

30 submissions a month. Looking at how the local application form (of which Alberti disapproves) is completed by local investigators, however, is one efficient way in which committees can assess whether applicants understand, and can justify and explain, what they are proposing to do (often with financial inducements).

It is important that members of ethics committees are sensitised to issues of which they may be unaware and have the opportunity to compare and exchange experiences. They do not, however, devote a day or more a month to conform with national norms; they do so because they believe that they have something particular to contribute. The importance of local committees is reflected in the anxiety of sponsors to know who their members are and how they operate, and to involve them when anything goes wrong.

Publication by competent researchers of the inconsistencies of local committees should not detract from their positive value to applicants, many of whom need help with scientific as well as ethics procedures. Researchers also need training.

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

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### Central ethics committee might have to face hostile locals

EDITOR.—We welcome the interest being shown in the organisation and operation of local research ethics committees.<sup>1</sup> The difficulties experienced in using these committees is a constant irritant to those of us who have to make frequent applications to them.

Some of the problems have apparently fairly simple solutions. The use of a common application form should not be difficult, and such a form is presented in *Standard Operating Procedures for Local Research Ethics Committees*,<sup>2</sup> which was given quasi-official status by being used in workshops by the Department of Health.

The institution of "central" or "national" ethics committees, as suggested by Claire Middle and colleagues,<sup>3</sup> has been debated keenly for some time. For a study we published in 1993 we had obtained clearance from the ethics committee of the Royal College of General Practitioners.<sup>4</sup> Despite this, three quarters of the 26 committees required full review and half required amendments to the protocol consent forms.

We were surprised to find considerable hostility to the use of a central committee by many local research ethics committees. Presumably this hostility could be overcome, but the precise definition of central versus local issues will be difficult. We found that in at least one case a general objection to the protocol was used to avoid possible confrontation with an investigator whom the local research ethics committee considered to be unsuitable. The basis for judgment is not always clear. The possible organisation of central committees has been the subject of a good deal of debate. A single central committee would probably be severely overloaded, but multiple committees might also present problems. It would be essential that only one committee be in charge of central review. If committees set up on a regional basis were to review all protocols for their region then the inevitable conflicting requirements between them would be far more damaging than irreconcilable requirements of one or two local research ethics committees.

These issues have been and continue to be debated at the annual conference on ethical review of clinical research, organised by the Association of Independent Clinical Research Contractors, which is attended by up to 100 chairpeople and members of ethics committees. We think that this could usefully be added to K G M M Alberti's list of training facilities since it is a well attended, non-commercial training conference.

We hope that the *BMJ's* interest will give new impetus to action by the Department of Health. In the meantime a number of local research ethics committees are attempting effective measures, but these are bound to be local and piecemeal. Only the Department of Health has the power to offer national solutions.

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

2 Bendall C. *Standard operating procedures for local research ethics committees—comments and examples*. London: McKenna, 1994.

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

4 Watling M, Dewhurst J. Current experience of central versus local ethics approval in multicentre studies. *J R Coll Physicians Lond* 1993;27:399-402.

### Problems of students must not be ignored

EDITOR.—K G M M Alberti's editorial draws a depressing picture of the current situation with regard to ethics committees,<sup>1</sup> and the three accompanying short papers paint a familiar picture instantly recognisable by all trying to carry out research in the NHS.<sup>2,4</sup> Problems that Alberti does not mention include research projects labelled as reviews to avoid the need for referral to, scrutiny by, and approval of ethics committees. Clinicians and others, bound by their NHS contracts, feel that they must answer the researchers' questions, which are sometimes intrusive, poorly framed, or even ethically unsound. Policymakers can also fail to take into account the agendas of those who commission such studies. These may suit the needs and agendas of all concerned (except the patients) but may fail to delineate the real situation. It is then easy to produce wrong or incomplete answers on which to make policy decisions.

A third problem that Alberti dismisses as irrelevant is the need for student projects to get ethical approval. As more students study for MSc degrees that require the completion of dissertations incorporating research, this problem will not go away. Dismissing these studies as "lacking the power to generate any useful data" misses the point. I teach on an MSc degree course, and the students are required to carry out research projects for their 25 000 word dissertations in their final year. The research projects are usually relevant to their work as NHS professionals, but the difficulties that the students have just in meeting the financial costs of producing 24 or more copies of their research proposal for a meeting of an ethics committee are compounded when their proposal is not even considered and is put back to the next meeting, sometimes months later. With deadlines to meet, some students are denied the opportunity of carrying out studies that might generate useful data and instead are forced to carry out non-clinical research. Today's students are tomorrow's researchers. It would be damaging if ethics committees followed Alberti's advice to reject such applications. If they did so then one such study carried out by one of my students (a nurse), which has changed working practices in the accident and emergency department in which she works, would never have seen the light of day, and the

unsatisfactory state of affairs she identified would have continued unchallenged and care continued to suffer.

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

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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.)

### Attitude of their members is the critical factor

EDITOR.—I agree with the subtitle of K G M M Alberti's editorial on local research ethics committees—it is "time to grab several bulls by the horns."<sup>1</sup> Before the profession and others can do so, however, we need to be much more precise about our thinking.

Firstly, in Editor's choice the *BMJ's* editor is guilty of a basic semantic error: those who are asked to look at issues of experiment on humans are not members of "ethical committees" in that—despite much evidence to the contrary—all committees on which we serve are, or should be, ethical. Rather, we are members of ethics committees, and I wonder if we would not be better recognised if we used a title such as "committee on ethics."

Secondly, although Alberti rightly attacks many justifiable but easily identified targets, my experience both as a clinical research coordinator for the former North West Thames region and as the chairman of an ethics committee, makes me believe that the most important thing is the attitude and commitment of the members. They need to agree on what they are doing and what ground rules they are prepared to accept. If they are to be truly independent (which I think is a basic requirement) they must be prepared to give up time and intellectual effort to making themselves efficient and accountable. They should not be dependent, as Alberti suggests, on "clear guidance from the top," and I would look askance at the idea of training days, which could inculcate the Department of Health's views rather than independent views. I agree that decisions and their basis should be more widely circulated, but in this we are rightly informed by peer reviewed publication in journals.

Finally, the ethics of human experiment is not something that we should regard as a marginal activity to be undertaken either by an exhausted chairperson last thing at night or with the almost ritual use of undefined guidelines to cover "chair action." Many members of local research ethics committees regard their job with the utmost seriousness. In principle, however, and in the current climate of reasonable inquiry from citizens, ethics committees should be seen to have time for proper deliberation and be supported by an independent budget. Mine is. It loses none of its independence but gains the chance to devote itself properly to ethical issues, including the consideration of generic protocols.<sup>2</sup>

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

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