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# It is time to heed Solomon Benatar's call to disrupt the global research ethics paradigm

**J V Lavery**,[1,2] MSc, PhD; **R E G Upshur**,[3,4] MD (Fam Med), MSc; **P A Singer**,[5] MD (Int Med), MPH; **E M Meslin**,[3,6] MA, PhD

[1] *Hubert Department of Global Health, Rollins School of Public Health and Center for Ethics, Emory University, Atlanta, GA, USA*
[2] *Division of Social and Behavioural Health Sciences, Dalla Lana School of Public Health, University of Toronto, Toronto, Canada*
[3] *Division of Clinical Public Health, Dalla Lana School of Public Health, University of Toronto, Toronto, Canada*
[4] *Joint Centre for Bioethics, University of Toronto, Toronto, Canada*
[5] *Faculty of Medicine, University of Toronto, Toronto, Canada*
[6] *Centre of Genomics and Policy, McGill University, Montreal, Canada*

***Corresponding author:*** *J V Lavery (james.v.lavery@emory.edu)*

The history of research in low- and middle-income countries is rife with practices that have extracted the time, energy, data, biological samples and, in many cases, the health and lives of those who participated, often justified by beliefs about their racial, cultural and civilisational inferiority. As global health research expanded in the late 20th century, this history raised substantial ethical concerns, including exploitation, double standards and the broader social, economic and political contexts in which international research occurs. Although research has contributed to reductions in mortality, morbidity and poverty, its benefits continue to accrue disproportionately to the wealthiest countries, even as access to the fruits of science has been recognised as a human right.

In 1999, Prof. Solomon Benatar challenged the Global Forum for Bioethics in Research to confront research as an 'extractive enterprise' and to acknowledge the need for 'a paradigm shift in thinking and action', grounded in interdependence, duties, social justice and the promotion of human flourishing. The prevailing global paradigm, shaped largely by the US Common Rule regulations, emphasises institutional accountability, standardised procedures and a protectionist focus on individual research participants through regulatory compliance. Despite its influence, it remains unclear whether this model has advanced Prof. Benatar's vision of a research enterprise that fosters inclusiveness and promotes the broader societal value of research.

We outline possible shifts toward a more proactive, creative, inclusive, context-sensitive and innovative model that embraces empirical testing and global learning, with an emphasis on creating social value. These shifts reflect Prof. Benatar's lifelong commitment to moral imagination, his call to reject extractive practices and his vision of a global research enterprise that enhances human flourishing, especially for the world's most disadvantaged populations.

**Keywords.** Research ethics, global health, Common Rule, bioethics, ethical paradigms, global health governance, human participants, extractive research practices

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In 1869, at the height of the Industrial Revolution, poor black farmers in the Transkei region of South Africa (SA) were so moved by reports of the poverty and deprivation of workers in cotton factories in England that they sent a GBP46 contribution to the Lancashire Cotton Relief Fund.[1] In *Why Nations Fail*, Nobel laureates Daron Acemoglu and James Robinson explain how inclusive private property ownership rights and fair access to the institutions and practices of trade and commerce enabled these poor but economically independent farmers to support their subjugated brethren in the factories of far-off England.[1] The farmers' gesture of compassion and solidarity predated the Natives Land Act of 1913,[2] which formed part of the legislative architecture of apartheid in SA. Apartheid transformed the inclusive economic institutions that had enabled the farmers into – in Acemoglu and Robinson's terms – an extractive system that stripped them of their rights and agency and facilitated the exploitation of their labour.

At first blush, the history of property rights among smallholder farmers in SA may seem far removed from the ethics and regulation of research involving human participants. However, the history of research in low- and middle-income country (LMIC) settings, from missionary medicine and colonial experiments to the large trials of modern industrialised science, is rife with practices that have extracted the time, energy, data, biological samples and, in many cases, the health and lives of those subjected to biomedical research. Furthermore, these practices were often rationalised by deeply held beliefs about racial, cultural and civilisational inferiority.[3]

Unlike apartheid, the pursuit of new knowledge facilitated by the research enterprise has been widely understood as a noble endeavour, with unlimited potential to improve lives and shape societies. Yet the prominence of research, the perceived nobility of its purpose and the high social status of researchers and research institutions may obscure the considerable power they wield to command resources and compel participation. Confronting and managing these unequal power relationships has therefore been a major concern of the global research ethics community.[4] For more than seven decades, a defining challenge in research involving human participants has been how to appropriately balance their rights, welfare and interests against the considerable social, economic and political power of the institutions undertaking such research.

