

Research ethics: does faith make a difference?

Until I joined the Alfred Hospital Research Ethics Committee in June 2008, my experience of such committees had been from the other side! As a nurse researcher, I had submitted, either as principal researcher or assistant researcher, a number of proposals to various Ethics Committees, and so I had an initial understanding of the role of such a committee.

The background to my approach to Christian Ethics draws heavily on the work of Stanley Hauerwas. In *The Peaceable Kingdom* he speaks of the ways in which communities derive their ethical principles. He sees them being drawn from their positive and substantive practices. He argues that one does not first have the principle “life is sacred” and then deduce that abortion is wrong. Rather, one learns about the value of life, and in particular human life that comes in the form of one’s children because the community does not practice abortion. In my ethical deliberations I am conscious of Hauerwas’ encouragement that instead of “what ought I do?” my question should be rather “what kind of person ought I become or am I called to become?”

When I was approached in 2007 to consider joining the Ethics Committee at the Alfred, I was immediately interested. There had been recent media coverage about a major clinical trial ‘mishap’ in London which left six volunteers in Intensive Care, and question marks had been raised about the clinical protocol which had been used. I wondered about the Ethics Committee which had approved the trial, and whether they had raised concerns before approving the trial, and what information they had been given to them by the researchers in order for them to make an informed decision. Since joining the committee, initially on a trial basis and now as a permanent member, I have been impressed with the level of commitment and enthusiasm displayed by the members, and been challenged to think critically and ethically about a number of issues.

Each month I am allocated between 2 and 4 projects

which I am asked to review, either as a primary or secondary reviewer. In addition, I have access to all of the projects for that month which I have an opportunity to comment upon. This pre-reading is the first important step in the process, as it gives me an opportunity to rigorously examine a proposal to see if there are any ethical issues that could impact upon it. In particular, I look for issues such as informed consent, what sort of sensitive information is going to be collected and whether it is identified or de-identified, and are there any dependant relationships between the researcher(s) and the participants which might make it difficult for the prospective participant to decline the invitation to be involved. I have the opportunity to ask the Ethics Department to put any such issues to the researchers prior to the monthly meeting, and often there is a simple change to the study design that removes the ethical issue.

The meeting itself can be long, sometimes over 3 hours, and at times (particularly when there is complex science being discussed) a little bewildering. Importantly, however, there is always an opportunity for all those present to ask questions, to seek clarification, and to put their opinion forward. I am constantly amazed at how others in the group will consider aspects of a proposal which I had not thought of, and I frequently find myself challenged to re-consider my own beliefs and attitudes, and whether these are valid and important in the context.

It is encouraging to see just how many proposals are passed without the need for alteration. In my opinion, researchers are more aware of the ethical issues which their research may pose, and often structure their projects in such a way that the dilemmas are eliminated, or at least minimized. In the case of the committee deciding on further clarification or change, however, the proposal is sent back to the researcher for consideration and alteration.

I believe absolutely in the importance of having a

minister of religion on an Ethics Committee. A Christian understanding of ethical questions and dilemmas is, by its very nature, unique, and is well-positioned to find alternative viewpoints and seek different outcomes; because a Christian ethic is revealed as a liberation ethic. The love of God must result in a struggle for a condition – for structures – that will facilitate humanness. In the case of an Ethics Committee, then, any structural causes of injustice must be identified and called into question. Any sense of a ‘greater good’ must be weighed against any injustice that may result from a particular course of action.

I have been challenged and confronted in my time on the Ethics Committee. I hope that I, too, have challenged others; challenged them to think in a different, more just way, and perhaps I have caused people to think in a different way. In any case, the Christian voice is an important addition to an Ethics Committee, and I am privileged to be able to provide that voice.

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Research with human subjects: do Christians have anything positive to say?

In the 1950's and 1960's, several hundred institutionalised severely mentally disabled children were deliberately exposed to blood and other bodily fluids from other children with hepatitis in order to study its natural course and transmission. Despite later being widely criticised the information gained is still used. The researchers involved never admitted that the research was unethical.

In 1963, a group of patients with advanced Parkinson disease and heart failure were injected with cancer cells to investigate whether they would develop cancer as a result. The patients were not told that they were part of an experiment or that the injections contained cancer cells.

Until 1974, one hospital carried out a study that only monitored women with early cervical cancer, rather than treating them as usual with chemotherapy or surgery. The women were not told that they were part of a study, or that their management was unusual. Nevertheless, the study was later published in a leading medical journal.

It can sometimes seem like Christians only care about the places that science should *not* go. Newspapers show scenes of angry protesters intent on rejecting stem cell experimentation, while television sound bites inevitably suggest that some new researchers are ‘playing at being God’. Many of these objections are considered and valid, and it is not my intention here to suggest otherwise. It is

interesting, though, that the emphasis on where we should not go often overshadows the message of those Christians whose faith provides a reason to search out the unknown and to explore scientific frontiers.

