NHS research ethics committees

Still need more common sense and less bureaucracy

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Competing interests: None declared.
Provenance and peer review: Non-commissioned; externally peer reviewed.

BMJ 2007;335:6
doi:10.1136/bmj.39201.508692.2C

National Health Service research ethics committees exist to ensure that research performed within the NHS complies with recognised ethical standards and to protect the rights, safety, and dignity of all actual or potential participants. In the past decade the operation of research ethics committees has come under, and continues to come under, close scrutiny. Researchers now consider the process of acquiring ethical approval to be so onerous that it is compromising clinical research.[1-3] Medical educators also think that the process is too unwieldy to allow undergraduate students to acquire research experience,[4] an essential learning outcome required by the General Medical Council.[5]

To understand why such dissatisfaction has arisen we need to go back to the early 2000s, when the Central Office for Research Ethics Committees (COREC) was established and the Department of Health issued the *Research Governance Framework for Health and Social Care*.[6] The implementation in 2001 of the European Union Directive 2001/20/EC (the clinical trials directive) forced changes in the system, leading to the introduction of a single application form for multisite applications and a rule that research ethics committees had to respond to applications within 60 days. These changes substantially helped those involved in complex, usually multicentre, studies.

In response to the growing discontent expressed by researchers about the complexity of the research governance process, the Department of Health established an advisory group to review the operation of research ethics committees.[7] Its report confirmed that researchers still perceived the process as too bureaucratic, and its conclusions were sensible and long overdue. These included an immediate recommendation that research ethics committees and research and development departments within trusts should make multiple use of information supplied only once. The review group considered that some research—such as surveys, service evaluation, and research on NHS staff—did not require formal ethical review and proposed the creation of scientific officers who would act in a triage capacity to provide a preliminary assessment of such applications. The response of the Central Office for Research Ethics Committees, *Building on Improvement: Implementing the Recommendation of the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*, was disseminated for consultation last year.[8] The recommendations of the advisory group report[7] have largely been translated into practical and feasible solutions. "Scientific officers" become research ethics advisers, to exist at both a national and local level. Their job will be to provide a rapid review of studies with no untoward ethical implications, to triage applications that require full ethics committee consideration, and to provide educational support to applicants. The central committee acknowledged the need for further improvements in the application form (it is still long, although the latest version has an early filter question to ensure only relevant questions are activated). Was this eventually the spoonful of sugar to make the process of ethical approval more palatable for researchers?

Maybe, but if we look more closely at how the recommendations will be implemented, is there still the potential for sound intentions to be undermined by disproportionate bureaucracy? The research ethics advisers need to be very experienced: the report recommends experience as a chair of an ethics committee. The proposed triage procedure will need piloting, and training requirements will need to be identified. Several levels of filter are suggested from initial review by a coordinator, through to a senior coordinator, then the research ethics adviser, and if necessary, the research ethics committee. Although the report acknowledges that the large volume of undergraduate student applications will not present substantial ethical concerns, it rejects the need for a separate application process or separate system of committees for student projects—recommendations that were suggested in the Doyle report,[9] made in 2004 by a national interprofessional working group. For postgraduate students this seems eminently appropriate, but is this a missed opportunity to streamline undergraduate applications? In the consultation process after release of the recent central committee recommendations,[8] a fast track system for approving low risk studies was wholeheartedly supported by patients, in recognition that this would allow research ethics committees to concentrate their resources more appropriately. In a recent study exploring the impact of research governance on medical students' ability to gain an understanding of research methodology, a fast track application process and the introduction of a specific shortened form were considered the most important strategies to facilitate this aim.[4] Failure to deal with the problem of student research will make it more difficult to ensure coverage of research within the undergraduate curriculum as required by the GMC.[5] Such a lack of academic exposure at undergraduate level will only contribute to the already critical shortage of doctors entering academic medicine.[10 11]

Both medical researchers and teachers support the principles of research governance.[4] The proposed changes to research governance to allow certain research, such as surveys and studies involving NHS staff, to be exempt from research ethics committee review[8] and may rekindle medical teachers' interest in helping undergraduate students gain research experience. *Building on Improvement* provides a longed for opportunity to make research more accessible to all researchers; let us hope it is not too little too late for undergraduate research.