

Do Research Subjects Need Better Information?

Christine Hogg

Guidelines on good practice in research recommend that people invited to take part in research should be provided with information and advice about what the procedure involves, the possible benefits and risks, and alternatives. However, this information can be difficult to communicate and is frequently misunderstood by people invited to take part in research.

Studies show how important information is for people when they are deciding whether or not to take part in research. However, often the information they are given is designed to comply with regulatory requirements on risk and guidelines on informed consent. People may have different concerns.

Why better information is needed

Improving the information given to research participants has enormous benefits for the research community:

- Ensuring more informed consent, which may lead to better compliance by research participants who understand what is expected of them
- Improved recruitment - the way that patients are approached and the lack of or poorly presented information often deters patients from taking part or, if they consent, to feeling exploited¹
- Better quality research - though research fraud maybe rare, there is evidence that most fraud is around not obtaining informed consent

Consumers for Ethics in Research

Consumers for Ethics in Research (CERES) was set up in 1989 to promote good quality research by encouraging greater involvement of people taking part in research. Since then, run by volunteers, CERES has produced guidelines for researchers on writing information leaflets², and involving people who speak little or no English³. Leaflets and tapes in several languages⁴ provide information about taking part in research.

Increasingly, CERES has been contacted for advice by people who wanted to, or had been invited to, take part in research. They wanted independent information. Some felt inhibited

about asking the researcher who was also their clinician. Sometimes, people contacted CERES who had experienced difficulties and problems as a result of taken part in research; they too needed independent advice.

The project

In 2002, CERES contacted stakeholders in patient groups, research ethics committees, and the research community to discuss how this need might be met. In collaboration with other stakeholders from the research community, and with support from the Department of Health and the Association of the British Pharmaceutical Industry (ABPI), a proposal for a three-year project has been developed to set up a phone helpline for research participants. This was developed by a working group set up by CERES with members from the Association of Research Ethics Committees, the Institute of Clinical Research, the Consumers in NHS



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Research Support Unit, and the National Cancer Research Network, as well as CERES. CERES feels strongly that such a scheme will be most effective with the active support of the research community.

The ICH Good Clinical Practice guideline⁵ recommends that research subjects should be given a contact to whom they can talk about taking part in research. This has been adopted by the European Union and underlies the European Directive on GCP in clinical trials⁶. However, it seems that no one has worked out the best way of providing this information and advice, or the degree to which this can be independent of study staff.

The project will explore how setting up a phone helpline might provide independent advice. In planning the service, the difficulty has been in estimating how many people might use the service and what sort of information they might want. For this reason, it was decided to set up a three-year action research study to find out the answers to these and other questions.

Funding is being sought from different sponsors to reflect the collaborative nature of the project.

If funding is secured, the project will start in May 2004.

What the project will do

A telephone helpline will advise callers of their rights and options. Helpline workers will not recommend a particular course of action (such as to take part in or leave a research programme), but will encourage callers to take up concerns directly with researchers. They will not undertake casework or deal with complaints that may involve claims for damages.

Where the caller is not happy to go back to the researcher, or wants clinical or other specialist advice, they will be referred to a specialist service provided by CERES. At this stage, helpline workers will have access to the patient information sheets of projects from the collaborating areas. They will also have access to expert advice for more complex concerns, such as research ethics, research methods, the NHS, and legal and clinical information or advice. In some cases, it may be necessary for the project staff to contact researchers at the request of the caller for further information or to ask to see the research protocol where information is not clear in the patient information sheet.

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All staff will be bound by a confidentiality agreement of any information given.

Where the service will operate

Working with Research Ethics Committees (RECs), the service will be provided to people invited to take part in research in four or five parts of England; areas that have expressed interest in working with us are in inner and outer London, Sheffield, and Bath. Once established the service, may be rolled out depending on the demand and take up.

Researchers in these areas will use the patient information sheet to tell potential participants that they can contact the service for independent advice, and give them a leaflet about the service. As the project is itself looking at what investigators do, the investigators will be able to opt out. The reasons why investigators might opt out are in themselves important research results, and will be included in the independent evaluation. If many investigators were to opt out, this might cause bias but, with the support of the RECs, we hope that very few will do this. For example, the RECs concerned may wish to require investigators who want to opt out to demonstrate that

they have made alternative arrangements for providing independent advice to participants.

Evaluation

The project will last three years and there will be an independent evaluation undertaken by an academic department. As a result of the project we hope to find out whether independent advice for research participants is needed, and if so, how it might be provided. This evaluation will explore practical issues, including:

- Estimating the likely number of people who experience difficulties in a dialogue with investigators, and identify why;
- Identifying the components of a service best able to empower participants
- Estimating the impact of this service on the research community.

At the end of the project

We have planned a three-year project because there is so much we do not know. We do not know the likely demand. We do not know what sorts of issues people may raise, or how best to deal with them. For example, we may find that:

- 1 There is evidence that people want independent information and advice but the service does not meet it effectively



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- 2 There is evidence that people want independent information and advice and:
 - A national phone advice service can effectively provide this; or
 - Research subjects prefer face to face contact and regional or local services are needed; or
 - Information can be provided by existing agencies such as Patient Advice and Liaison Services (PALS), NHS Direct, Citizen's Advice Bureau (CAB), or Independent Complaints Advocacy Services (ICAS).
- 3 There is no evidence of need, and the project can be wound down or discontinued

Half way through the project a strategy will be developed based on the interim evaluation reports. We will decide whether and how to design and roll out the service, and how to secure continuation funding. We will look at the outcomes so far, but also take into account any difficulties encountered and adjustments made. This will enable planning for the future development, transition or exit. We will also identify additional information needed to contribute to any decisions about how a national service might be provided.

Christine Hogg is an independent health policy researcher and a member of CERES. More information about CERES can be found on www.ceres.org.uk, and can be contacted on info@ceres.org.uk.

References

- 1 Literature Review by Dr Tony Stevens, available from CERES.
- 2 "Spreading the word on research or patient information: how can we get it better?" Notes on writing information for people asked to take part in health research. Available from www.ceres.org.uk
- 3 Pfeffer N et al. (2003) "Involving people who speak little to no English in health care research: information for investigators. CERES and Barts and the London NHS Trust. Available from www.ceres.org.uk
- 4 CERES leaflets and tapes can be ordered from www.ceres.org.uk:
 - Health Research and YOU- covers medical and general health research
 - Genetic Research and YOU covers all genetic research including where diseases run in families
 - Genetic Research – taking part in large studies – covers population research
 - Leaflets are available in English, Bengali, Cantonese, Somali, Turkish and Vietnamese. Tapes are available in English, Somali and Sylheti.
- 5 Section 4.8.10(q), International Conference on Harmonisation (1996): "ICH consolidated guideline E6 on Good Clinical Practice (GCP)" Available from www.ich.org/pdf/ICH/e6.pdf
- 6 Section 3.4, "European Union Directive on GCP in Clinical Trials" (May 1st, 2001): Official Journal of the European Communities L121, p34–44. Available from europa.eu.int/eur-lex/en/search/search_oj.html