Commentary: Better support for investigators is essential

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Wald's description of his encounter with the new research ethics committee forms provides a graphic illustration of the frustration and bemusement of most researchers when faced with the hurdles that must now be surmounted to conduct a clinical trial.[1] As well as the expansion in the volume of paperwork, the need to understand and comply with the regulatory requirements for good clinical practice, reporting of adverse events, and the supply and labelling of trial drugs make it almost impossible for a clinician to undertake a clinical trial without support. This is not necessarily a bad thing if it leads to better quality studies that are safer for patients, but training and support must be funded and provided if clinical trials in the public interest are to continue.

Wald was unfortunate to be initiating a clinical trial in the transitional period before all the systems to implement the new clinical trials regulations were in place.[2] He therefore had to deal with old and new elements and did not benefit from the harmonised competent authority and ethics committee application. Some of the questions he found particularly irritating, because of their apparent irrelevance to ethics, are part of that common data set. Neither the Central Office for Research Ethics Committees nor the Medicines and Healthcare Products Regulatory Agency should be blamed for the content of the forms, most of which is specified in European Commission guidance[3] or the regulations themselves. The exception was Part D of the COREC application (for NHS trust approval), which has since been dropped. However, trust approval is still required and currently each trust has its own application process. For researchers who undertake multisite studies, a single form that does not duplicate information supplied elsewhere would be a boon.

Explanation and support

Although we will, in time, get used to the new processes, much time wasting and fury could be avoided by clear explanation. Some fields are not compulsory for a valid application (for example, certain of the reference numbers Wald mentions), and this needs to be made obvious. Pharmaceutical companies have regulatory staff to navigate through the new systems, but investigators conducting non-commercial research are at a disadvantage. The Medical Research Council and Department of Health joint project is doing what it can,[4] but practical assistance from research and development staff in trusts and universities to help researchers through the regulatory maze is vital. Anecdote suggests that although many departments are supportive and facilitate clinical research, some seem to see their role as protecting their trust from it.

The Department of Health's research for patient benefit working party has recognised the need to streamline regulatory requirements to avoid "duplication and administrative delays which contribute nothing to the quality of the research or the protection of patients."[5] This would be very welcome, but although paperwork may irritate, a far greater threat to clinical research would be the adoption of trial management and pharmacovigilance systems appropriate to trials of new products in all clinical trials, regardless of the phase of development of the intervention or risks to patients or the public.

One of the aims of the UK Clinical Research Collaboration will be to clarify the interpretation of all regulations that affect clinical research and to develop good practice on compliance. A shared understanding by investigators, research and development staff, funders, and regulatory authorities of appropriate research practices that are proportionate to the risks of different types of investigation is essential if the vision of the NHS as a the world leader in clinical research is to be realised.

Competing interests: SM is a member of the working group for the MRC/DH joint project to codify good practice in publicly funded UK clinical trials with medicines. She has received an honorarium from the NHS Research and Development Forum for speaking at a conference.

1 Wald DS. Bureaucracy of ethics applications. *BMJ* 2004;329:282-4.
2 *The medicines for human use (clinical trials) regulations 2004*. Statutory Instrument 2004 No 1031. www.legislation.hmso.gov.uk/si/si2004/20041031.htm (accessed 13 July 2004).
3 European Commission. Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on the medicinal products for human use. http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2004/april/cp%20and%20guidance%20%20EC%20%20%20rev%2021%20April%2004.pdf (Accessed April 2004).
4 Medical Research Council, Department of Health. Joint project on clinical trials. www.ncchta.org/eudirective/index.asp (accessed 13 July 2004).
5 Department of Health. *Research for patient benefit working party: final report*. http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/PrioritiesForResearch/fs/en?CONTENT_ID=4082668&chk=xUzx/B (accessed May 2004).

Endpiece

Improvement of the practice of medicine

That such practitioners of Physick and Surgery as have the good of mankind and advancement of their own profession earnestly at hand, would note down such practical hints suggested by their own observation, reading, or reflexion, as are new, and appear to them rational, and as they have not the boldness to put into execution, till they be further satisfied about them; and after mature deliberation publish them from time to time.

Flemyng M [physician, Hull]. *A proposal for the improvement of the practice of medicine*. 2nd ed. Hull: G Ferraby,1748:10

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