

## Research ethics committees in the UK—the pressure is now on research and development departments

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Picture this. You have a research question of international importance. Against the odds, you have secured non-commercial funding for a well-designed multicentre project that will answer the question. Naturally, you must obtain research ethics committee (REC) approval. You apply to an REC online. After clarifying questions about your application on just one occasion, you get a decision at no charge, within 60 days, and it is valid for the whole of your country.

While this scenario is a fantasy in countries such as the USA,<sup>1</sup> Canada,<sup>2</sup> and Australia,<sup>3</sup> a recent Department of Health (DoH) report celebrates this new era of REC operation in the UK.<sup>4</sup> But to what extent do the procedures in the UK meet this ideal, and have they improved? Do other regulatory hurdles lurk in the shadow cast by the mighty new REC system? In other words, is British researchers' long battle against red tape over?

### FIRST, LOCAL RESEARCH ETHICS COMMITTEES...

Although the DoH recommended the creation of informal RECs as long ago as 1968, it was not until 1991 that it formally delegated responsibility for ethical review of research in the UK National Health Service (NHS) to local research ethics committees (LRECs) based in each health authority.<sup>5</sup> Although LRECs' standards of practice were said to be good,<sup>6</sup> the evidence that their process and consistency were poor was overwhelming.<sup>7–18</sup> The application procedures were heterogeneous, uncoordinated, bureaucratic, expensive and time-consuming, which probably resulted in unethical delays to valuable research.<sup>19</sup> Worst of all, their voluntary membership developed varying levels of autonomy and a diversity of working practices that fostered inconsistent and unpredictable decisions, due—in part—to their rapidly expanding workloads and a paucity of guidelines.<sup>20</sup>

This decentralized system posed particular problems for the growing number of multicentre research projects,

which required approval from many different RECs. Simple solutions were proposed: administrative and technological cures for the bureaucratic disease, and the formation of regional RECs to facilitate multicentre research.<sup>21</sup>

### ... THEN, MULTICENTRE RESEARCH ETHICS COMMITTEES

So it was that in 1997 a standardized system for the review of multicentre research began with the creation of 13 multicentre research ethics committees (MRECs).<sup>22</sup> A multicentre research project (taking place over five or more LREC geographical boundaries) required the opinion of just one MREC about its ethics. Once approved, its decision and details of the project had to be distributed to every LREC in the geographical location of the study, whose executive subcommittee was only allowed to consider—within a proscribed timeframe—the suitability of the local site, researcher(s) and/or facilities.<sup>23</sup> Furthermore, in recognition of the minimal risk to patients in multicentre observational epidemiology and health services research, MREC standard operating procedures were modified to tailor the extent and duration of LREC review to the degree of patient contact in these research designs.

This system was designed both to minimize the burden of ethical review for LRECs and to reduce the unsatisfactory delays that they had caused for researchers in the past. MRECs probably achieved the first aim, but LRECs seemed to have difficulty with their altered role and initially—at least—persisted in their time-consuming, costly, bureaucratic and variable ways.<sup>24–31</sup> Both the successes and the shortcomings of the MREC system were acknowledged.<sup>32,33</sup> Suggestions for improvement were made<sup>25,34</sup> and a national survey of researchers, research sponsors, and LRECs involved in the first year of the MREC system was conducted. Once again, a national body was called for to further improve training, guidance, support, payment, and communication with REC members.<sup>21,35</sup>

### ... NOW, THE CENTRAL OFFICE FOR RESEARCH ETHICS COMMITTEES (COREC)

The DoH established COREC in 2000 to implement, develop, maintain, standardize and oversee MREC/LREC operating procedures throughout the UK. The emphasis is

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on the *process* of ethical review. Although COREC works on behalf of the DoH in England, its mission statement indicates that it works closely with colleagues in Scotland, Wales and Northern Ireland. While COREC distributes rather than centralizes decision-making, it is the organizational hub of the REC process. COREC liaises with DoH over the regulations implementing the European Clinical Trials Directive (2001/20/EC). The directive's aspirations for good clinical practice and REC operation (such as the 60-day limit on reviewing applications) have been applied in the UK to *all* types of NHS research, not just clinical trials.

But to what extent has this reorganization of REC operation facilitated ethical research? There is no doubt that research will benefit because ethical review of any project, however large, will occur once and will be communicated within 60 days of application (see [www.corec.org.uk](http://www.corec.org.uk) for exact details).<sup>36</sup> COREC has implemented laudable mechanisms to improve RECs' speed of review, consistency, standards, training and appeals procedures, but evidence of their effect has not been provided (yet). Researchers' pleas for user-friendly online forms have been heeded. But some researchers have still found COREC's 57-page form too long, complicated, and time-consuming for their liking,<sup>37,38</sup> and asked for the additional 11-page NHS research and development (R&D) data collection form to be disentangled from the process of ethical review.<sup>38</sup> Happily, researchers can apply in parallel for both REC and R&D approval of their project. But—and this is a big but—for multicentre projects with REC approval, it seems absurdly duplicative to require *both* a local 'site-specific assessment' (submitted by a named local investigator) as well as R&D management approval at every site involved. Ironically, while researchers continue to dissent, others argue that the wording of the UK regulations implementing the 'industry-led' European clinical trials directive has led to 'a subtle change in emphasis from the protection of research participants to the facilitation of research'.<sup>39</sup>