For many Christian researchers, particularly those in the basic sciences, research is an intrinsically good activity. This is not to say that it is an absolute good, (ie there may be competing reasons that mean not all research is worth doing) but that the activity of discovering new information about our world is one that is good for its own sake. “The heavens declare the glory of God” says the psalmist, and it is a common sentiment for researchers to feel that the activity of understanding our world is a way to glorify God. As the wonders of creation are explored and appreciated, the creator is lauded and celebrated, and so the act of research can be an act of worship.

As well as the good that is associated with understanding creation, research may have additional benefits that come from its findings. This is especially obvious in human medical research, where results are often immediately applicable through new medications or procedures that directly impact medical care. For Christians involved in this kind of beneficent research, this is an avenue by which their expertise and vocation can be used to love their neighbours. Just as another person might love through building a house or cooking a meal, those with Christian faith and skills in research may employ them in service to those in need.

Despite this potential for good, the history of medical research provides many examples of unethical and damaging studies. The three vignettes that opened this article are all real examples of unethical medical research that has been well documented. These studies did not occur in dictatorships or other secretive or oppressive conditions, but were all carried out by major medical centres in Western countries. In all cases, despite eventually being exposed and heavily criticised for their actions, the researchers were unrepentant and refused to accept that they had done anything wrong.

For Christians, this pattern of behaviour is entirely expected. Again and again, we see endeavours that have the potential to glorify God but are corrupted and abused by people who use them for their own ends; in short, we see the effect that sin has on this world. In doing so, research changes from being a means of loving people and glorifying God to being something that dishonours God and harms people.

Research ethics, then, is about much more than simply restricting access to areas where science should not go. Rather, it is a way to encourage and support research being done in such a way that both the means and the ends may glorify God. It requires openly acknowledge that we are likely to do the wrong thing if left to our own devices, and provides a way that we can make research practices transparent and open to scrutiny.

As someone who has been involved in medical research ethics as a researcher, subject and ethics reviewer, I have wondered, though, where it is that our faith contributes. Research ethics is not exclusively, or even primarily, a Christian activity. Secular principles are in common use to promote ethical research, particularly in relation to protecting the research subject. Does the field need Christians? What Christian distinctives do we have to offer secular research ethics? On reflection, I would like to suggest four ways in which I think that the Christian faith should make a difference in human research ethics.

By offering positive motivations for research

As we mentioned earlier, Christians have powerful motivations for scientific research. These relate both to the value of research itself, through exploring creation and glorifying the creator, and to the benefits that research may bring. Research is an opportunity for Christians in science (and those who support them) to worship and serve. Alongside this, it also provides a chance to make our motivations for doing and supporting clear. Research, even in 'secular' fields, can be evangelistic when it allows us a window to explain to those around us why our faith drives what we do.

By being realistic about the human condition

After the Nuremberg trials of German medical 'researchers' in WWII, a code of research practice was developed. This was almost entirely ignored, with one American researcher commenting that it was 'fine for barbarians but unnecessary for ordinary physicians'. Unfortunately, history proved him wrong, with many ordinary physicians and researchers going on to commit grossly unethical acts in the name of scientific advancement. The confidence in humanity and the profession that this comment reveals could never be justified in a worldview that recognises sin, and the Christian faith should provide realism in our need for restriction and guidance to protect the weak and sick.

By demonstrating a proper understanding of ethical principles

Much is said about ethical principles in modern research ethics. Australia's code for human research ethics suggests that research integrity, respect for subjects, justice and beneficence are critical. While many Christians would agree with these aspects of ethical consideration, there can be a world of difference between what a Christian and non-Christian consider 'just' or 'respectful'. A Christian worldview brings a powerful understanding and interpretation of ethical principles, and can contribute this perspective at various stages of ethical consideration.

By being humble in our own activities

Finally, those of us who are actively engaged in research involving human subjects need to be especially mindful of our own inadequacies in this area. Our Christian faith does not preclude us from treating others badly or using people for our own benefit. It should, however, make us aware of our deficiencies and open to criticism and correction. Christian researchers, and those who support them, need to be at the forefront of research ethics and convinced of the need for systems and structures that allow transparency and protect the most vulnerable people in human research.

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Research Ethics – Worth Doing

The intersection of law, medicine and ethics raises totally fascinating questions: Does changing the law change people's behaviour? Can we rely on the medical profession's Hippocratic Oath as an adequate ethical safeguard for patients? Is there any distinctive Christian set of ethics for health services?