The urgency of addressing this foundational ethical challenge gained intensity and specificity with the explosive growth of global health research beginning in the last decade of the 20th century, driven in

large part by the HIV pandemic. This phase of research globalisation raised substantial ethical issues, including difficult questions about the nature and scope of exploitation in research,[5] and highlighted the ethical implications of the complex social, economic and political contexts in which international research was being conducted.[6] It also prompted debate about the most appropriate systems and instruments of governance to avoid 'double standards' between high-income countries and LMICs in research ethics.[7,8]

The positive impact of the globalisation of research is incalculable: it has contributed to reductions in mortality, morbidity and poverty, fuelled technological advances that have improved quality of life, and facilitated economic growth and prosperity, even in some of the world's poorest countries.[9] Yet the benefits of research continue to accrue disproportionately to the wealthiest countries, which also hold the greatest power over global institutions of trade and finance.[10] Although access to the fruits of research and science has been recognised as a human right and enshrined in the International Covenant on Civil and Political Rights,[11,12] current conventions in research ethics policy, practice and governance have only recently begun to engage meaningfully with this aspiration.[13,14]

**A disruptive call for a paradigm shift**

In his keynote address at the inaugural meeting of the Global Forum for Bioethics in Research (GFBR), held at the Fogarty International Center of the US National Institutes of Health in 1999, University of Cape Town Prof. Solomon Benatar confronted attendees with a blunt proposition: 'It is clear to many people in developing countries that researchers from elsewhere do not come to visit us predominately for altruistic reasons. There is a widely held perception by many vulnerable people that they are being exploited.'[15] He argued that much of the research conducted by foreign researchers in LMICs is 'almost a sweatshop equivalent of labor to produce information that will be of very considerable interest to markets elsewhere.'[15] Against this backdrop of research as an extractive enterprise, he encouraged attendees not to shy away from the true complexity of the forum's ethical mission: 'You want to foster the empowerment of people through the type of co-operation that may enhance human flourishing generally, and make the public of developing countries feel [like] essential partners in the process of human advancement.'[15] Prof. Benatar challenged the GFBR to spearhead 'a paradigm shift in thinking and action, acknowledging a reciprocal relationship between individuals and society as a notion of interdependence.'[15]

A quarter century after the founding of the GFBR, as we reflect on and celebrate Prof. Benatar's singular contributions to research ethics and global health, it is worth considering whether the paradigm he alluded to has shifted in ways that move research in LMICs away from the extractive practices of its history and toward the inclusive global enterprise he envisioned and has argued persuasively for throughout his illustrious career.

In his challenge to the GFBR, Prof. Benatar was deliberate in his call for a change in 'paradigm' in research ethics, despite his awareness of the conceptual weight the term carries, particularly in the history of science. A paradigm may be understood simply as 'a pattern or model',[16] but more commonly refers to a model that has achieved dominant influence in a particular area of practice or policy. Prof. Benatar's concern was that the prevailing model of research ethics was not fit to meet the challenge he presented. In a subsequent article in *International Affairs*, Benatar *et al.*[17] outlined key features of their vision for a better paradigm:

> 'A set of values that combines genuine respect for the dignity of all people with a desire to promote the idea of human development beyond that conceived within the narrow, individualistic, "economic" model of human flourishing, could serve to promote peaceful and beneficial use of new knowledge and power. A global agenda must extend beyond the rhetoric of universal human rights to include greater attention to duties, social justice and interdependence. Health and ethics provide a framework within which such an agenda could be developed and promoted across national borders and cultures. We contend that failure to make paradigm shifts in ethical discourse and in human co-operation worldwide will increase the likelihood of "revolt from below" and the destruction of so much that has been gained in recent decades (p. 108).'

