Committees should devise special forms for the social sciences

EDITOR,—We welcome the recent editorial and papers on research ethics committees,^{1,4} which were published at the time when we were revising our ethical and scientific standards. Our organisation deals with questionnaire surveys relating to reproductive health carried out in various European and Asian countries. We are all too familiar with the problems recognised in the articles. In our view, many are related to the fact that, apart from general principles of scientific credibility and quality, there are no clear guidelines about the ethical aspects of social medical research.

Our organisation is a private one and, like many others, funded by the pharmaceutical industry. The sponsor often generates suggestions for research. An international board of trustees, comprising four experts in reproductive health based in universities and the chairman (DdeW), reviews the suggestions as well as the protocols subsequently designed by the staff, determines the research programme, and carries responsibility for the scientific quality of the activities undertaken.

Given the source of funding and suggestions for research, we felt we needed to be explicit about our procedures. We were also motivated by experiences with some research ethics committees, which reacted to our protocols as if we were amateurs even though most of our studies have been published in peer reviewed journals.

We therefore decided to submit, for each study, the protocols and memorandum explaining our ethical, methodological, and data management standards to research ethics committees, even when their approval is not formally required by national regulations. We have found that it is often not clear which committees, if any, are in charge of national surveys of knowledge, attitudes, and practice. In the case of clinic based surveys, none of the committees approached ever sent us forms that were specially adapted for social medical studies. We share Garfield's experience of inconsistent (and sometimes conflicting) recommendations of various committees for the same study.³

Our initiative to develop standards was related to our specific source of funding. In our experience, however, there is a wider need for clear and uniform ethical guidance for researchers and ethics committees involved in social medical research. Our standards are available on request for critical comments and wider use. We advise research ethics committees to design special application forms for social medical studies.

B J ODDENS
Research director
D DE WIED
Chairman, board of trustees

International Health Foundation,
Avenue de Broqueville 116/9,
B-1200 Brussels,
Belgium

1 Alberti KGMM. Local research ethics committees. *BMJ* 1995; 311:639-40. (9 September.)

2 Middle C, Johnson A, Petty T, Sims L, Macfarlane A. Ethics approval for a national postal survey: recent experience. *BMJ* 1995;311:659-60. (9 September.)

3 Garfield P. Cross district comparison of applications to research ethics committees. *BMJ* 1995;311:660-1. (9 September.)

4 While AE. Ethics committees: impediments to research or guardians of ethical standards? *BMJ* 1995;311:661. (9 September.)

Differences in application process cause problems

EDITOR,—We wish to contribute to the debate on the role of local research ethics committees.^{1,4} Recently, we carried out a pilot study investigating the cost effectiveness of specialist outreach clinics in general practice in two specialties, dermatology and orthopaedic surgery. We sought approval from nine local research ethics committees to approach patients attending outpatient clinics in

Details of applications to nine local research ethics committees for approval for study, and time taken to receive approval

Committee	No of pages on form	Format of application	No of copies required	Approval	Attendance required at meeting	Changes required	Time from submission to approval (weeks)
A	0	Typed form	12	After two meetings	Yes	Yes	12.5
B	1	Headings	11	By chairperson	No	No	2
C	7	Form on disk	1	By chairperson	No	No	1
D	2	Headings given	1	By chairperson	No	No	5
E	10	Form on disk	18	By committee	No	No	2.5
F	5	Typed form	12	Outside terms of reference	Yes	Yes	5.5
G	9	Typed form	11	After two meetings	No	Yes	10.5
H	11	Typed form	1	By chairperson	No	No	6
I	3	Typed form	1	By chairperson	No	No	8

hospitals and general practice. We asked patients to complete a questionnaire about their health status and experience of attending the clinic and to give their consent for us to access medical records.

We echo the comments made in the recent papers concerning the amount of work caused by non-standard forms, on which details had to be typed.^{1,4} Forms ranged in length from one to 11 pages (mean 6.3) (table). Many sections of the forms related to invasive treatment and were inappropriate for research seeking the views of patients. Only two of the committees provided copies of the form on disk. We also found the photocopying required (up to 18 copies of the forms and protocol (mean 7.6)) daunting, though four committees initially requested one copy of the documentation.

Our submissions were approved by the chairperson of five committees. Our most exasperating experience entailed a long journey to attend a meeting where the committee members gave advice on the content of the questionnaire, although they stated that the study was outside their terms of reference. Two committees, one of which met each month and the other every two months, did not approve our submission until it had been discussed at two meetings. The time taken to approve our application ranged from one to 12.5 weeks (mean 5.9); approval by the committee was not always slower than approval by the chairperson.

Having carried out the pilot study, we are now looking for a feasible research design for our main study of outreach clinics. As sets of forms usually have to be submitted two weeks before the meeting we think it should be possible to approve applications within a month of submission. We strongly support the suggestions for a national committee or regional committees having a role in multicentre studies.^{1,4} Clarification of the chairperson's role in approving applications and the legitimacy of requiring researchers to attend meetings would also make the application process less like a lottery and make planning fieldwork more straightforward.

MARY BLACK
Research associate

BRENDA LEESE
Research fellow
TOBY GOSDEN
Research assistant

National Primary Care Research and
Development Centre,
University of Manchester,
Manchester M13 9PL

1 Garfield P. Applying to research ethics committees: a cross district comparison. *BMJ* 1995;311:660-1. (9 September.)

2 Alberti KGMM. Local research ethics committees. *BMJ* 1995; 311:639-40. (9 September.)

3 Middle C, Johnson A, Petty T, Sims L, Macfarlane A. Ethics approval for a national postal survey: recent experience. *BMJ* 1995;311:659-60. (9 September.)

4 While AE. Ethics committees: impediments to research or guardians of ethical standards? *BMJ* 1995;311:661. (9 September.)

Medical insurance in Republic of Ireland

EDITOR,—Alan Murdoch's report on medical insurance in the Republic of Ireland is misleading.¹ He states that the Voluntary Health Insurance Board was set up "to provide medical cover for those who were not eligible for free services under Ireland's means tested public health system." This is historically correct, but the reality for the past decade has been that all hospital services, maintenance, and fees have been free (except for some nominal charges) to all of the population. The Voluntary Health Insurance Board covers the 30% who wish to choose their consultant, the institution, and the timing of their treatment. The premiums do not increase with greater risk, such as getting older, and are tax deductible at the standard rate of income tax.

The public seems to accept the balance provided, and the health services are no longer at the centre of election manifestos.

BARRY O'DONNELL
Retired consultant paediatric surgeon

Ballsbridge,
Dublin 4,
Republic of Ireland

1 Murdoch A. Irish psychiatrists are worried about foreign insurers. *BMJ* 1995;311:527. (26 August.)

Improving oral examinations

Interobserver agreement does not necessarily imply reliability

EDITOR,—Richard Wakeford and colleagues describe the work that has gone into developing the vivas for membership of the Royal College of General Practitioners and recommend this process to other organisations.¹ The main point of improving examiners' training and the structure of examinations, however, is to improve the reliability of the examinations. The part of the article's discussion that deals with reliability is brief and confusing. There are two separate vivas, each carried out by a different pair of examiners. The 94% agreement quoted by the authors seems to be between the two examiners in each viva, although the text is contradictory on this.

The analysis in the article is insufficient to make the figure of 94% mean much. Factors that should be considered include whether examiners' marks congregate around the middle of the scale. If this is the case such concordance could explain a lot of the apparent agreement. Examiners can and do change their gradings after discussion, which clearly makes for agreement. Although examiners do not discuss their views on candidates until after the