# THIS WEEK



# Who watches the watchmen?

*Some commercial firms that oversee the ethics and scrutiny of clinical trials have been found wanting. Human volunteers in research deserve better.*

Late last month, the US government proposed an overhaul of regulations covering research on human volunteers. It includes a move to allow single institutional review boards (IRBs) to oversee US multi-site clinical trials. Such boards underpin the ethics and safety of a trial, reviewing all research protocols and consent forms before it is launched. Currently, dozens or scores of IRBs — one for each trial site — can separately review and approve a clinical trial and its necessary paperwork, leading to massive duplication of effort and delays.

Commercial IRBs have multiplied in recent decades, reviewing and passing proposals for profit. Their creation was spurred partly by an explosion of industry-sponsored clinical trials, but they are increasingly passed business from academic centres, to relieve overstretched in-house ethics committees. There are now dozens of these companies and they will see potential business in the proposed shift to single-IRB oversight of multi-site trials. Commercial boards advertise themselves as faster at approvals than their academic counterparts. This promised speed and convenience could see organizers of multi-site trials turn to a commercial board rather than, for instance, the IRB at the principal investigator's institution.

Why does this matter? Commercial IRBs, like their academic counterparts, are as expert and committed as the people who sit on them. But the for-profit groups have an unsettling incentive to approve trials. If they are too tough, applicants may take their next proposal and their fees elsewhere. (In the proposed changes to the regulations, the government acknowledges that such 'IRB shopping' is a risk and asks for public comment on how it could be prevented.)

There is evidence that not all the commercial IRBs are as thorough as researchers, and their human subjects, would like. In the same week that the government published the proposed rule changes, the Essex Institutional Review Board in Lebanon, New Jersey, was issued with a warning letter from the Food and Drug Administration (FDA).

A common way to test IRBs is to submit fictitious applications containing problems that should raise alarm bells. According to the FDA, when Essex received one of these sting applications, reportedly from journalists, it approved the trial without putting appropriate warnings — including of a serious heart risk and of a common risk of graft rejection — in the informed consent, or even discussing the heart risk, according to minutes of its meeting. Nor did it spot that both the trial sponsor and the lead investigator were invented. The company, which has done work for the National Institutes of Health's AIDS Clinical Trials Group, among others, received similar FDA warnings more than a decade ago.

The FDA has also censured other IRBs. Two years ago, the Coast IRB in Colorado Springs, Colorado, disbanded after the Government Accountability Office (GAO) submitted a phony clinical-trial application that the IRB approved. Some commercial IRBs carry out first-rate, conscientious work. Members of two other for-profit IRBs dismissed the phony GAO application as "awful" and "junk". One reviewer called it the "riskiest thing I've ever seen on this board".

And IRBs at academic institutions have their own ulterior motives to approve trials — among them institutional profile and prestige. And they, too, make mistakes. But the dollar remains the most powerful incentive to cut corners. The volunteers on whom clinical trials depend deserve the highest possible protection. Before implementing change that could see private companies overseeing an increased number of multi-site trials, the government should ensure that scrutiny of these IRBs is expanded to match. ■

# NEON and on

*The launch of an ecological monitoring network is good news at a difficult time.*

After years of wrangling, scientists in the United States are set to wire up the natural landscape to a state-of-the-art environmental monitoring system. The National Ecological Observatory Network (NEON) will take Mother Nature's pulse and track her vital signs during both bad times and good.

In the coming years, NEON will pour massive quantities of biological and physical data from plains, forests and lakes into computer spreadsheets to look for trends (see page 135). It is a bold initiative whose time has clearly come, but it will take more than the flip of the on switch to make NEON glow.

The project's elegance is appealing, but behind its beguiling simplicity lurk a number of potential pitfalls. Some are technical: it would be foolhardy to underestimate the challenge of collecting hundreds of data streams in a uniform manner across dozens of sites and over the course of decades. Others are social and institutional: ecologists have long gathered data independently; NEON represents a dramatic shift towards the kind of collective data-driven system that physicists and astronomers have been pursuing for decades. How will it be received on the ground? And what's more, how many scientists will be ready to use the data when they come in?

The plan for NEON is to develop a healthy community of scientists who can make good use of the data. There are no guarantees, but the project is a risk worth taking. Human pressure on the biosphere will only escalate, and the sooner scientists get a firm handle on what that means the better. NEON could be a powerful tool for those investigations. And, in an exceedingly difficult fiscal environment, the new ecological network represents a refreshingly forward-looking initiative. Ecologists (and headline writers) everywhere should welcome it. ■



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