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Item Type	Article
Authors	Krastev, Yordanka;Grimm, Michael;Metcalfe, Andrew, Faculty of Arts & Social Sciences, UNSW
Publisher	Monash University
Rights	Creative Commons Copyright (CC 2.5)
Download date	2026-11-06 15:21:05
Link to Item	http://hdl.handle.net/20.500.12424/228722

RESEARCH GOVERNANCE AND CHANGE IN RESEARCH ETHICS PRACTICES AT A MAJOR AUSTRALIAN UNIVERSITY

***Yordanka Krastev**, University of New South Wales*
***Michael Grimm**, University of New South Wales*
***Andrew Metcalfe**, University of New South Wales*

Recent revisions of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research put a great emphasis on research governance. Institutional responsibility for the governance of the research is not limited only to the ethical review by the Human Research Ethics Committee (HREC), but also to the accountability for quality, safety, privacy, risk management and financial management of the research. Despite the development of proposed research governance frameworks, many Australian institutions do not have such structures in place and rely excessively on HRECs to perform administrative functions that are not their responsibility. In this paper we report on implementation of a research governance framework at University of New South Wales which led to reduced HREC workload and allowed more attention to its core functions. We present the approach undertaken by the university to separate the ethical review process by HREC from the research governance. We recommend that with proper research governance frameworks in place, the role of HRECs and the institutional responsibility of governance of the research can be defined clearly.

INTRODUCTION

Ethical review is a fundamental requirement for the conduct of research involving humans. In Australia the National Statement on Ethical Conduct in Human Research (National Statement) and the Australian Code for the Responsible Conduct of Research are the two major guiding documents for institutions and researchers conducting high quality, ethical and sustainable research involving humans (see NHMRC et al. 2007a, 2007b; Babl & Sharwood 2008). In their recent revisions there is a great emphasis on the governance of research as the responsibility of the institution, distinct from the ethical review and Human Research Ethics Committee (HREC) reporting requirements (Babl & Sharwood 2008). This institutional responsibility for the governance of the research, however, is not limited only to the ethical review by the HREC, but also to the accountability for quality, safety, privacy, risk management and financial management of the research. Both documents are issued by the National Health and Medical Research Council

(NHMRC) (along with the Australian Research Council, and the Australian Vice-Chancellors' Committee) which is the country's largest funding body for medical research. Most medical and public health research is conducted in universities, hospitals and other research institutions and for many is seen as a major venture for these institutions (Walsh et al. 2005). As part of the funding agreement with NHMRC, there is an annexure referring to the institutional responsibility that the research has undergone ethical review by HREC and this approval is valid for the whole duration of the project (Allen 2007).

Although there has been development of proposed research governance frameworks, many institutions currently have no research governance structures and processes in place and still rely on HRECs to perform functions such as administrative requirements of the proposed research (see Walsh et al. 2005; NHMRC 2010a). Even in those institutions with established research governance frameworks there is limited evidence of the effectiveness of these governance processes.

In this paper we aim to describe how the recent separation of the ethical review process by HREC from research governance improved current ethical practices at the University of New South Wales (UNSW). Our additional aim is to bring attention to the importance of institutional responsibility for conduct of research involving humans and to highlight core tasks of HRECs in conducting ethical review.

CURRENT ETHICAL REVIEW SYSTEM IN AUSTRALIA AND THE ROLE OF HREC

The current ethical review system is comprised of two components: the ethical review process by a HREC, and research governance (NHMRC et al. 2007a). The role and functions of HRECs in ethical review of research were defined in 1976 in a Supplementary note to the NHMRC requirement for ethical approval of grant applications (Loblay 2008). However, the HREC system has evolved to be characterised by under-resourced and overworked committees, lacking support and performing both ethical review and research governance functions (see Walsh et al. 2005; Allen 2007; Frew & Martlew 2007), and lacking balance between the resources and capacities of the HREC system and the demands of researchers, regulators and the community (Chalmers 2002). The expectations of HRECs are very high and are getting higher in terms of HRECs performing both their core role and their research governance role (Frew & Martlew 2007).

