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## Ethics takes front seat in research

Scientists are hoping ethics approval processes might soon be simplified. **Sean Parnell** reports

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ASK some people what they know about ethics and you might be told it is a county in England, much like denial is a river in Africa.

But if Health Minister Tony Abbott has his way, ethics in medical research will be at the forefront of people's minds and scientists will have to meet a community standard, not just an ethical standard, when embarking on new projects.

Community awareness of the need for ethical practices in research has grown significantly in recent years, largely due to developments in genetic modification, and publicity given to so-called "Frankenstein" foods and cloned sheep.

In human research, however, ethics can be a vexed issue given the competing interests. Scientists are expected to do all they can to advance and protect the species, while not necessarily taking away from what Mother Nature or God intended.

Ethical process - the standards, guidelines, committees and obligations - has, for the most part, been working well in Australia, but some scientists have begun to question whether it might also be restricting bold new research.

Attempts are now being made to loosen those restrictions, to keep Australia at the forefront of medical research, so the news that Abbott wants to initiate a broader debate on ethics in human research was met with some anxiety this week.

Associate Professor Maria Kavallaris, president of the Australian Society for Medical Research, warns allowing more external input into ethical process might be counterproductive. "You would risk people's personal and emotional views interfering with what is already a fairly robust process," Kavallaris says.

While Abbott, a Christian, has his own convictions, and has made them known during debates on stem cell research and abortion policy, he believes others might hold views which would be at odds with those of blinkered scientists.

He recently obtained a report, commissioned by the Australian Health Ethics Committee (AHEC) on his behalf, on key ethical dilemmas in human research. While the minister has yet to outline what he will do with it - the report only arrived in late December and Abbott is currently on leave - his office points to a speech he gave in 2005 to the Ethics in Human Research Conference where he called for the community to have a greater input into ethical process.

"In many ways, medical research has never been more ethically conscious," Abbott said at the time, noting that the AHEC advises the National Health and Medical Research Council and all major institutions have human research ethics committees.

"Even so, an abundance of ethical process does not guarantee ethical outcomes unless, of course, one assumes that ethics committees can't be wrong. This would be difficult given that ethics committees dominated by the intellectual disciples of Professor Peter Singer, on the one hand, or observant Christians, on the other, might reach quite radically different conclusions."

The main standard for human research, the National Statement on Ethical Conduct in

Research Involving Humans, is under review. The new version will be released soon and contribute to any debate initiated by Abbott.

The statement, as it stands, requires all research involving humans to be approved by a human research ethics committee. The NHMRC has 226 registered HRECs, more than one-third of them in the public sector.

Kavallaris says HRECs play an important role, but the increasing popularity of, and need for, multi-centre research has created problems. If every site has its own HREC, then most, if not all, will want to review and monitor the research, she says. This creates delays in approval, and adds to administrative and legal hassles, particularly if the HRECs have differing requirements or expectations of the research team.

"Logistically, they're a nightmare to manage," she says of multi-centre research, pointing to a need for ethical process to evolve.

The NHMRC is acting on those concerns, and acknowledges that, even though the statement encourages "prompt and efficient" consideration of multi-centre research, the current situation is vastly different.

"This situation creates difficulties and inefficiencies for HRECs, researchers, industry and government," the NHMRC states in one of its planning documents.

"It creates a significant impediment to the timely recruitment of participants, involves considerable inefficiencies and duplication of resources, is costly to administer and jeopardises Australia's international competitiveness in attracting and participating in multi-centre research." The NSW Health Department is currently examining feedback on its proposed model of a single ethical and scientific process for multi-site research.

But the NHMRC believes the NSW model, like those being developed in other states, only addresses the situation within their jurisdiction and Australia must follow the lead of the United Kingdom, Europe and New Zealand in developing a national model. The Australian Health Ministers' Advisory Council last year established an inter-jurisdictional working group to look at such a model. A consultants' report was prepared for the October AHMAC meeting, where councillors agreed on the need for a "nationally-harmonised system of scientific and ethics review of multi-centre health and medical research". A co-ordinating body will be established within the NHMRC to implement the system, based on mutual recognition and a separation of research ethics from research governance.

Abbott is likely to take a particular interest in the new statement, and the new system. In 2005, he made clear his belief Australia should avoid having "scientists judging scientists". "If war is too important to be left to generals, scientific research is too important to be left entirely to scientists," he warned.

"Ethical scrutiny is important at every stage because research can sometimes develop almost unstoppable momentum as scientists race each other to a suddenly achievable goal."

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