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Ethics approval for a national postal survey: recent experience

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Before any study can be done on a national scale, permission must be sought from a large number of local ethics committees. We describe the resources required and the problems and issues that arose when we sought approval from ethics committee for a national postal survey in England and Wales.

Methods and results

We wanted to mount a postal survey in all parts of England and Wales of a national sample of children who were born in 1988 and were stratified by birth weight. After identifying the children from birth registration and tracing them through the NHS central register, we planned to send self administered questionnaires to the children's parents, general practitioners, and teachers. We identified 162 local research ethics committees in England and Wales from the *Medical Research Ethics Committees Directory*.[1] Each was sent a letter outlining the project and asking how an application should be made.

Seventeen committees told us that it was not appropriate to apply to them for ethics approval for this study; the remainder needed some type of formal application. Thirteen committees did not have a specific application form but requested between one copy and 21 copies of the protocol. Of the 132 committees that used an application form, 118 had a unique form, ranging in length from two to 18 pages. In the former Northern region a single application was considered by a "lead" committee on behalf of the seven others. In the former South Western region an application followed a standard format but each committee considered it separately. Seventy six committees requested 10 or more copies of the completed application form and protocols.

In all, we sent a total of 1095 protocols and 1116 application forms, together with a number of supporting documents. We estimated that, in total, this required seven to eight weeks of staff time. The cost of staff time, photocopying, and postage was estimated to be £4606, an average of £32 for each committee. This does not include the costs and time spent on additional telephone calls to clarify issues, responses to requests for additional information, and setting up and maintaining a database to record details of correspondence.

Three months after submitting applications to the 145 committees, 113 had responded. Eighty two expressed no objection to the study. Others raised a number of issues, including concerns about the aims of the study, its cost, confidentiality, consent, and the wording of the questionnaires and information sheets. Thirty one requested resubmission.

Comment

Seeking approval for a study covering a large geographical area is time consuming and expensive for both researchers and ethics committees. Researchers

have to obtain ethics approval before they can seek funding for the project. The location and composition of committees linked to commissioning authorities and of those set up by provider units are constantly changing. There may be additional costs in the future if committees levy a charge for considering applications.

These issues, together with the concerns that, despite guidelines,[2] local committees differ widely in their response to applications,[3] have led to a debate on the role of a national ethics committee in multicentre clinical trials and national surveys.[4,5] We suggest that there may be complementary roles for a central committee and local committees. A national committee could be asked to consider the scientific and methodological aspects of the study before the application is submitted to the funding body. A single copy of the application and the national committee's recommendations could then be sent to local committees, whose unique understanding and knowledge of their populations and local factors could inform their decision whether to review the project protocol further using a standard application form available in electronic form. This arrangement would reduce the time and cost for both local committees and researchers, without jeopardising the interests of research subjects.

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Conflict of interest: None.

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Cross district comparison of applications to research ethics committees

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Meade has criticised the current need to obtain approval for multicentred research from many different ethics committees.[1] Variability between committees has led to research having to be modified or even abandoned in some districts but not others.[2] I report the results of applying to 13 ethics committees within a region for approval of a study of young people.

Subjects, methods, and results

A regional study of the mental health needs of young offenders was proposed in which adolescents aged 13 to 17 were to be identified by health, social, and juvenile justice agencies. They were to be studied by means of a social and psychiatric interview, an educational assessment, an interview with staff, a postal questionnaire from parents, and a study of notes. The regional health authority identified 14 ethics committees. Approval for the study was obtained from one committee in advance. Applications were then sent to the remainder, informing them that this was a cross district study and that one committee had already given approval.

One committee did not respond to the initial inquiry. Two neighbouring committees had reciprocal arrangements for approval from each other. Eleven committees provided application forms, which were all different. One committee provided a form specifically for non-clinical studies. None provided a form on disk. Information requested varied between committees (table). Two forms asked if the study was multicentred, seemingly without this making a difference. One committee's guidelines stated that non-therapeutic research was generally unacceptable in children. One indicated that consent to a study using only interviews or questionnaires might not be required in writing, while another advised that consent for postal questionnaires should be obtained in person.

Two committees lost the original application. Two committees invited the researchers to the committee meeting: in one case four days' notice was given. One committee accepted its neighbour's decision. The table shows the responses of the remaining committee. The median time from application to the committee meeting was 4·0 weeks and from the meeting to a reply 3 days.

Eight committees had a median of three queries. Most of the queries concerned how consent was to be obtained and recorded, although three committees

Characteristics of application forms and responses from 12 committees

Committee	No of pages in application form	Information requested on application form						Time (weeks) from:			No of changes requested
		Aims	Scientific background	Method of consent	Consent of children	Data analysis	Adverse effects	Application to meeting	Meeting to reply	Application to approval	
A	2	Yes	No	No	No	Yes	Yes	2·4	0·4	8·6	1
B	4	No	No	No	No	No	Yes	3·4	0·1	13·0	1
C	0*	NA	NA	NA	NA	NA	NA	5·0	3·0	8·0	0
D	10	Yes	Yes	Yes	No	No	Yes	8·6	0·4	9·0	1
E	5	Yes	Yes	Yes	Yes	Yes	Yes	6·3	0·3	9·6	2
F	5	Yes	Yes	Yes	No	No	Yes†	4·9	0·2	9·1	2
G	5	Yes	Yes	No	No	Yes	Yes‡	4·0	0·9	14	4
H	5	Yes	Yes	Yes	Yes	No	Yes	0·3	1·9	2·2	0
I	9	Yes	No	Yes	Yes	Yes	Yes	3·1	0·1	13	3
J	4	Yes	No	Yes	Yes	No	Yes	4·0	1·7	5·7	0
K	3	No	No	Yes	Yes	Yes	Yes	NA§	NA	8·9	1
L	8	Yes	No	Yes	No	Yes	Yes	3·4	0·2	3·6	0

NA=Not applicable.
*No application form.
†Requested side effects of physical treatments only.
‡Requested side effects of drug treatment only.
§Chairman's action taken: initial reply after 3 weeks.