These constraints on research management also applied at UNSW: while there was some degree of separation of the two components of the review system, the HRECs retained inappropriate regulatory functions.

The core membership of HRECs is designed for the task of ethical review rather than research management. The committees are established to:

- protect the rights and welfare of research participants
- minimise the risk of harm arising from research studies involving humans
- facilitate ethical human research through efficient and effective review processes in accordance with the National Statement
- promote ethical standards of human research by education of the academic community (UNSW 2010).

Management activities of the HREC such as administrative requirements of the proposed research, risk management and confirmation of investigators' qualifications form part of the research governance process.

WHY IS RESEARCH GOVERNANCE IMPORTANT?

Research governance is significant to ethics committees, because it defines the roles and responsibilities of all parties involved in ensuring high quality, safe and ethical conduct of research (Bloom & Frew 2008). Its cornerstones are: accountability for the scientific quality, transparency, ethical acceptability and responsibility (Poustie et al.2006). In the implementation of research governance it needs to be recognised that the health system, research institutions and researchers all play a role in ensuring the proper conduct of research. An example of development of such a framework occurred in NSW Health which undertook the following initiatives in the last 5 years (Bloom & Frew 2008), although with mixed outcomes (Hicks et al. 2009):

- standard operating procedures for NSW Health HRECs
- policy and procedures for single ethical review of multi-centre research through lead HRECs
- research governance officer role in each institution conducting research to ensure appropriateness of the institutional resources, adherence to site-specific policies and credibility of the researchers
- separate sign offs for HREC and site-specific governance.

Another example is the Griffith University model for research governance. One of the key components is the Executive Officer support separate from the ethics secretariat, with advisory, policy development and educational roles. The rest of the components

target optimisation of the ethical review process through three ethical review pathways; enhanced research advice and training for researchers and targeted arrangements for review of research by coursework, undergraduate students, multi-centre research and research conducted overseas (Allen 2007).

Nevertheless there are still expectations and current practices in many places for the HREC to perform both ethical review and research governance functions for which they are neither equipped nor authorised (Anderson et al. 2006).

In addition, at the end of 2010, the NHMRC developed a discussion paper with the aim of receiving feedback on good practice in research governance in multi-centre human research and the roles and responsibilities of the parties involved in this process (NHMRC 2010b).

THE UNSW APPROACH TO SEPARATE RESEARCH GOVERNANCE FROM ETHICAL REVIEW

There has been significant discussion about the desirability of separation of governance from ethical oversight in UNSW since 2008. Attempts to develop standard operating procedures (SOPs) in 2008/2009 became stalled because of discrepancies between then-current practice and the delegated authority to approve research. This diffuse concern about governance issues was brought to a head, however, by preparation of the HREC for Harmonisation of Multi-Centre Ethical Review (HoMER) certification. The purpose of the HoMER project is to streamline single ethical and scientific review of multi-centre health and medical research across Australian institutions and to avoid duplication of ethics committee approvals for the same project (NHMRC 2008). As part of the HoMER project, the ethical review processes of institutions are being certified to ensure that they can facilitate single ethical review and that they meet the requirements of the National Statement (NHMRC 2008). The first phase of this process was conducted in 2010 and UNSW HREC was assessed against a set of criteria, before being granted a certification for the various types of research.

The HoMER process makes it explicit that the advice received from an HREC undertaking single ethical review will not replace the need for local decision-making on matters of research governance. Moreover, the final approval of the research should happen through the institutional governance process (NHMRC 2008).

WHAT HAS CHANGED SINCE JULY 2010?

