Implementing the district hospital recommendations for the National Health Service Research Ethics Service in England

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Science and Ethics inextricably intertwined

Dawson and Yentis argue that research ethics committees (RECs) have an obligation to consider the science of applications because this is inextricably entwined with ethics. They lament the fact that the recent English ministerial review of RECs suggests that science should be assessed by others for RECs and not by the committee members themselves. In fact, these views are not as incompatible as they might first appear.

The plain truth of the matter is that in a maximum membership of 18, at least a third of whom must be lay members, the capacity of each of the 186 RECs currently in the UK to review science will be variable in terms of both the expertise of the committee members and the nature of any particular proposal they might be asked to consider. For instance, each REC does not have a resident pharmacologist, epidemiologist, pathologist, surgeon, physician, microbiologist, oncologist, immunologist, psychiatrist, statistician, general practitioner, clinical biochemist, radiologist, obstetrician, paediatrician and social scientist. Some RECs have some of these, one or two may have a good spread, but scientific self-sufficiency is not designed into their constitution.

The remit of a REC nevertheless includes satisfying itself that the study presented has been subjected to adequate scientific review, and in doing this RECs must, in large measure, rely on scientific appraisal carried out by others on their behalf. Where projects supported by major research funders are concerned, this is effectively in-built by the rigorous peer review required. For medicinal trials falling under the European Clinical Trials Directive, the Medicines and Healthcare Products Agency Regulatory Authority has the responsibility of ensuring that risks are reviewed before issuing a licence. But where there are inadequate external checks and balances (and this happens), the REC can find itself in the position of reviewing projects where the study design or scientific hypothesis seems dubious. If there is the slightest risk of harm to participants, an REC must therefore be able to access expert advice before reaching a decision.

The ministerial review suggests employing "scientific officers" within the National Central Office for RECs for this purpose. Clearly, what is needed is independent scientific expertise that can be rapidly commissioned, but this is

unlikely to be vested in one or two people, any more than it would be in the committees.

What is currently proposed is that there should be a national network of independent research ethics advisers (committee veterans, professionals and laymen) who could help committees to work better by removing proposals that they do not need to consider and ensuring that those they do have to review are well presented, with referees' reports if necessary. The advisers would have access to a bank of referees' with a wide spectrum of scientific and statistical expertise that would form an important part of a new National Research Ethics Service (NRES).

So Dawson and Yentis are right in saying that science and ethics are inextricably intertwined, but wrong to suggest that each REC has an obligation to scrutinise the science of each proposal itself, because it is not designed to do so. Within the proposed NRES, however, we hope there would be readily available independent expertise to strengthen and support this essential aspect of research ethics review.

J Med Ethics 2007;**33**:168.
doi: 10.1136/jme.2006.016667

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Received 7 April 2006
Revised 7 April 2006
Accepted 18 April 2006

Competing interests: None declared.