

Impact case study (REF3)

Institution: University of Central Lancashire		
Unit of Assessment: 30 Philosophy		
Title of case study: Preventing Ethics Dumping with a Global Code of Conduct for Research in Resource-Poor Settings		
Period when the underpinning research was undertaken: 2003-2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Prof Doris Schroeder (DS)	Professor and Centre Director	2002-present
Dr Kate Chatfield (KC)	Senior Research Fellow and	2001 - present
Dr Miltos Ladikas (ML)	Deputy	2003 – 2019
Dr David Coles (DC)	Senior Research Fellow	2007 - 2018
Julie Cook (JC)	Senior Research Fellow	2005 - present
	Research Fellow	
Period when the claimed impact occurred: 2018 – present		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>The <i>Global Code of Conduct for Research in Resource-Poor Settings</i> (GCC) was adopted by the European Commission in 2018 to counter 'ethics dumping', the off-shoring of unethical research to resource-poor settings. Recipients of EU funding now have to show adherence to the GCC. If they fail to do so, EC ethics panels can request modifications of study protocols. Additional international research funders who have implemented the GCC include the European & Developing Countries Clinical Trials Partnership (EDCTP) and the Dutch Research Council. The first charitable foundations to adopt the GCC were the Abaseen Foundation (UK) and the Global Values Alliance (Switzerland) and the first universities were the University of Cape Town, the University of Central Lancashire, and the University of Witwatersrand. For the EC and the EDCTP alone this equates to nearly GBP354,000,000 of research funding being spent in accordance with the GCC, ensuring that research complies with the core values of fairness, respect, care and honesty.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>Achieving equity in international research is one of the pressing concerns of the 21st century. Globalisation presents many "opportunities" for the deliberate or accidental export of unethical research practices from high-income countries (HICs) to low and middle-income countries (LMICs). This has given rise to the concept of 'ethics dumping'.</p> <p>Cases of ethics dumping [4] occur across the spectrum of research disciplines and can affect individuals, communities, animals and the environment (see Figure 1). In recognition of the need to prevent ethics dumping, the EU-funded TRUST project (2015-2018) developed a new ethical framework around the four values of fairness, respect, care and honesty. The <i>Global Code of Conduct for Research in Resource-Poor Settings</i> (GCC) is one of the products that uses the framework. For its development, Schroeder led an interdisciplinary collaboration with 13 teams and 12 international advisors. The group included multi-level ethics bodies, international organisations (e.g. UNESCO), policy makers, civil society organisations, research funders, industry, academics from a range of disciplines, and representatives from vulnerable research populations [5].</p>		

Schroeder and her team have been working collaboratively with communities in LMICs to achieve equity for vulnerable populations in research since 2003. Collaborations with the San indigenous community in South Africa began in 2003, and with sex workers in Nairobi in 2007. During the ProGRess project (2013-2016), which Schroeder led, the need for a short, value-based and interdisciplinary ethics code to protect vulnerable populations in LMICs from exploitation became clear. The GCC is the culmination of this value-based work.

Focusing on the core value of fairness led to publications on obligations towards research participants after research projects had finished. This included work that was translated into Portuguese to train Brazilian ethics committees, highlighting the duty to provide a successfully tested drug to those who took part in the clinical trial after their participation was completed [2]. Focusing on the core value of respect, Schroeder expanded her intercultural work from Africa to the Middle East in 2010, leading to a co-authored book with a former President of Iran [6] as well as other publications [3]. This research also led to the decision not to include 'dignity' in the new TRUST moral framework.

Focusing on the core value of care, Schroeder has become well known for her work on vulnerability, having developed this widely cited definition:

“To be vulnerable means to face a significant probability of incurring an identifiable harm, while substantially lacking the ability or means to protect oneself.” [1]

Based on almost 15 years of research to protect vulnerable populations in LMICs from exploitation, Schroeder's team formulated the value-based approach to research ethics around fairness, respect, care and honesty. Using these values, Schroeder drafted the first version of the GCC as the lead drafter. The final version of the GCC was agreed by 56 authors, drawn from all continents and all research stakeholder groups.