Before 2010, the UNSW HREC not only had to assess the ethical aspects of proposed research, but also had initial dealings with cases of research misconduct. This additional process required setting an inquiry, seeking opinion from the Deputy Vice Chancellor Research (DVC(R)) and it resulted in a considerable workload for the HREC Presiding Members and the Ethics secretariat. A change in process now requires that all cases of potential breach of the UNSW research code of conduct are sent directly to the DVC(R) and these are not discussed at HREC meetings. This new research governance arrangement led to noticeable reduction in the workload of the HREC. While the HREC Executive and the Ethics Secretariat still handle complaints and queries about research, there is a clear triage process and the governance related issues are sent directly to the Office of DVC(R) for consideration.

During the preparation for HoMER certification Standard Operating Procedures were finalised and published online as an 'Operations Manual for the Human Research Ethics Committees' (UNSW 2010). This manual clearly outlines the roles and responsibilities of HREC and the authority of DVC(R) to give final approval for research to commence. Initially the new approval process – i.e. DVC(R) giving final approval – caused concern among HREC members who were eager to defend the independence of their ethical decisions. The concern was that, if the DVC(R) was seen as the person 'approving' research, the DVC(R) was claiming the right to override the HREC's decisions, in a manner not authorised by the National Statement. This initial response was widely shared by other members and chairs of HRECs at a national meeting of ethics committee chairs late last year. In fact, however, this division of responsibility is now seen by HREC Presiding Members as a welcome clarification of the HREC's role and a welcome distinction of HREC and governance functions.

The major change in the work of HREC was the new style of letter 'recommending approval'. The HREC's responsibility is to determine if research proposals are in accordance with the National Statement. If this accordance is affirmed, the HREC communicates this decision to the DVC(R). This HREC decision is a necessary but not sufficient requirement before the DVC(R) approves the research. When the HREC initially communicates its decisions to researchers, therefore, it no longer claims to approve research. Instead it affirms accordance with the National Statement and informs researchers that their project has been recommended for approval by the DVC (R). Later, when the Ethics Secretariat has been informed of the DVC(R)'s approval, a formal letter is sent to researchers stating that the protocol has been found to meet the requirements set out in the National State-

ment and also that the DVC(R) has approved the project to proceed. This procedure has made the functions of the HREC much clearer. It should be noted, though, that the role of the Ethics Secretariat is not quite as clear. Currently the Ethics Secretariat supports the work of the HREC, but it is also responsible for conveying to researchers the governance decisions of the DVC(R).

THE WAY FORWARD

In recent years there has been growing discussion and recognition of the importance of research governance. The main aim of the separation of governance of the research from its ethical oversight is for research institutions to recognise their responsibility for overall research governance as their duty, rather than the duty of their HRECs. This should reduce the burden on HRECs and could improve their performance in reviewing the ethical aspects of research proposals (Frew & Martlew 2007). With proper research governance frameworks in place, the role of HRECs and the institutional responsibility of governance of the research can be defined clearly. There have been different activities for development of research governance frameworks across Australia, but a national approach is still lacking.

Our experience from HoMER certification of UNSW HREC showed that this process can play a trigger role in the implementation of a research governance framework in institutions and it can be advocated for wider implementation at a national level. There might be initial uncertainties and reservations about the new system, for example comments that the HREC had given up the right to 'approve'. There are certainly pros and cons in the new system and it needs time for new changes to be communicated between the institution's representatives, HREC members and researchers. In our example the separation of the ethical review process by the UNSW HREC from the research governance reduced HREC's workload and allowed more attention to its core functions of ethical review and education. The processes of ethical review can be more responsive to the needs of different fields of research by emphasising the importance of research governance and reasserting the important roles that researchers and institutions have in this system (Anderson et al. 2006). It is important for HRECs not to resist this clarification of their functions. It enhances rather than undermines the independence of ethics committees.

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Cite this article as: Krastev, Yordanka; Grimm, Michael; Metcalfe, Andrew. 2011. 'Research governance and change in research ethics practices at a major Australian university'. *Monash Bioethics Review* 29 (4): pp. 16.1 to 16.7.