“Ethical Imperialism” and the Export of Research Ethics Regulation from the Global North to South Africa

Mark Israel
Flinders University and University of Western Australia
Australasian Human Research Ethics Consultancy Services
mark.israel@ahrecs.com

Abstract
The global export of principlism forms part of broader international flows of capital, students and academics, as well as knowledge and ideology. The impact of global capital has had a long-standing effect on research ethics governance. Pharmaceutical companies have sought to open up new markets and take advantage of cheaper sites for multi-centre drug trials. Multinational research teams have looked to those countries with lower risks of litigation, low labour costs, pharmacologically ‘naïve’ participants, weak ethics review and the absence of other regulatory processes. As a result, research in low- and middle-income countries has burgeoned. As developing countries struggle to keep pace, the Helsinki and UNESCO Declarations have created regulatory templates for those without the infrastructure to create their own, and a range of capacity-building initiatives in research ethics have encouraged researchers in many developing countries to follow these models. Increasing student and academic mobility and international research collaboration between the global North and South may also ease international transfer of a range of research and education policies that favour universalist approaches to research ethics. Contemporary regulations in countries such as South Africa have shadowed developments in the North and have extended biomedical regulation to all forms of research. However, in some parts of the global South and the Fourth World, there is an emerging distrust and a critique of the motivation for some of the funding for capacity-building in research ethics. For many, opposition to universalist claims is not simply targeted at insensitivity in application but draws on critical ethical traditions such as indigenous, postmodern and postcolonial ethics to challenge the universal basis for principlism, and calls for a deeper understanding of and engagement with how different societies, cultures, peoples and disciplines understand ethics, research and ethical research.

Introduction
Zachary Schrag’s book (2010) on the growth of the regulation of research ethics in the United States portrays a history of mission creep and intensification of the gaze. This has occurred in the guise of reform, concern for the protection of participants and, of all things, deregulation. Schrag interprets the extension of oversight from biomedical sciences to social sciences within his own country variously as bureaucratic empire-building, thoughtless imperialism, and ‘merely collateral damage’ in the goal to ‘contain medical research’ (p.189). Regulations have been extended to cover social sciences on the basis of ‘ignorance and power’ (p.9), ‘haste and disrespect’ (p.192). Federal officials have had little understanding of the practices of social sciences and have demonstrated scant interest in rectifying the situation. Social sciences have rarely been invited to contribute to the development of regulations that cover their work. The pattern has been
for jurisdiction to be extended without consultation and for disciplines to be caught off-guard by a meta-narrative of ethics governance that they do not yet understand and by regulations couched in language that initially appears to exclude them.

While wary of over-generalising from the experiences of the United States, I want to take Schrag’s idea of ‘ethical imperialism’ (which is anything but ethical) and assess the value of applying it to the export of patterns of research ethics governance not just between disciplines, but between countries. I explore the growth of research ethics regulation in South Africa and examine what might be driving research ethics policy transfer from the global North to the global South and how that might be having an impact on the work of social scientists.

Research Ethics Regulation in South Africa
Like much of Africa (Israel, 2015), research ethics regulation in South Africa has been propelled by bioethics. South Africa became one of the first countries to respond to Beecher (1966) and Pappworth’s (1967) concerns about questionable biomedical research practices in the United States and the United Kingdom. In 1977, the South African Medical Research Council produced its Guidelines on Ethics for Medical Research, the most recent edition of which was published in 2015. Moodley and Myer (2007) reported the ethics review system in South Africa was functioning reasonably, but found wide variation in capacity to conduct reviews in a timely and informed manner between committees depending on their geographical location and institutional history. Membership was dominated by white males, scientists and clinicians and failed to contain adequate representation from those communities from which participants might be drawn (Moodley and Rennie, 2011). As a result, committees might be seen as reinforcing ‘the asymmetrical power relationship that already exists between predominantly white researchers and predominantly black participants’ (Moodley and Myer, 2007).