#### **THE REPORT OF THE AD HOC ADVISORY GROUP ON THE OPERATION OF NHS RESEARCH ETHICS COMMITTEES**

The recent, commendable DoH report comprises both a succinct salute to the improved operation of RECs since COREC, as well as clear recommendations for finessing the REC and R&D systems.<sup>4</sup> Surprisingly, there was no REC representation on the Advisory Group, although the committee did visit COREC. One would expect those most concerned about REC operation to have made the largest number of submissions during the report's consultation period: of the 75 written and oral responses, the majority were from the research community, 18 (24%)

were affiliated to RECs, and 11 (17%) were affiliated to R&D departments. Sadly, for a system that should be consistent across the UK and indeed further afield, one of the consequences of devolution was that the Advisory Group's remit was only to review COREC and English and Scottish RECs (although there were observers on the Group from Scotland, Wales and Northern Ireland).

The DoH report made several important recommendations of interest to researchers.

First, surveys, health service evaluation, and studies of NHS staff should be deemed exempt from ethical review. Without specifying which particular study designs should be exempt, there is a risk that requiring REC review of some types of observational research but not audit will perpetuate an existing double standard.<sup>40</sup> Ethical concerns about confidentiality and data protection are equally applicable to observational research and audit.<sup>41</sup>

Secondly, the report emphasizes that an REC's main task is ethical rather than scientific review. Therefore, the focus of REC members' training should be on ethical issues, their training should provide quality assurance thereby making RECs' decisions more consistent;<sup>42</sup> these will be monitored by a new system of peer review between RECs. RECs should, however, accept prior *scientific* peer review of a project (for example, by a grant-giving body) in all but exceptional cases (no examples were given). For a project that has not undergone scientific review or whose investigator is unsure of the need for REC review, the scrutiny of a 'scientific officer' within COREC should be required; the skills and qualifications required of these officers were not specified.

Thirdly, the report perceives over-capacity in the REC system. It recommends rationalizing the number of RECs and their membership so that fewer RECs meet more frequently and run a lower risk of becoming inoperative. The report emphasizes how REC membership should be independent of researchers, hosts and sponsors. The Advisory Group found voluntary membership of RECs to be unsustainable because, with a new streamlined design (Annex 3 of their report), REC members' time commitment should be formally recognized, members should be paid, and voluntary membership is likely to under-represent certain segments of society.

Lastly, researchers' fundamental remaining concern is with the last hurdle they have to cross once they have obtained funding and REC approval for their project: obtaining permission to conduct the research from host institutions' R&D departments. The DoH report agrees that the process of both site-specific assessment (for multicentre studies) as well as approval by each host organization's R&D department is '... cumbersome, and it would appear to add little value...'.<sup>43</sup>

## THE REMAINING CHALLENGES

International research would be facilitated by consistent international standards of ethical review and REC operating procedures.<sup>43,44</sup> The DoH report recognizes that the UK is in advance of the rest of the European Community in meeting the requirements of the European Clinical Trials Directive. If the report's recommendations for a 'step change' in REC operation and the quality of ethical review are heeded by the National Patient Safety Agency (soon to consult on how to implement the recommendations), the UK REC system could be a prototype for RECs across the world.

There is an urgent need to heed the 'most pressing' of all the DoH report's recommendations, which is to amalgamate researchers' applications for site-specific assessments of multicentre studies with applications for R&D approval. The DoH report states that '...responsibility for site-specific assessment should be transferred to NHS hosts...' and imaginative ways of harmonizing ethical review and research governance across the UK are needed. These should expand on innovations such as the new online R&D application form ([www.rdform.org.uk](http://www.rdform.org.uk)), which is now segregated from COREC applications but is populated by data from the online COREC form (and vice versa). Anecdotal reports indicate that approximately half of R&D departments accept this new form—the other half require researchers to use a form particular to the R&D department in question. These R&D departments are thwarting laudable efforts to standardize, streamline, and speed up the process of gaining regulatory approval, provoking comparisons with the LRECs of yesteryear. Even when REC and R&D approval has been obtained, another local governance requirement that further slows down multicentre studies (especially clinical trials) is the need for a chief investigator or member of their team to have an honorary contract at every local site.

The DoH has accepted the report's recommendations for England, but they must be applied consistently in England, Wales, Northern Ireland, and Scotland. Harmonization across the UK is vital.

The DoH report found researchers' understanding of ethical issues to be 'very variable', and there is no doubt that researchers must ensure they are up to date with current legislation, professional guidance, and REC process ([www.corec.org.uk](http://www.corec.org.uk)). Furthermore, researchers must continue to evaluate regulatory systems: proof is required that COREC has achieved its timelines, and R&D departments must be held to account for any excessive delays they contribute to ethical research. Many pressures have driven change in the regulation of clinical research, not least researchers' independent evaluations of the system.

*Competing interests* The author runs a multicentre research project, and experienced delays in obtaining ethical approval for it under the old MREC/LREC system.<sup>25</sup>

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