The development of research ethics in the period following World War II advanced several key principles, including voluntary informed consent, the protection of the lives, dignity and confidentiality of individuals participating in research, and the need to balance risks to research participants against the importance and potential benefits of the research to others. These practices were key elements in the Nuremberg Code of 1947[18] and the World Medical Association's Declaration of Helsinki of 1964,[19] both of which heightened awareness of weak oversight and egregious ethical violations in research. These documents became foundational models of ethical guidance and practice: the Nuremberg Code provided an important template for subsequent developments in human rights,[20] and the Declaration of Helsinki established key ethical requirements for research conducted by physicians on their patients. Both have had enduring influence on research ethics. The Declaration of Helsinki has been revised several times since 1964 in response to developments in medicine and ethics, and has been incorporated, in whole or in part, into national laws in some countries.[21] Other international guidelines have also contributed to the development of enduring norms and ethical principles, including greater appreciation of the ethical importance of active community participation in research that affects them,[22,23] thereby improving the conduct and governance of research globally.[24]

**The emergence of an American position**

Building on the momentum created by the Nuremberg Code and the Declaration of Helsinki, Henry K. Beecher's 1966 article in *The New England Journal of Medicine* exposed ethical violations in published research studies in the US,[25] demonstrating to the US public and political leaders that the ethics of research involving human participants was very much a domestic issue. Also in 1966, Peter Buxtun, an epidemiologist at the Communicable Disease Center (CDC) – renamed in 1970 as the Centers for Disease Control – lodged the first complaint about the US Public Health Service's Syphilis study among black sharecroppers in Tuskegee, Alabama. Buxtun's complaint was dismissed internally at the CDC, and the full extent of the Tuskegee study's ethical violations did not become public until 1972,[26] after which a damning report revealed the scale of the tragedy.[27]

Among the cumulative effects of these reports and revelations was the passage of the National Research Act of 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[28] The Commission was mandated to 'identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects [and to] develop guidelines … to assure that it is conducted in accordance with such principles.'[28] Its landmark output, the Belmont Report, provided both a conceptual framework of ethical principles and considerations and practical guidance on their application to protect human research participants, including informed consent, assessment of risks and benefits, and the selection of subjects.[29] The

US government drew directly on the Belmont Report's principle-based framework to develop federal regulations, which remain the primary governance instrument for research ethics in the US. This translation of 'basic ethical principles' into corresponding procedures, formalised in regulation, represents a unique US contribution to the evolution of global norms in research ethics.[30]

In 1991, these regulations were adopted by the 15 major US federal agencies sponsoring research involving human participants. Because the regulations were 'common' across these agencies, the policy became informally known as 'the Common Rule'.[31] Among its defining features, the Common Rule made eligibility for federal research funding conditional on institutional compliance with its regulations. Failure to comply with these regulations can result in the withholding of awarded funds and, in some cases, corrective intervention by the federal regulatory authority, the Office for Human Research Protections (OHRP), originally known as the Office for Protection from Research Risks (OPRR).[32] Table 1 presents our interpretation of the key features of the Common Rule and the norms it reflects.[33]

**The globalisation of the American position**

The Common Rule's focus on institutional accountability for compliance with a standardised set of research procedures has played a significant role in shaping the global research ethics paradigm. Although the Common Rule is a domestic policy of the US, it has been widely 'exported' and has exerted substantial influence on the development of research ethics globally. Research institutions enter into legal agreements with the US government, known as 'Federal Wide Assurances' (FWA), which require them to comply with US regulations as a condition of receiving funding from the US government. This requirement has led to thousands of research institutions worldwide committing to the Common Rule, even where national policies already exist.[34]

More than 130 countries have developed domestic guidelines for research involving human participants, amounting to >1 000 individual guidance documents,[35] while >9 000 institutions worldwide hold an active FWA with the US OHRP, including >2 900 US-based institutions and >7 000 foreign institutions.[36] This requirement that foreign institutions comply with the Common Rule has normalised its standards globally, which has likely neutralised more critical engagement with the policy's logic and its implications for global research ethics.