Before 2004, there was no statutory national requirement that social science research be subject to ethics review. However, following a scandal involving breast cancer research, nationally binding ethical guidelines for health research were published by the Department of Health in 2004 and s72(6)c of the 2004 Health Act implied that all research with humans fell within the Act’s purview. The Health Act also established the National Health Research Ethics Council (NHREC) with responsibility for the oversight of local research ethics committees and researchers. The NHREC allows research ethics committees to use different procedures depending on the level of risk (creating a binary division between high and low risk). Universities responded to the 2004 Act by expanding review to cover social sciences and humanities. Where this occurred, review processes were initially resisted by some researchers (Louw and Delport, 2006) and regarded negatively by others. For example, Mamotte and Wasenaar (2009) surveyed social scientists at one university and one research organization. In the former, 60 per cent of researchers reported only negative experiences of the research ethics committee, though the low response rate of 10.1 per cent from the combined sample means that any interpretation should be cautious. Researchers in the university were frustrated by the ‘slowness of review, inadequate review, and problems that arose as a result of the centralization of review, the review of student research and researcher naivety about research ethics and ethics review’ (p. 74).
In 2015, the Department of Health published the second edition of its guidelines, *Ethics in Health Research: Principles, Processes and Structures*. The document specifically warned research ethics committees not to apply a ‘so-called “medical model” of ethics review’ (s.1.1.6) to social science research. However, once again there appeared to be tensions between its statutory remit, its somewhat confusing concurrently held ‘narrow’ and ‘broad’ definitions of health research, and claims that the NHREC intended the guidelines –

...to address research more broadly to achieve the specific goal of providing guidance for researchers so that all research involving human participants or animals may be conducted in accordance with the highest norms and standards. (s.1.1.13)

The argument that a health research document produced by a health research ethics council operating under the authority of health legislation might inform all research is not unique to South Africa. It rests on the proposition that principlism offers the possibility of a universal set of standards. This proposition has been rendered incontestable by South African regulators, who state that –

It is important to recognize that, although research methodologies and analytic paradigms may differ, all research must be judged against the same ethical principles. No philosophical justification exists for judging different methodologies against different ethical standards. (Department of Health, 2015, s.6.1)

*Ethics in Health Research* drew heavily on Wassenaar and Mamotte’s work (2012). While these two scholars have argued in favour of universal principles, they have also recognized that these principles might be difficult to apply in practice since ‘context, history, culture, and politics, as well as the social, gender, and economic status of participants, can have implications for how ethical principles are applied in different settings’ (p. 274). As a result, the 2015 guidelines acknowledged that research ethics committees that dealt with social science proposals needed to be familiar with social research paradigms, noting that different disciplines had varying accepted methodological standards. Indeed, the document devoted one chapter to qualitative research. This might have been an attempt to protect qualitative researchers, but might also have the effect of presenting qualitative methodologies as departures from the norm of quantitative research.

Social scientists originally argued that the 2004 *Health Act* did not apply to them and this might be part of the explanation for Mamotte and Wasenaar’s findings. There have also been calls, albeit contested, for particular disciplines to build alternatives to principlism. Spiegel (2005), for example, urged his colleagues to call upon both an ethics of care and the ‘flexible and responsive’ tradition of exposé anthropology that was a legacy of that discipline’s opposition to Apartheid. Spiegel argued that these might enable anthropologists to maintain an agenda appropriate to the country that continued to explore ethics and a research agenda beyond liberal questions of ‘public power and individual rights’ (p. 134). Drawing on the ongoing work of Thaddeus Metz (for example, Metz 2013), other anthropologists have suggested that an ‘Afro-
communitarian’ notion of mutuality, *ubuntu*, might be better suited than an imported ethics of care to sub-Saharan Africa (Morreia 2012). Metz has aimed at developing ‘a normative ethical theory of right action that has an African pedigree and offers something different from what is dominant in Western moral philosophy’ (2007, p. 332). However, the 2015 Guidelines refuted departures from its principles though it is possible for multiple philosophical approaches to underpin principlism.

Senior social scientists have also questioned how research in South Africa might be well served by intensification of regulatory oversight without any accompanying effort to nurture better ways of working through ethical dilemmas. Indeed, Deborah Posel and Fiona Ross (2014) have argued that current regulatory regimes may be suppressing debate about ethical research practices among researchers who fear provoking resistance from reviewers if they present ‘an unsettling or unruly picture of the research process’ (p. 3). Instead, in South Africa –

…the trend toward more intense regulation does not guarantee a correspondingly full or thoughtful debate about questions of research ethics. Often, the regulatory concerns are more technical than ethically substantive. (ibid.)

