

Clinical & Scientific letters

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Ethics approvals and quagmires

All researchers are familiar with the phenomenon whereby a distant green field appears to present no obstacles, but on closer acquaintance is revealed as a deadly swamp which can be negotiated only with immense expenditure of time and trouble. Recent experience indicates that this may be just as true of research ethics approval as of research itself.

We report here the difficulties we experienced when several research ethics committees requested alterations to our patient information letter.

Our study covered a broad geographical area, and the Public Health Laboratory Service (PHLS) provided some of the study data; the requirements for ethical approval at that time resulted in ten separate submissions of our study documentation to nine research ethics committees.

Initial Multi-centre Research Ethics Committee (MREC) approval was gained without difficulty, but unfortunately the

MREC-approved version was not accepted by the PHLS committee. By the time PHLS approval had been granted, the letter was significantly different from the original version approved by MREC. It was therefore necessary to resubmit this altered version (now acceptable to PHLS), to MREC who in turn requested further changes. Some of these changes were to phrases which had been accepted at the original consideration. Table 1 below lists some examples of the differences of opinion.

Nor was this the end of the story: our subsequent experience with the local research ethics committees was depressingly similar.

None of the above committees raised concerns about the scientific aims of our study, and almost all the amendments were to the patient information sheet. Although the committees' suggestions were generally sound, it was notable that requests for alterations of the same letter from different committees were widely variable, to the point of being mutually exclusive at times.

We feel that the RECs could have recognised that beyond a certain point, adjusting the phrasing of a patient letter is subject to the law of diminishing returns. There will always be differences of opinion about the precise wording to use when discussing an issue with a patient, and the fact that there was little agreement between the RECs illustrates very clearly the subjective nature of these judgements.

Despite the laudable aims of research ethics committees,

The purpose of a Research Ethics Committee in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants¹,

we suspect that the lengthy cycle of reviews and submissions required to achieve a letter acceptable to all committees had little practical benefit for our patients. At times it appeared to us that, in their enthusiasm to produce the best possible letter, the ethics committees were operating well beyond their original mandate as quoted above.

In addition, we found ourselves in an extremely awkward position when different ethics committees made conflicting demands. It was unfortunate that there was no mechanism whereby the various committees could negotiate directly with each other to achieve a unified opinion.

We wonder how many others have been discouraged from pursuing research interests after floundering in this quagmire.

References

- 1 Governance arrangements for NHS Research Ethics Committees July 2001. Department of Health website: www.doh.gov.uk/research/documents/gafrec.pdf

AJ KVALSVIG,
DJ UNSWORTH
Southmead Hospital, Bristol

Screening for thyroid disease in pregnancy: an audit

Recent studies have shown that subclinical hypothyroidism during early pregnancy may affect the neuropsychological development of children¹⁻³. We developed local management guidelines for hypothyroidism during pregnancy. These guidelines were widely circulated in the hospital and community, and recommended thyroid function tests at booking (first hospital

Table 1. Examples of phrases that were acceptable to MREC but not to PHLS.

Section of patient letter	Accepted by MREC	Changes requested by PHLS	Changes requested by MREC
<i>How did we get your name?</i>	'Records of all cases ... are kept centrally, in a database in Manchester.'	Start with an introduction before 'how we got your name' referring to how meningococcal disease is notifiable by law.	Delete 'in a database'
<i>What will I be asked to do if I take part?</i>	'We need a sample of your blood.'	'We would be grateful if you would let us take a sample of your blood.'	
<i>What will I be asked to do if I take part?</i>	'We may need to read through your hospital notes....'	'With your permission, we may need to read through your hospital notes....'	