

The Write Stuff



Patient information leaflets: The ethics committee view

by Adam Jacobs

I have been a member of a research ethics committee for about two years now, and while this does not make me an expert on medical ethics, it has given me a pretty good idea of what makes the difference between a good ethics application that will sail through the committee at the first attempt, and a poor application that will be sent back to the investigators for extensive changes, or worse, rejected completely.

There are of course many factors that distinguish the good from the bad, but there is no doubt whatever in my mind what the single most important factor is. Contrary to popular belief, it is not whether the research is ethical. Most clinical investigators understand what is ethical and what isn't, and are usually at least as keen as the ethics committee to avoid exposing their patients to unjustifiably risky trial procedures.

No, the single most common reason why we send applications back to investigators is because they need to re-write the patient information leaflet (PIL). Everything Wendy says in her article elsewhere in this issue is true. Many PILs are extremely badly written, and include far too much medical jargon. Not only that, but often the risks of a study are not explained at all. All research has risks, and only a fool would pretend that he or she is running a risk-free trial. The important thing is that the risks be proportionate to the expected benefits, and the even more important thing is that the risks be explained honestly to the patient. Patients cannot give informed consent if they have not been informed about the possible risks. This doesn't mean you have to scare patients with a long list of rare side effects, but it does mean you have to be honest. Guidance for writing PILs is available from the COREC website (www.corec.org.uk).

One thing that has surprised me, is that PILs in industry-sponsored studies appear to be far worse than those in investigator-led studies. Before I joined the ethics committee, I had assumed that pharmaceutical companies would be able to afford to pay medical writers to write their PILs and that they would therefore be wonderful, but this doesn't seem to be true. Maybe the companies are showing off just how much money they have to spend on the PILs by getting lawyers to write them, who are of course much more expensive than medical writers, but, as Wendy so perceptively points out, write lousy PILs. Or maybe the PILs are written by medical writers who spend most of their time writing protocols, clinical study reports, or similar, and have not developed the necessary skills in writing for patients.

So, let me end with some practical advice. First, keep your legal department well away from any PILs. Second, if it is your job to write the PILs, ask yourself whether your skills in writing for patients could use some improvement, and find yourself a suitable training course if you need it.

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