This argument was supported by De Vries and Henley (2014) who described how, as researchers and as research ethics reviewers, they have witnessed the tension between ‘official ethics’ and ‘ethics on the ground’. As members of a university ethics committee they had not challenged the former in relation to some highly prescriptive models of informed consent, attributing their silence to: recognition that ‘official ethics’ may need to meet national or international regulatory requirements; uncertainty whether they knew the best way to obtain consent, and; conflict between their role as gatekeepers to research activity and their vested interest as members of an institution seeking to engage in high quality research. They suggested that these might be reason enough –

But perhaps the real source of our ethical dilemma is that we do not – or perhaps no longer – believe that ethics committees ‘do ethics’ in the way that we as social scientists think ethics needs to be done in practice. (pp. 85-86)

South Africa has used a legislative mandate to create national regulation of research ethics based on principlism. Explicitly constructed around the needs of health research, the ambit of the regulation might initially have been unclear. Nevertheless, over time and (where necessary) through subsequent iterations of guidelines, regulators have extended their remit and intensified scrutiny of the social sciences. As in the United States, social scientists had little say in the drafting of the guidelines that were to cover their disciplines, and have found their objections ignored or deflected. Social scientists were also unable to join the committees that conducted reviews under the regulations. Failure of national guidelines and ethics review bureaucracies to understand the nature of social science research has led to complaints from social researchers that research that they regarded as ethical was being delayed or blocked by unsympathetic reviewers. Even more troubling are stories that research ethics committees have insisted on approaches that researchers regarded as unethical. Nevertheless, despite limited empirical evidence
of the effectiveness of research ethics regulation on social scientists and a good deal of
criticism within their borders, the South African model may be influencing regional
patterns of research ethics governance.

Exporting Principlism
The global export of principlism forms part of broader international flows of capital,
students and academics, as well as knowledge and ideology. The impact of global capital
has had a long-standing impact on research ethics governance. Some of the earliest
medical research ethics committees around the world were established to allow medical
researchers to compete for United States health research grants. United States regulators
have used this funding as leverage to ensure that both the spirit and the letter of
American legislation are followed. More recently, pharmaceutical companies have
sought to open up new markets and take advantage of cheaper sites for multi-centre drug
trials. Multinational research teams have looked to those countries with lower risks of
litigation, low labour costs, pharmacologically ‘naive’ participants, weak ethics review
and the absence of other regulatory processes. As a result, research in low- and middle-
income countries has burgeoned. As developing countries struggle to keep pace, the
Helsinki (World Medical Association 2013) and UNESCO (2006) Declarations have
created regulatory templates for those without the infrastructure to create their own, and
a range of capacity-building initiatives in research ethics have encouraged researchers in
developing countries to follow these models.

One of the drivers for global policy transfer has been the influence of transnational
professional networks. These groupings may draw on their shared world view, and use
their recognized expertise in particular areas to assert authority over a policy domain,
develop and entrench particular norms and choices. The concept of ‘epistemic
communities’ has been used to analyse the development and influence of such networks
(Haas, 1992). Members derive legitimacy by drawing on internationally-recognized
approaches to respond to the particular circumstances in their own countries. In turn,
these ‘successes’ are used to garner support for similar initiatives elsewhere. A critical
feature of transnational epistemic communities might be the cohesion that develops from
mutual socialization through shared training (Cross, 2013). Growth in
internationalization of higher education might play a part in providing access to and
mobility within such global communities. Encouraging student and academic
international mobility has become a part of many countries’ national development plans,
either as a way of enhancing local intellectual capital or asset stripping other nations.
Student mobility has also become an important source of income for those countries and
institutions seen as favoured providers of education.

The destination countries for South African tertiary students are dominated by the global
North: United States, the United Kingdom and the rest of the European Union
(UNESCO-UIS, 2012). Movement to other countries in Africa has been minimal, though
South Africa has in its turn become a leading regional hub for sub-Saharan African
students (UNESCO-UIS, 2012), particularly those from the Southern Africa
Development Community. Knowledge is not simply transferred uncritically from
Northern academics to international students. However, there are various ways in which
enrolment at Northern institutions might socialize and discipline international students.
Having enrolled in international degree programmes, students need to meet the
requirements of those courses, even if they and their lecturers and supervisors share a
common critique of research ethics regulations (Sikes, 2013). Ideas may be adopted but they may also be resisted, avoided or shaped through interaction between students in ways that we may not yet understand. Students can also be exposed to the alternatives to principlism that can be found in feminist, critical, postcolonial and indigenous writings (Israel, 2015; Denzin et al., 2008; Mertens and Ginsberg, 2008). Not every research student and academic returns from the research heartlands to the research peripheries of the world, but those that do may ease international transfer of a range of research and education policies including those related to research ethics (Shamim and Qureshi, 2013).

