ETHICS CREEP OR GOVERNANCE CREEP?

CHALLENGES FOR AUSTRALIAN HUMAN RESEARCH ETHICS COMMITTEES (HRECS)

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Australian Human Research Ethics Committees (HRECs) have to contend with ever-increasing workloads and responsibilities which go well beyond questions of mere ethics.

In this article, I shall examine how the roles of HRECs have changed, and show how this is reflected in the iterations of the National Statement on Ethical Conduct in Human Research 2007 (NS). In particular I suggest that the focus of the National Statement has shifted to concentrate on matters of research governance at the expense of research ethics, compounded by its linkage to the Australian Code for the Responsible Conduct of Research (2007) in its most recent iteration. I shall explore some of the challenges this poses for HRECs and institutions and the risks it poses to ensuring that Australian researchers receive clear ethical guidance and review.

INTRODUCTION

There is a fundamental difference between research governance and research ethics. While I am willing to concede that the two are undeniably linked and even to some extent overlap, their primary focus is different. Research ethics focuses mainly on the rights and interests of research participants, whereas research governance is focused more on the actions of researchers and the interests of the institutions to which researchers belong.

The difference is subtle but important, and it is easy to confuse the two. It is my contention that the National Statement has confused both concepts, at times conflating the two areas to their mutual detriment. This has been compounded by the most recent versions of the National Statement to the Australian Code for the Responsible Conduct of Research (2007) which were conceived and developed as companion documents. This has in turn led to difficulties for ethics committees, researchers and research institutions.

THE NATIONAL STATEMENT

The National Statement on Ethical Conduct in Human Research (2007) has been described as the ‘primary source of guidance for the conduct of all research that involves human participants’ in Australia (Anderson, 2007). In other words it is the underpinning document for Australian ethics committees, institutions, and researchers.
However, the National Statement has changed considerably since its first inception, where the main concern was the ethics of medical research. In its most recent iteration the focus has moved beyond medical research and ethics. This is evidenced not only by the prominence given to Research Merit and Integrity as a ‘value’, but by its coupling with the Australian Code for the Responsible Conduct of Research (2007).

THE FOCUS OF THE AUSTRALIAN CODE

The Australian Code was created to complement the National Statement. It is divided into two sections: Part A consists of ‘principles and practices to encourage responsible research conduct’, while Part B deals with ‘breaches of the Code, research misconduct and the framework for resolving allegations’. This document aims at promoting a higher level of research governance in Australian universities, and goes well beyond ethical considerations in relation to the conduct of research. The Code addresses such matters as responsibilities of institutions and researchers, management of data, supervision of research trainees, publication, authorship, peer review, conflicts of interest and collaborative research across institutions. In other words, the Code addresses matters of governance, and the National Statement matters of ethics.

Although the Code and the National Statement are referred to as companion documents, the Code is the over-arching document because it goes beyond research involving humans to encompass all kinds of research, whether requiring ethics approval or not. Thus it refers to animal research, research requiring biosafety approval, and research requiring no ethical or safety clearance of any kind, such as purely documentary research. In other words, the National Statement is now subordinate to the Australian Code.

THE FOCUS OF THE NATIONAL STATEMENT

The National Statement only refers to research involving humans. In its chapter on ‘Values and principles of ethical conduct’, the National Statement refers to the values of ‘Research merit and integrity’, ‘Justice’, ‘Beneficence’ and ‘Respect’ (National Statement 2007: 12–13), with prominence given to ‘Research merit and integrity’. These latter three values, (‘Justice’, ‘Beneficence’ and ‘Respect’) align themselves more readily with matters of research ethics, and the value of respect is recognised as central (National Statement 2007: 11). These three values are the lens through which the ethical issues relating to research are viewed by ethics committees, and impact upon such issues as risk, consent, harm, privacy, conflict of interest, etc. ‘Research merit and integrity’, on the other hand, are more relevant to matters of research governance.