

Ethical research or research ethics?

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Are we doing ethical health research or just complying with research ethics and technical requirements? Like others,¹ we have observed a tendency for 1) ethical issues in clinical and health services research to be typically addressed only after the research question and methodology have been established, and 2) ethical review being conceptualised as compliance to bioethical moral principles.

We argue this detracts from good ethical research. To address this, we propose researchers and research institutions consider using a communitarian approach to frame and embed ethical issues at the beginning of the research process.

Medical and human health research ethics have a relatively recent tradition of principlism, where a framework of four bioethical principles (justice, autonomy, beneficence and non-maleficence)² is applied.¹ The context for these principles has evolved over time – from theological viewpoints to contemporary secular philosophical perspectives – transcending the doctor–patient relationship to encompass the World Health Organization’s (WHO’s) biopsychosocial definition of ‘health’ and the United Nation’s (UN’s) *Declaration of Human Rights*.

Advances in the health sciences (eg biotechnologies) and health humanities (eg adoption of policies that seek and use patient narratives) add to the richness in the decision making of

health research. The National Health and Medical Research Council’s (NHMRC’s) *National Statement on Conduct of Ethical Research*³ attempts to incorporate the complex ethical, legal and social dimensions of modern health research, spanning the spectrum of basic science, clinical trials, and cost effectiveness of health services. Some of these issues include the balance between high-tech preservation of life versus quality of life; equitable access to medical innovations, especially for disadvantaged groups; the governance and ownership of ‘big data’; and health privacy in the ‘information age’.

The twentieth century saw the rise of individualism in Western societies. In the health and research communities, this broader social change has been reflected with the emphasis placed on the autonomy principle.⁴ With this, emerged a minimalist ethic, both in research and more generally – where the morality of an act is primarily limited to judgements on ‘whether it avoids harm to others’.⁵ A minimalist research development process does not promote comprehensive consideration on the impact of health research on individual and community values, lived experiences, and social institutions.

Communitarianism, a political philosophy that considers individuals as the product of their community relationships, has been proposed as an approach to promote ethical decisions by balancing the four bioethical

principles, especially the autonomy–beneficence dyad.⁴ Dialogue is implicit in communitarianism, with its emphasis on a social, rather than an individual, starting point to ethical decision making. In a nutshell, the guiding principles of communitarianism include:⁴ people are social animals; private and public spheres overlap; common good takes precedence; individual human rights are essential but very few are unlimited; and democratic participation in community discourse. From the communitarianism perspective, protecting the community also protects the individual (*Box 1*).

The Australian Human Research Ethics Committees (HRECs) have an important function in protecting the public and facilitating useful health research. The HRECs’ protocols assess risks of harm and balance these risks against benefits. However, HRECs may have been minimalist in this approach. Proposals are typically submitted to HRECs using the National Ethics Application Form (NEAF; www.neaf.gov.au). The NEAF requires researchers to answer a series of technical questions on methodology, benefits and risks, participant consent and recruitment processes, confidentiality/privacy, among others. The form can be seen as a highly structured representation of principlism. It appears to give primacy to research governance and the need of HRECs, perhaps over those of researchers.⁶ Importantly, the focus on technical compliance to research ethics may obscure, rather than

facilitate, broad ethical thinking in health research, especially for less experienced researchers. For example, although site-specific approval emphasises the importance of local contexts, it may also act as a bureaucratic barrier.

Some of the issues we raised are already integral to the NHMRC *Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*. For example, section 1.3.2 states: 'It is possible for researchers to "meet" rule-based requirements without engaging fully with the implications of differences and values relevant to their research. The approach advanced in these guidelines is more demanding of researchers as it seeks to move from compliance to trust.'⁷

Value proposition

A communitarian approach to health research ethics may help redress the modern tendency towards minimalism by emphasising social moral good, such as justice and beneficence, along with individual good like respect for autonomy. Ethical questions should be optimally considered during the development of research questions, not after. Building relationships with communities based on respect and trust

may guide the meaningful prioritisation of research questions. It can also foster an understanding of risks to community, family and the individual that is grounded in the local sociocultural context.

Positioning health research ethics as an ongoing discourse between researchers, stakeholders and bioethicists is imaginably more effective at promoting ethical research than framing it as a hurdle to be overcome.

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Box 1. Principlism, minimalism, individualism and communitarianism?

Consider the development of an evaluation of the effectiveness of a treatment (eg herbal pill) to prevent dementia using a cluster randomised control trial in general practice.

The current approach would focus on effectiveness on the individual, and perhaps costs to the health system. We would then consider and address the ethical issues in a minimalist approach, guided by the principlist approach embedded in the National ethics application form (NEAF).

On the other hand, the communitarian approach starts with the questions:

- How does this research and treatment benefit the communities of individuals, carers, families and health and other professionals in the neighbourhood?
- Is there potential harm to these communities?
- Do the benefits to the common good outweigh costs or harm?
- Are there tensions between individual rights to this treatment (autonomy) and the public good and rights of the community (justice, beneficence and non-maleficence)?

These questions will guide the development of the relevant research questions and appropriate methodologies to answer them.

This approach supports and enhances the principlist approach of the NEAF, making it easier to complete. More importantly, it also contributes to greater understanding of the relationship between principlism, minimalism, individualism and communitarianism, and the biases that may arise in the development and implementation of the research.

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