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ABSTRACT

On 19 December 2005 the recommendations of the Lockhart Review were released. One of the key recommendations was that current laws be amended to permit the creation of embryonic stem cells by somatic cell nuclear transfer. The Lockhart Report analysed the ethical arguments for and against the creation of embryos by nuclear transfer. It rationalised that, although there were various objections to such technology from some sections of Australian society, the good that this science has the potential to produce in the form of stem cell therapies to assist with or cure disease should prevail. This article will critically analyse the ethical arguments presented to the Lockhart Review and assess how the Review Committee resolved the debate as to the ethical status of a preimplantation embryo. It will be contended that the recommendations for reform should be fully implemented by the Federal Government, to enable scientists to have full access to both embryonic and adult stem cells, including custom-made stem cell lines created through the SCNT process, to allow medical research to progress to its fullest potential.

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ETHICS COMMITTEE

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ARTICLES

‘Obstructive and power hungry’?: the Australian human research ethics process

Lynn Gillam, Marilys Guillemin and Doreen Rosenthal 30

ABSTRACT

Objectives:

To investigate the views of Human Research Ethics Committee (HREC) members and of researchers concerning the human research ethics review process in Australia.

To examine whether there are differences between views of researchers and HREC members.

Design and setting:

Registrants at the NHMRC Ethics in Human Research Conference held in Canberra in May 2005 were surveyed by anonymous questionnaire comprising 14 questionnaire items and background demographic questions.

Results:

Of the 407 registrants, 252 completed the questionnaire (62% response rate). Respondents comprised 219 (87%) HREC members or administrators, and 33 (13%) researchers who were not HREC members. Researchers generally had a less positive attitude to the HREC process than did HREC members. Researchers were less likely to believe that HRECs: make clear and reasonable decisions in an acceptable timeframe; provide informal guidance to researchers; and have the necessary expertise to make appropriate decisions. The largest difference related to relations between researchers and HRECs: 82.5% of HREC members thought relations were good, but only 59.3% of researchers held this view. Despite these differences, both HREC members and researchers held the view that the ethics review process in Australia is working well.

Conclusion:

Although our study suggests that both HREC members and researchers are satisfied with the process of human research ethics review in Australia, there are areas of concern that merit further investigation. These include the timeliness and clarity of HREC decisions, the methodological expertise available to HRECs and the basis for HREC decisions.

Making the vulnerable less so

Inmaculada de Melo-Martín 39

ABSTRACT

Recent discussion on the need to reassess research ethics standards has called into question familiar concepts such as equipoise, coercion, undue

inducement, and the protection of vulnerable subjects. Reassessment of these concepts can be useful for a variety of reasons. It can eliminate conceptual murkiness, can assist in the proposal of regulations to better protect human subjects, and can elucidate ethical concerns. In this essay, I call attention here to a different, and often neglected, reason why reassessment of research ethics concepts can be helpful. It can undermine the all-too-common practice of taking as a given the social and political conditions in which biomedical research takes place and can encourage the inclusion of broader questions about social justice, human flourishing, or about the importance of taking into account the social determinants of health and disease. I will focus on some recent attempts to reevaluate the concept of vulnerability in research ethics. I will argue that such attempts, by calling attention to the characteristics that can render participants vulnerable, can promote, rather than discourage, moral reflection about social and global justice concerns among bioethicists, policy makers, investigators, and members of Institutional Review Boards.

Conducting international research fairly: a response to de Melo-Martin

Angela Ballantyne

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**Indigenous health research ethics in Australia:
applying guidelines as the basis for negotiating research agreements**

Terry Dunbar and Margaret Scrimgeour

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ABSTRACT

The introduction of the National Health and Medical Research Council guidelines for the ethical conduct of Indigenous health research: Values and Ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (NHMRC, 2003), has prompted renewed debate about the ethical assessment of Indigenous health research in Australia. Concern has been expressed that these guidelines provide inadequate protection of Indigenous interests and that their introduction will result in a rolling back of important Indigenous research reform gains of the past three decades. Another view is that the participatory focus of the Guidelines will help ensure that key Indigenous values are positioned as central to the development of research involving Indigenous interests. In this article we provide an overview of recent commentary on the Guidelines, and canvass practical proposals for their implementation into practice. In particular, we present a case for applying the Values and Ethics Guidelines as a foundation for establishing negotiated research agreements between Indigenous peoples and professional researchers at the local community level. The intention of this proposal is to give voice to the concerns and perspectives of Indigenous peoples through research, and to provide a framework for monitoring research after ethics approval has been granted.

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Danny Edwards

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