The extensive reach of the US federal government's authority to regulate research involving human participants through the provisions of the Common Rule is anchored in the 'commerce clause' of the US Constitution (Article 1, Section 8, Clause 3),[37] which permits the government authority to regulate commerce with foreign countries. There is, however, a strong general presumption against the application of US law in other countries – known as 'extraterritorial application'[38,39] – and even some esoteric debate in legal scholarship about the extraterritorial application of the Common Rule regulations in particular.[40] One argument in defence of such application is that institutions retain the choice to accept or decline US federal research funding; no country is compelled to adopt the Common Rule. It is, in this sense, a conditional and voluntary policy. Nevertheless, the sheer scope of US funding for global research is considerable, and few recipients decline such awards.

**Mapping Prof. Benatar's paradigm shift**

The US model of governance and oversight of research involving human participants has achieved a form of global omnipresence, owing both to the bioethical foundation provided by the Belmont principles and subsequent scholarship,[41] and to the scale and conditions of its export. It is an undisputed central component of the global research ethics paradigm. Although the US model has made a significant positive contribution to the evolution of research ethics – especially through expanding institutional capacity and promoting institutional commitment to protecting individual research participants from harm – its alignment with Prof. Benatar's vision of a research enterprise that enhances human flourishing remains a matter of debate.[42-46] There has been a proliferation of national research ethics guidance documents in LMICs, often without significant increases in domestic research investments. These documents frequently emphasise the ethical importance of local sociocultural contextual factors alongside the core procedural requirements of the US model.[47] Taken together, these developments suggest growing recognition of the limitations of the Common Rule model.

Although Prof. Benatar was not referring exclusively to the Common Rule in his 1999 call for a paradigm shift, he was acutely aware of its central role and influence on research ethics practices globally at the time, the nature of the power relations underpinning its extensive global application, and the persistence of extractive research practices under its auspices. For these reasons, the Common Rule can be understood as a central element of the 'paradigm' he identified as requiring critical review and reform.

Prof. Benatar's call to action at the GFBR was intentionally disruptive, advocating a fundamental change to the model, its underlying assumptions and the ethical discourse it generates[17] – a 'paradigm shift'. Table 2 elaborates a set of possible 'shifts' associated with the key features outlined in Table 1, which seem most responsive to his call for research ethics to more intentionally reject extractive practices and to foster inclusiveness and human flourishing.

## The mother of invention

In 1999, Prof. Benatar urged thought leaders from around the world to expand their thinking about the ethics and governance of research involving human participants in ways that could contribute to new forms of value, including greater attention to the broader societal implications of research in ethics review (beyond implications for individual research participants), deeper engagement with the true ethical complexities of research (beyond the minimal procedural requirements of the US model), stronger inclusion of local and regional perspectives in the evolution of the research enterprise[48] and elimination of predatory practices in participant recruitment and research data management.

Prof. Benatar framed his expansive global aspirations as opportunities to be considered, embraced and realised. At the time, they were provocative and not easily implementable, but they were not fundamentally at odds with the foreign policy of the US federal government. The current context, however, is markedly different. The US government has shifted away from global engagements and commitments,[49] including through its 2025 America First Global Health Strategy,[50] which emphasises efficiency in foreign aid and reframes commitments to strengthening health systems capacity in partner countries in terms of strategic bilateral agreements. Ostensibly, such bilateral partnerships may enable more efficient progress in areas such as health system and research capacity, which have been slow to materialise under previous multilateral agreements.[50]

However, a recent investigation by Stephanie Nolen[51] described an aggressive effort by the US government, in bilateral negotiations with the government of Zambia, to acquire health information databases and biological samples, alongside expanded access to the country's copper and lithium mining rights. These concessions are being leveraged through the threat of withholding funding for health system improvements and promised debt relief.[51] Prof.

**Table 1. Key features of the US Common Rule**

| Feature | Description/Explanation |
|---|---|
| Reactive | Nuremberg; Tuskegee; Beecher. |
| Corrective | The need to ensure voluntary participation; the need to address the roles and responsibilities of institutions in previous violations. |
| Institutional | The Common Rule is primarily a policy of institutional accountability v. research ethics guidance for investigators. |
| Protectionist | Emphasises the protection of participants from research-related harm. |
| Procedural | Emphasises institutionalised procedures v. substantive guidance. |
| Regulatory compliance | Emphasises compliance with rules and procedures. |
| Conditional | Compliance is required only by institutions receiving US federal research funding. |
| Acontextual | The regulations are applied equally to all research involving human participants, regardless of methods and research contexts; universalist. |
| Fixed | Standardised processes, which do not evolve with experience, evidence and analysis; the 25-year 'revision' of the Common Rule resulted in very little change (the 'New' CR took effect 21 January 2019).[33] |
| Industrialised | Professionalisation of research ethics review; accreditation of institutions. |
| Individualistic | An exclusive focus on individual research participants – consideration of ethical obligations beyond individual research participants is prohibited by IRBs. |

US = United States; CR = Common Rule; IRBs = Institutional Review Boards.

