Improving the governance of health research

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ABSTRACT

- Australia has so far been spared serious mishaps in health research, but rising pressures on researchers, deemed to have contributed to two deaths of research participants in the United States, clearly also exist in Australia.
- Health research investment in our institutions is large and represents an often overlooked area of risk by boards of management.
- Research governance (the framework through which institutions are ultimately accountable for the scientific quality, ethical acceptability and safety of research conducted in the institutions) has not received sufficient attention.
- An adequate governance framework requires institutions to have policies and procedures in place to meet national ethical, legal and research practice standards.
- We suggest that many institutions presently do not have such frameworks in place and inappropriately rely too heavily on human research ethics committees.
- To ensure ongoing adequate protection of research participants, we recommend some simple improvements for research governance and suggest ways by which institutions can demonstrate adherence to agreed national standards.

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Australia has so far been spared mishaps in health research of the kind that caused the untimely deaths of two young people and led to major changes in the regulation of human research in the United States.[1-3] However, pressures on researchers, including the pressure to publish and commercialise research — deemed to have contributed to those mishaps — also exist in Australia.[4] It would be foolish to await similar events, likely to undermine public trust in research, before examining our existing system of protection for research participants.

Most health and medical research involving human participants takes place in hospitals and affiliated university faculties and research institutes.[5] Indeed, research has become a major enterprise in many institutions. For example, in 2003, the Alfred Hospital campus of Bayside Health in Melbourne had over 200 research projects under way, representing funding of over $25 million.[6]

Some medical research involves significant risk of harm to participants, and institutions depend on human research ethics committees (HRECs) to assess such risks. After ethical approval, there is only limited monitoring of the research and virtually no evaluation of the systems for maintaining standards of research practice. Safe research practice relies heavily on the integrity and self-regulatory processes of the health professionals undertaking the research.

While most health care institutions have effective and documented systems of clinical and academic governance, risk management and human resource management, responsibility for research management ("governance") seems to rest, by default, with HRECs. Many HRECs are under-resourced and overworked, and some lack written mandates and reporting lines to the board that established them. The core membership of HRECs is designed for the task of ethical review rather than research management.

We suggest that boards of management need to examine how effectively research is currently governed. We identify organisational reforms that may help to more clearly allocate responsibility and coordinate existing processes of governance.

What is research governance?

Research governance is a framework through which institutions are accountable for the scientific quality, ethical acceptability and safety of the research they sponsor or permit. In a key document prepared for the UK National Health Service in 2001,[7] research governance was described as a system that sets standards of research practice, provides mechanisms to deliver those standards, provides for monitoring and assessment of research practice and applies to all professional groups who are involved in health research and those who deliver patient care. In the United States, the term "human research protection program" implies a whole-of-institution approach. The terms "research management" or "research administration" could equally be used.

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The current basis of research governance

The system of overseeing health and medical research in Australia is based primarily on a series of National Health and Medical Research Council (NHMRC) guidelines. These guidelines derive their authority from the *NHMRC Act 1992*, which gives the Council the power to refuse to fund or to withdraw funds from research that does not comply with the guidelines. The key documents are the NHMRC *National statement on ethical conduct in research involving humans*[8] (the "National Statement") and the NMHRC *Statement and guidelines on research practice*,[9] issued jointly with the Australian Vice Chancellors Committee (the "Joint Statement"). Release of NHMRC research grants is tied to the prior approval by an HREC established by the researcher's institution and functioning in compliance with the National Statement. The National Statement places an obligation on the institution to provide the HREC with terms of reference, clear reporting relationships, a complaints process and the support necessary to fulfil its role.

The National Statement and the Joint Statement are reinforced in a number of ways. When an institution agrees to accept research

1 Roles and responsibilities of stakeholders*

Role	Responsibility
Sponsor	Takes primary responsibility for research design and the adequacy of the staff and other resources needed
Funder	Financially supports the research
Host/ institution	Responsible for the care of patients who participate and for the facilities used
Principal investigator	Takes direct responsibility for the design and conduct of the research and reporting of findings
Employer	Employs and thus is responsible for the principal investigator and associated financial oversight
Researcher	Conducts the research and reports to the principal investigator
Participants	Have no responsibilities in governance, but are key stakeholders in the process

