
- The name and telephone number of a researcher to contact when needed
- Respect for privacy and confidentiality

Each of these topics includes further details, such as the nature of each intervention, timing, and the meaning of relevant terms, such as, 'randomised trial' or 'placebo'. The list may look daunting, and guaranteed to elicit 100% refusal rates. Yet people are willing to take part in research despite considerable risk and inconvenience, and the details can be fitted into two or four sides of A4 paper.

Far from replacing discussion between health researchers and patients and other volunteers, leaflets can help to increase and enrich it. Academic and scientific language has great strengths, such as precision. Yet it can prevent knowledge and control over decisions from being shared more fairly through society. By helping to redress the imbalance of knowledge and power, clear leaflets help to encourage the informed public support on which the future of effective health research depends.

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- 3 Gillick v West Norfolk and Wisbech HA [1985] 3 All ER.
- 4 Bearison D. *'They never want to tell you': children talk about cancer*. London: Harvard University Press, 1991.
- 5 Ellis R, Leventhal B. Information needs and decision-making preferences of children with cancer. *Psycho-oncology* 1993; **2**: 277–84.
- 6 Alderson P. *Children's consent to surgery*. Buckingham: Open University Press, 1993.
- 7 Nicholson R, ed. *Medical research with children: ethics, law and practice*. Oxford: Oxford University Press, 1986.
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- 9 British Paediatric Association. *Guidelines for the ethical conduct of medical research involving children*. London: BPA, 1992.
- 10 Smith R. Information for patients: writing simple English is difficult, even for doctors. *BMJ* 1992; **305**: 1242–3.
- 11 Alderson P. *Spreading the word on research, or patient information, how can we get it better?* London: CERES, 1994. (From CERES, PO Box 1365, London N16 0BW, £2.50 each or £20.00 for 10 copies.)
- 12 Albert T. *Medical journalism*. Oxford: Radcliffe Medical Publications, 1992: 52–4.