**Table 2. Proposed features of Prof. Benatar's 'paradigm shift'**

| Current paradigm feature | Shift | Description/Explanation of the shift |
|---|---|---|
| Reactive | Proactive | Anticipate ethical challenges in research and how they may be addressed and managed. |
| Corrective | Creative | Build on successes with institutional, legal and civil society strategies to protect the rights and interests of human subjects by creating new approaches to improve the social value of research. |
| Institutional | Global | Move beyond the insular regulatory culture of institutional accountability to a global culture of learning and problem solving, e.g. similar to how clinical problems are addressed globally. This aim could be advanced through better uptake of the rich conceptual and empirical academic literature in research ethics. |
| Protectionist | Inclusive | Reimagine the role and contributions of research in society with greater emphasis on promoting broader engagement with and participation in research to create social value. |
| Procedural | Substantive | Re-examine the purpose and effectiveness of established (and required) procedures and build better substantive guidance for investigators, research institutions and funders. |
| Regulatory compliance | Effective | Expand the focus of research ethics strategies beyond the currently narrow regulatory focus on informed consent, confidentiality and privacy to a culture of quality and value, i.e. to what degree are research ethics strategies effective at addressing ethical challenges that arise in research and improve the value of research for society, particularly those that fall beyond the narrow focus of the Common Rule? |
| Acontextual | Context-sensitive | Tailor research ethics to challenges associated with unique features of specific local research contexts, rather than ignoring these features. For example, should there be an implementation science for research ethics?[48] |
| Fixed | Innovative | Incorporate deliberate innovation in research ethics governance to address unique circumstances and to evaluate the effectiveness and adequacy of established practices. |
| Industrialised | Empirical | Evolve from a culture of administering standardised regulatory procedures to a global culture of empirical testing of research ethics strategies with strong links to organisational learning in research institutions and in organisations participating in the research enterprise. |
| Individualistic | Emphasis on social value | Move beyond the restrictive focus on the protection of individual research participants to develop better strategies for anticipating and addressing broader community and societal implications of research. |

Benatar's concerns about the coercive and extractive potential of the global research paradigm[15] thus appear increasingly salient. His aspirations now read less as provocation and more as necessity.

The shifts presented in Table 2 provide only a modest reflection of how Prof. Benatar has shaped our own moral imagination regarding possible futures for research ethics and global health. They offer a coherent framework for shaping and advancing ongoing critiques of the global health paradigm associated with the Common Rule, as well as of the extractive tendencies reflected in the America First Global Health Strategy described above, which may exacerbate existing weaknesses in the still-dominant global research ethics paradigm.

Prof. Benatar's early career was as a physician and scholar working under SA's apartheid regime – the very conditions that had radically altered the political and economic institutions that once enabled the generosity and solidarity of smallholder farmers in the Transkei. The consequences of this destructive paradigm shift in his home country had a profound influence on his worldview and fuelled his lifelong dedication to justice in research and global health. Among his most enduring contributions is his emphasis

on moral imagination[52] – the insistence that the willingness and ability to envision better and more fair circumstances for the world's most disadvantaged populations is itself a moral imperative. His extensive body of scholarship provides direct access to his own moral imagination: a clear and compelling vision of what may be possible through thoughtful, collective global action.

We have benefited greatly from both his wisdom through collaborations in research, writing and teaching, as well as from the richness and generosity of his friendship. Alongside his emphasis on moral imagination, Prof. Benatar has advocated for,[53] and consistently demonstrated, moral courage in advancing the interests of the least advantaged in the face of powerful constraints on equity and fair opportunity. A quarter century after his call for a paradigm shift in research ethics, perhaps the circumstances are right and the collective fruits of his labour as a teacher and global leader are now ripe enough to allow us to complete that shift.

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