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Abandoning clinical trial safeguards won't boost local industry

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Abstract

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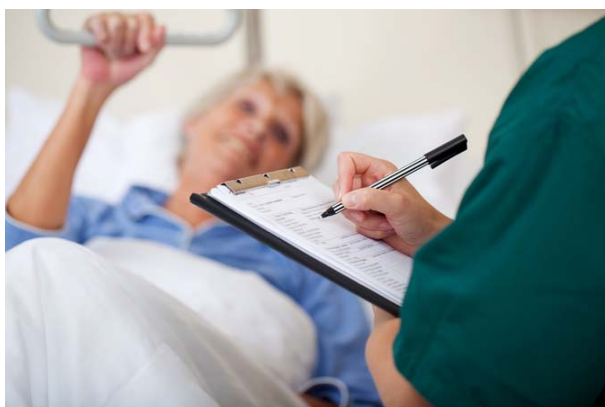
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Ethics committees are the very bodies that ensure the safety
of clinical trials. Image from shutterstock.com

CLINICAL TRIALS – *Human clinical trials are an important last hurdle in the development of new drugs and therapies. Today, The Conversation takes a closer look at this vital scientific endeavour with three articles that look at different aspects of the process.*

Testing new drugs in clinical trials is a billion-dollar industry in Australia, with most of the money coming from international pharmaceutical companies. But as investment grows in India, China, and other emerging competitors, some people argue we need to make Australia more attractive to such investment. One of their solutions is to water down the ethics approval process.

Responding to these concerns, the Coalition's election policy on medical research promises to "move swiftly" with reforms to the ways in which clinical trials are conducted, by developing:

a nationally consistent approach to ethical standards to reduce complexity, speed up the process and where possible, rationalise the number of ethics committees to reduce the large number that currently exist.

Before major changes are introduced, however, it is important to remember that ethics committees are the very bodies that ensure the safety of clinical trials and maintain public confidence.

Developed in response to concerns about the untrammelled power of medical institutions in the 1970s, as well as reports of egregious excesses by researchers in the United States and elsewhere, the ethics committee system has become highly refined in both its processes and in the substance of the issues it addresses.

In Australia, it is also remarkably devolved and democratic, drawing in thousands of men and women from different walks of life across the country to engage in conversation, for no personal gain, about ethical issues in health care and research.

Established by hospitals and universities, the panels review research proposals and ensure they're ethically acceptable. Their deliberations cover potential risks and benefits to both individuals and the wider society and issues relating to consent, confidentiality, privacy, conflicts of interest and protection of vulnerable participants.

Criticisms of the ethics committee system

Critics of the system complain about the time and expense involved in the ethics review process and the added burdens it allegedly imposes on researchers and drug companies. They argue that it creates delays, adds to costs and acts as a disincentive to investment.

They draw particular attention to alleged difficulties associated with obtaining approval for multi-centre trials – that is, trials conducted at several sites simultaneously – because of unnecessary duplication and frequent inconsistent outcomes.

It is generally concluded that all these problems would be solved by replacing the present decentralised system with a centralised committee system that has authority to make decisions for the entire country.

None of these criticisms is well founded and it is possible that the proposed solution may be both counterproductive and inappropriate – particularly where research must take account of local concerns, such as is the case with multi-site Indigenous health research.

In fact, the evidence shows ethics committees in Australia operate with remarkable efficiency, with the time between submission and approval of a project often occurring in no more than a few weeks.

And the ethics review process is generally concluded well in advance of other essential organisational processes, such as legal approval, establishment of insurance policies, and other governance decisions, including those concerning institutional commitments, staffing and logistic issues.

Concerns over multi-centre trials may have once been well founded, but this is long past. A single national application form has been in place for more than five years and there are well-established coordinating mechanisms at both the state and national levels to allow unified ethics review processes.

In comparison with world standards, the system is economical and the times to approval are comparable with best practice elsewhere in the world.



Ethics committees draw in thousands of men and women from different walks of life. Flickr/TEDxKyoto

Global trends

Over the past 15 years, the number of new clinical trials approved in Australia has been relatively static – not in decline as is sometimes claimed. But the reason for this has nothing to do with ethics committees or the ethics review process.

Rather, approval of new trials reflects primarily the prevailing economic conditions – with a predictable drop having occurred worldwide during the global financial crisis of 2008 to 2009 - and the changing attractiveness of Australia in response to fluctuations in the value of the dollar.

Most importantly, the development of a thriving clinical research capacity in India, China, South-East Asia, Latin America, Brazil, Russia and Eastern Europe – many of which are grappling with very similar problems - has meant that an increasing volume of work is being undertaken in these countries. Indeed, the Australian experience has been mirrored almost exactly by that of the United States and the European Union.

Retaining trust in clinical trials

So, would dismantling or watering down the ethics review system attract more research dollars to Australia? This is highly unlikely. Not only would it have no impact on the factors mentioned above but it's likely to undermine the high levels of public trust and confidence on which recruitment of patients for clinical studies critically depends.

The sense that essential protections are being weakened in order to increase investment income may well cause irreparable damage to the status and prestige of clinical research in this country.

This is not to say that the present system is perfect. Attempts to improve the efficiency of data collection – such as electronic systems for collecting, processing and storing data – can help to keep prices down as well as assist with monitoring and improving safety.

Recent initiatives to make it easier for members of the community to participate in clinical research, such as ClinicalTrialsConnect, are welcome and will no doubt also improve the efficiency of recruitment. But changes such as this will not reverse the large scale global trends to which we are all subject.

We need to continue the debate about how to maximise research investment. But we can't lose sight of the great contribution the ethics committee process, and the men and women who constitute it, makes to ensuring the safety of drug development and the continuing high status of the research enterprise in Australia.

Attempts to undermine or destroy the ethics committee system will ultimately be harmful to all of us.

Click the links below for other articles in the package:

Looking back on the chequered past of drug trials

Care and consent: the fraught ethics of international clinical trials

And from our archives:

Clinical trials are useful – here's how we can ensure they stay so

What Australia should do to ensure research integrity

Register all trials, report all results – it's long overdue

Remove industry bias from clinical trials before it's too late