Capacity-building programs funded by the global North delivered in the South may also promote policy transfer through epistemic communities. In Africa, for example, funds and training programmes have been provided by, among others, the World Health Organization, the Fogarty International Center of the United States National Institutes of Health, and the Pan African Bioethics Initiative and Training and Resources in Research Ethics Evaluation (TRREE) for Africa. In some initiatives, researchers and administrators are brought to designated centres in the global North as groups for specific courses or within faculty exchange programmes. In other cases, regional fora are run in developing countries, often with the help of local returnees from courses in the developed world. South Africa has acted as host for two regional health research ethics capacity-building programmes – the South African Research Ethics Training Initiative (SARETI), and the International Research Ethics Network for Southern Africa (IRENSA). Over eight years, IRENSA provided a one-year diploma and internship for almost 100 mid-career health care professionals. These professionals included members of 40 research ethics committees, mostly in South Africa, but also drawn from other Anglophone countries on that continent. It would be churlish not to acknowledge the importance of ethics capacity-building programs for health research. However, some initiatives might be problematic. Commentators have questioned whether some systems being supported by United States-funded research ethics initiatives in lower- and middle-income countries are sustainable and whether they rely too heavily on professionals from the global North, are well-designed or accurate, or are appropriate in these, or even any, setting (Eckstein, 2004). More stridently, De Vries and Rott (2011) portrayed some courses as less of a dialogue and more like ‘missionary work’, a one-way flow of western ideas and influence. Not all training is necessarily valuable and it is possible that some of these initiatives, by failing to reject the mistakes of United States regulation, may be particularly unhelpful to social science research.

The attitudes of some North American and European institutions towards working with Southern partners may also serve to entrench Northern approaches and undercut competing Southern-based claims to expertise. Leslie London and Helen MacDonald (2014) described two cases where Northern regulators had initially appeared to recognize local expertise in South Africa, only to ignore and marginalize recommendations made by those experts. In the first instance, a European funding agency requested South African review of a research proposal from a European-based American anthropologist. The research project would employ a doctoral student to explore HIV healthcare offered through a non-government organization in South Africa. According to London who was acting as the local reviewer, the NGO knew nothing of the research and the proposal failed to demonstrate understanding of local ethical sensitivities or ethics regulatory
requirements. Among other matters, London was critical of ‘parachute research’ and a
division of labour whereby Southern researchers gathered empirical data for analysis by
Northern theorists, analysis that would not be shared in any obvious way with the South
African research or participating community: ‘Once shared, the researcher disappears
with the knowledge, the experience and the intellectual capital’ (in London and
MacDonald, 2014, p. 101). Despite this assessment by South African reviewers, the
research was funded by the European agency.

In the second example, a US undergraduate student planned an eight-week ethnographic
research study of aspects of AIDS-related stigma in the Western Cape. The Institutional
Review Board (IRB) at her university passed the proposal but required ethics clearance
in South Africa and, to enable this, the student negotiated affiliation to the University of
Cape Town. MacDonald reviewed the proposal on behalf of the Department of Social
Anthropology, found ‘glaring’ weaknesses and concluded that the form mandated by the
IRB had produced a lengthy shopping list of ethics issues to be addressed, but not ones
that could elicit the ethical thinking that might be needed by an ethnographer working in
this field in South Africa. However, the IRB refused to cede the authority to review
modifications to the review committee in Cape Town making it difficult for the local
committee to insist on or even allow redrafting in response to changes in the field. In so
doing, ‘the northern institution made a large investment in ethical oversight but oriented
this investment entirely towards limiting its legal liability, with little regard for local
ethical practices in South Africa’ (in London and MacDonald, 2014, p. 94). London and
MacDonald blamed the behaviour of the two Northern institutions variously on
methodological naïveté, lack of expertise in ethnography, arrogance, and the trumping of
ethics by legal liability. Of course, these behaviours were only able to stand without
modification because of the power differentials between European and North American
institutions on the one hand and perhaps the highest ranked African research institution
on the other. The ways transnational research relationships tackle research ethics needs to
be understood within the context of the political economy of research. Research ethics
regulatory policy and practices have been exported from the global North to the South as
part of the flows of capital and academic labour. In order to secure grants from the
United States, medical institutions in the South have had to establish research ethics
guidelines and review structures that reflect arrangements in the United States. These
arrangements have been supported by transnational professional networks populated by
academics and graduates returning from North America and Europe, as well as by health
research capacity-building programs funded by the North. As we have seen, they are not
easily challenged by social scientists.