*Modified from George et al.[18]

funding from the NHMRC, it signs a "deed of agreement" with the NHMRC that, among other things, binds it to follow NHMRC guidelines. For clinical trials of unregistered therapeutic goods (pharmaceuticals and devices), the *Therapeutic Goods Act 1989* (Cwlth) makes it illegal for a trial to commence unless the trial protocol has been approved by an HREC registered with the NHMRC and the trial has been notified to the Therapeutic Goods Administration.[10]

In addition to these key NHMRC statements, health research involving humans is governed by laws (national and/or state), other guidelines and codes of conduct relating to such matters as privacy, confidentiality, consent, biosafety, professional standards and radiation safety. Institutions (and not their HRECs) are responsible for ensuring that research participants are adequately indemnified, that appropriate financial management arrangements are in place to support the research, and that legal requirements are met.

Limitations of the current system

To date, the Australian regulatory model for overseeing health care research, built around the HREC system, has served the community well. Its success reflects the integrity of researchers and the dedication of HREC members. The strength of the HREC system is based heavily on the voluntary service of over 2000 people from various walks of life, serving on over 200 HRECs, of which about 60% are located in health care institutions.[11] Other strengths of the system include locating the responsibility for ethical review close to where the research is conducted, the fact that membership of HRECs is drawn from both the community and the institution, and the fact that the system is not rigidly based on law (as is the case in the United States) but rather on ethical guidelines, and can thus be flexibly adapted to meet emerging needs.

Nevertheless, weaknesses have been identified. The institutionally based HREC system was designed for an earlier era when research was primarily conducted in single institutions and did not involve large multicentre studies.[12,13] HRECs are held to be overloaded, under-resourced, insufficiently skilled,[14,15] and lacking in accountability and transparency.[15] Their capacity to monitor research is minimal. Moreover, most HRECs provide minimal orientation or training for new members.

In addition, many institutions have not paid sufficient attention to separating research governance issues from the task of ethical review, and have come to rely too heavily on HRECs to do tasks for which the HRECs are not well equipped.

Required standards for effective research governance

Standards that underpin effective research governance exist in the domains of ethics and law, science, information protection, health and safety, intellectual property and commercialisation, financial management, and public relations. In the first of these domains, the core standards are laid down in the NHMRC National Statement,[8] with additional guidelines covering ethical principles for research involving Aboriginal and Torres Strait Islander peoples.[16] For the conduct of clinical trials, the *Therapeutic Goods Act* sets out the laws that must be followed in relation to therapeutic goods research.

Scientific standards for good research practice are found in NHMRC guidelines, particularly the Joint Statement.[9] These include the adequacy of the training and experience of those who will conduct the research, prior thorough study of the published literature, acceptance of peer review, long-term preservation of original data, and the need to publish and to share information with participants.

Standards also exist for the protection of the health and safety of participants and staff involved in research. Institutions must be cognisant of the need to ensure probity in handling funds awarded for research. There must be clearly documented policies on intellectual property rights that must be made known to staff. Adequate insurance indemnity must be in place for all research projects, with all staff personally indemnified for their professional roles.

Although not specifically mentioned in any existing national guidelines, institutions should establish guidelines for contact with the media over research.

Stakeholders in research governance: roles, responsibilities and accountabilities

UK standards for "research governance"[7] and US standards for "human research protection programs"[1,17] show that there is close agreement as to who are the stakeholders (Box 1). In Australia, research participants are also seen as stakeholders.[19]

The institution has a responsibility to see that staff members are appropriately qualified for their roles and, in particular, that principal investigators have sufficient knowledge and experience to fulfil their role.

Researchers, both senior and junior, have a responsibility to understand and comply with national guidelines (eg, the Joint Statement and National Statement), and institutions must address their education and training needs (through induction of new research staff, formal and continuing education in the science and ethics of research, and prompt sharing of relevant new information).

The term "sponsor" is restricted to the body or institution that takes ultimate responsibility for the study design, its conduct, reporting of adverse events, insurance, intellectual property matters, notification of clinical trials and final reporting of results. Sponsors may also be the funders of research (eg, the pharmaceutical industry). There will be times when internal funds are used

2 Components of research governance at the Alfred Hospital, Melbourne

Initial assessment of research proposals

- Are the review committees appropriately constituted, with the necessary expertise?
- Are their assessments conducted in a diligent and timely fashion?
- Are their assessments consistent and in keeping with written policies?
- Are conflicts of interest within the committee addressed adequately?
- Are communication procedures and appeal procedures adequate?
- Is there adequate recognition of "high risk" projects?