Then there are particular questions with regard to the ethics of research. Is Professor Margaret Somerville right when she says, "Ethics time always lags behind science time"? Do research scientists in their laboratories take risks with human tissue, stem cells and with drugs with scant regard for good ethics?

These questions are in my experience best answered *in the field* - that is, within research institutes, within hospitals and within government departments and regulatory bodies. Like any specialties, research scientists do not take kindly to outside critics, especially from the churches, and especially if the critics display little knowledge of the science. Christian critics often put forward their own specifically Christian standards as though the whole of Australian society should observe them. They frequently show little understanding of 'the common good' or policies that include the disadvantaged or ethnic groups.

The complexity of the task

For more than 25 years I have been a member of various government advisory or regulatory bodies, mostly in the health sector. I have been party to making recommendations to Government or authorities on State concessions for pensioners, bionic ear research, violence in and around licensed premises, special accommodation for homeless persons, genetically modified crops, and complex issues in infertility. Particularly relevant to research ethics are two public hospital boards where I have served for 12 years altogether as chair of their research ethics committees. What kind of issues have I been involved with in these various roles? Peter MacCallum Cancer Centre, with 300

projects under way at any time, involving more than 400 research staff, is one of Australia's largest research institutes. At its ethics committee we worry about whether patients can really give 'informed consent' to complex research studies. The trouble is that patients tend to say 'yes' to being involved in a research study because they want some benefit from the study for themselves – perhaps even a cure for their illness. Other debates at the committee centre around the high cost of drugs, the seriousness of side effects of taking not-yet-approved drugs, the absence of clear explanations about what a 'randomised control study' is, and the lack of access of non-English speaking patients to research studies.

Obligations of Ethics Committees

In order to protect patients and promote good research, members of a Human Research Ethics Committee (HREC) are obliged to read the project proposals carefully and understand the science behind them. If they have questions, a researcher can be invited to the Committee meeting to answer those questions. If the concern is a major public issue, like the possibility that the research is part of a campaign for government approval of an experimental drug being used in the research study, the researchers can be invited to the Committee to engage in dialogue on the issue.

A HREC also has an obligation to make sure that research staff - and the clinicians and nurses who involve the patients in research - are adequately trained in the meaning and process of 'informed consent' and the generally accepted ethical principles that guide the conduct of research. At Peter Mac, these issues are often the subject of 'Grand Rounds', which are Monday lunchtime staff education sessions. The Ethics Committee members themselves also undertake training, and have to complete an on-line course to meet international requirements. The National Health and Medical Research Council, an Australian Government appointed body, has required categories of membership for HRECs (community members, a lawyer, a minister of religion or pastoral worker, clinicians and researchers), and demands observance of high ethical standards. All HRECs report to the NHMRC on their standards and activities.

These ethical standards are grounded in the values of the common good, the patient's benefit, social justice and access, human rights, and informed consent. There are negative values as well: human tissue cannot have a price put on it; if a researcher is involved commercially or receives any benefit from a study sponsor, this must be declared transparently, etc. Every research institute must ensure that all research under its roof must be conducted responsibly, without causing undue burden to patients. The HREC is held accountable by the hospital board for what happens. Its annual report is made public along with the hospital's other accountability measures. In turn, the HREC also requests progress reports from the research teams on all studies, to see which succeed and which fail to produce the results hoped for; for example, the mixture of two cancer drugs may or may not produce a better result than one drug administered alone; or the drug may be

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effective, but the side effects may be too severe.

In my experience, none of these values clash with Christian principles or indeed with biblical values. Research leads to improvements in health care (for example, survivorship of people with cancer has greatly improved). Patients experience a better quality of life, even those with terminal illness. Research with public patients opens up commercial sponsorship of drug research that would never be possible with limited government funding. Research on DNA and stem cells has resulted in remarkable improvements in the treatment of burns victims and controlling Alzheimer's disease. All of these outcomes contribute to improving the common good - 'having life, and having it abundantly'. There is every reason, therefore, for people of Christian faith to be involved in research ethics, whether as community members of HRECs, or as researchers, hospital staff or clinicians. What is important, then, is to share more of these experiences, and encourage one another in this ethical pilgrimage.

Where I have seen people of faith active in the 'ethics business', I have seen a moderation of views, a more deliberate analysis of what research is worth doing, a clearer articulation of 'the common good' and increased accountability to the public for research. This is not to suggest that Christians are the only people with good ethics. Christians have many colleagues in the business of ensuring that research is done ethically.

This, then, is a plea for ethical alertness: what Hugh Mackay calls "moral mindfulness". It is also a plea for balance in our faith experience, which too often these days focuses on personal relationships and integrity at work, but not nearly enough on the public policy arena and the actual practice of ethics in our institutions.

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