One rationale for the adoption of principlism is that countries in the South need to
conform to international conventions in order to either protect their citizens or remain
competitive in the market for international research. The assumption appears to be that
supranational initiatives are inherently better than local ones. The issue of where the
locus of responsibility for developing policy and regulation should rest is not unique to
research ethics. Within federal entities such as the European Union, various conceptions
of subsidiarity have supported a countervailing response to pressures for greater
centralisation of governance. Subsidiarity is based on the premise that moves to
centralise authority need to be justified and cannot just be asserted as good. So, only
those matters that cannot be dealt with at the state level might warrant international
regulation, offering a ‘rebuttable presumption for the local’ (Føllesdal, 2016). Under a liberal contractual model of subsidiarity, individuals are recognised as having an interest in shaping the social institutions that might control their lives, so that among other things: institutions are responsive to the needs and interests of citizens; local communities can resist external domination, and; members of a community can engage in active citizenship (Føllesdal, 2014). Additionally, other groups who have no legitimate interest in the way a community shapes its regulation on a particular matter can avoid excessive interference, though they might provide assistance in order to avoid a competitive deregulatory spiral (Genschel and Plumper, 1997).

Within research ethics, Kotalik (2010) recognised that the principle of subsidiarity might be operating within states that had national statements, but left the interpretation of those statements to local review bodies. However, he failed to consider how international actors might be ignoring the same principle at national level. Different states might indeed acknowledge the importance of a range of international bodies, declarations and principles, but deploy subsidiarity to assert the right of individual states, sub-state communities and individuals to play significant roles in fashioning local policy and regulation in response to their particular social and cultural contexts. Of course, the principle of subsidiarity does pose its own problems, the most obvious being determining at what point and on what basis can a higher level intervene in the decisions of a more local grouping. Nevertheless, it might provide a way for states such as South Africa and for disciplines such as the social sciences to resist the universalist claims of supranational bioethical regulation.

Conclusion
Research ethics regulations largely: are produced and conducted in the global North; are based on universalist claims about ethics and the primacy of the individual; exclude other belief systems; take advantage of institutionalized power differentials, and; erase colonial and neo-colonial experiences. Other contexts and experiences are excluded or, if incorporated, seen as offering only inflexible, historical points of reference. When biomedically-derived regulations are imported, the experience of social scientists in South Africa suggests that it may be difficult to influence their initial formation and ambit. Researchers who fail to comply with imported ethical requirements risk forfeiting funding, having their papers rejected by publishers or losing their jobs. Even where social scientists have mobilized, changes in the imported regime may be difficult to achieve.

It is deeply troubling that so many countries have imported regimes from the global North that are flawed within their own context, but also appear incapable of respecting different ethical traditions, learning from local knowledge of context, or engaging with local researchers, institutions, participants and other stakeholders in the world of research. In many ways, Schrag’s language of ‘ethical imperialism’ seems to be a useful analytical device for understanding the export of research ethics regulation from the global North to South Africa. It may also hold some rhetorical value. However, it may also disguise sophisticated patterns of incorporation, accommodation and resistance which, for us to understand, require a level of empirical research that is yet to be undertaken at a local level. When researchers resist the roll-out of universal ethical norms, they may be seeking guidelines that display greater cultural sensitivity. However,
for many, opposition is not simply targeted at insensitivity in application but draws on critical ethical traditions to challenge the universal basis for principlism, and calls for a deeper understanding of and engagement with how different societies, cultures and peoples understand ethics, research and ethical research.

Acknowledgements
Thank you to Robert Dingwall for pointing to the value of subsidiarity in this context, and to Ron Iphofen and Wil van den Hoonaard for their comments on drafts. A longer version of this paper which compares the South African and Brazilian experiences of research ethics regulation will appear as Israel (in press, 2017). I thank both the editors and the publisher for allowing me to provide a condensed version to the African Studies Association of Australasia and the Pacific (AFSAAP) conference proceedings. Some of this paper is also drawn from Israel (2015).

REFERENCES


World Medical Association (2013) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, as amended by the 64th WMA General Assembly, Fortazela, Brazil (http://www.wma.net/en/30publications/10policies/b3/)