Legal and professional issues

- Is there compliance with relevant laws (state and federal) and codes of conduct relating to such matters as privacy, confidentiality, consent, biosafety, professional standards and radiation safety?
- Is the approach to privacy protection adequate?

Insurance issues

- Are insurance arrangements adequate?
- Has the extent and any limitations of insurance cover been adequately communicated to participants?

Financial accountability

- Are financial arrangements fully transparent and appropriate?
- Will there be uncompensated costs to the institution?

Credentialling

- Are those responsible for the project adequately qualified to assume responsibility?
- Do they have adequate time and resources to manage the project diligently?
- Are others involved (eg, research assistants) familiar with ethical and good-research-practice requirements?

Intellectual property

- Is the intellectual property belonging to the institution protected?
- Is it clear what may become of intellectual property generated in specific research projects?

Monitoring

- Is the study being conducted with adequate diligence and supervision?
- Is there adherence to the protocol and any ethics committee requirements?
- Is there adequate and systematic supervision of junior staff, and careful record keeping?
- Are good-research-practice guidelines being followed, especially with regard to privacy protection and data storage?
- Is there adequate follow-up of abnormal study results?

Closure

- Is the study closure orderly and systematic?
- Is information provided to participants?
- Are adequate arrangements in place for record storage and later destruction?

for research, and, in this case, the institution is both sponsor and funder.

For every research proposal, the institution must clarify its role and the roles of other stakeholders, preferably in writing. As some research will involve not only hospitals but also affiliated university departments and research institutes, as well as external institutions, the respective responsibilities of all these parties must be clearly documented.

What improvements are needed?

The fundamental requirement is to establish mechanisms for identifying and minimising institutional risks while maintaining all existing protection for research participants. Any institution or organisation that is committed to undertaking health and medical research should satisfy the following requirements:

- It must have a clearly documented research governance framework that incorporates explicit accountabilities and expected measurable standards, and demonstrates that overall accountability rests at the level of the board of directors and the chief executive officer.
- The documentation needs to describe the roles, responsibilities and accountabilities of all participants; the processes and delivery systems to be used; and compliance with standards at all levels.
- There should be periodic external evaluation against those standards.
- The role and reporting line of the institution's HREC must be clearly defined, as must the institution's processes for handling complaints relating to health research.

With good leadership, these elements should coalesce into a cooperative model that promotes learning and improvement.[18]

At the Alfred Hospital in Melbourne, this need has been addressed through establishing a research council that reports to the board of the health care network and brings together all the key components of effective research governance (Box 2).

Board members need to know what they are ultimately responsible for in relation to research conducted within the institution or by staff employed by the institution. These responsibilities include, among others:

- establishing and adequately resourcing an HREC;
- delegating certain roles to the HREC;
- having clearly documented paths for complaints about research and/or allegations of research misconduct; and
- taking final responsibility for the professional conduct of researchers they employ.

The challenge for governments and for institutions that conduct health and medical research is to be confident that the governance framework of this activity is strong enough to withstand challenges such as those faced in the United States and the United Kingdom. We suggest that, without some key improvements (Box 3), it is difficult for governments and for most institutions to have this confidence.

It may be claimed that Australia cannot afford to put increased resources into research governance. We argue that (a) we cannot afford *not* to do this; (b) the essential first steps of increased awareness of roles and responsibilities in research governance and clearer reporting lines will not be costly; and (c) there are ways of saving resources — such as through centralised ethical review of

3 Recommended improvements

- Boards of management must take clearer overall responsibility for research governance.
- Standards for adequate research governance must be articulated more clearly at the national level.
- The existing accreditation system for health care facilities should be extended to include assessment of governance processes for health and medical research. (In the meantime, health care institutions would be wise to seek regular external review of the adequacy of their processes.)
- Institutions should review the level of monitoring of health research according to its assessed risks.
- Sanctions for non-compliance with research governance standards need to be developed, either by the accreditation body or the National Health and Medical Research Council.

multicentre research and greater use of expedited review of research — that carry minimal risk of harm.

Competing interests

John McNeil currently chairs the Research Ethics Committee at the Alfred Hospital. Kerry Breen currently chairs the Australian Health Ethics Committee of the NHMRC. The views expressed in this article are personal ones.

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