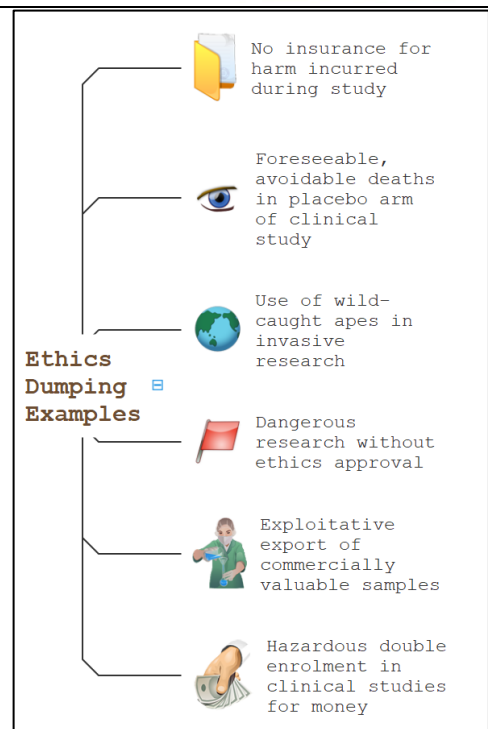


Figure 1 - Examples of Ethics Dumping

3. References to the research (indicative maximum of six references)

- Schroeder, D. & Gefenas, E. (2009) Vulnerability: Too Vague and Too Broad? *Cambridge Quarterly of Healthcare Ethics*, 18(2): 113-121. <https://doi.org/10.1017/S0963180109090203>
- Schroeder, D. (2008) Post-Trial Obligations, *Reciis*, 2(Sup1): Sup63-73. <https://doi.org/10.3395/reciis.v2.Sup1.210en>
- Schroeder D. (2008) Dignity – Two Riddles and Four Concepts, *Cambridge Quarterly of Healthcare Ethics*, 17(2): 230-238. <https://doi.org/10.1017/S0963180108080262>
- Schroeder, D., Cook Lucas, J., Hirsch, F., Fenet, S. & Muthuswamy, V. (eds.) (2018) *Ethics Dumping Case Studies from North-South Research Collaborations*. Springer Briefs in Research and Innovation Governance. Cham: Springer International Publishing. <https://www.springer.com/gb/book/9783319647302> (Open access)
- Schroeder, D., Chatfield, K., Herrisone-Kelly, P., Singh, M., Chennells, R. (2019) *Equitable Research Partnerships: A Global Code of Conduct for Research in Resource-poor Settings*. Springer Briefs in Research and Innovation Governance. Cham: Springer International Publishing. <https://www.springer.com/gp/book/9783030157449> (Open access)

6. Schroeder D. & Bani-Sadr, AH (2017) *Dignity in the 21st Century – Middle East and West*. Springer Briefs in Philosophy. Cham: Springer International Publishing. <https://link.springer.com/book/10.1007%2F978-3-319-58020-3> (Open access)

All books and journal articles listed were peer reviewed.

Project Name	Years	Funding	UCLan Staff
PROGRESS Promoting Global Responsible Research & Social and Scientific Innovation	2013-2016	EC FP7 EUR1,486,664	DS, ML, JC
TRUST Creating and enhancing TRUSTworthy responsible and equitable partnerships in international research	2015-2018	EC H2020 EUR2,650,960	DS, KC, DC, JC

4. Details of the impact (indicative maximum 750 words)

Researchers in at least 44 countries are aligning their study protocols with the GCC, of which Schroeder is the lead author.

Adoption by the European Commission

In June 2018, the European Commission's Deputy Director-General for Research announced in the European Parliament:

"I would like to inform you that the Code ... will be soon included in the Participant Portal of Horizon 2020 as a reference document to be consulted and applied by all relevant research projects and serve as an education tool for the younger generation of researchers" [A].

The GCC also received a personal endorsement from the Director General for Research and Innovation of the European Commission, Jean-Eric Paquet: **"No more 'ethics dumping' in research in middle- and lower-income countries. Join the fight against double standards by following the Commission-endorsed TRUST project" [D].**

As a result, the GCC has had immediate international impact because it applies to all applicants for EU funding who work with partners from LMICs. A conservative estimate for EC funding associated with the GCC requirement up to March 2020 is EUR44,000,000 [B].

In funding proposals to Horizon 2020, applicants who intend to work in LMICs have to explain how their research will align with the GCC, which is checked by ethics reviewers. As an advisor on research ethics to the EC noted in Nature in July 2018: **"I could envisage [ethics] reviewers now looking suspiciously at any application for funds that entailed research by wealthy nations on the less wealthy that did not mention the code" [C].**

Almost 700 ethics reviewers are recruited from all over the world for the EC and have to be up to date on all mandatory reference documents, including the GCC. The same applies to all EC personnel who work with the ethics documentation. To this end, training of 40 EC personnel was undertaken in Brussels in December 2018 by Schroeder, supported by representatives from vulnerable research populations.

Adoption by international research organisations

The GCC has been adopted as a mandatory reference document by the European & Developing Countries Clinical Trials Partnership (EDCTP), which funds clinical research to combat poverty-related diseases in sub-Saharan Africa. By July 2020, the EDCTP had applied the GCC for two years, regarding projects with an estimated total value of EUR350,000,000 [E]. Dr Makanga, Director of the EDCTP, writes in a letter: **"... the GCC became indispensable for us in very**

short time” [E]. In January 2020, the Dutch Research Council piloted the GCC in a call for research projects focusing on “**policy interventions in developing countries**” [F].

The first three university adopters are the University of Cape Town (RSA), the University of Central Lancashire (UK), and the University of Witwatersrand (RSA). All research staff at these universities who work in resource-poor settings now have to show adherence to the GCC in their ethics approval applications. Associate Prof. de Vries from the University of Cape Town writes that the GCC “**has been tremendously useful in further elevating the standards of health research on the African continent**” [G].

The Abaseen Foundation (UK) and the Global Values Alliance (Switzerland) are the first two charitable foundations to adopt the GCC, in April 2019 and January 2020 respectively.

GCC as a Professional Ethics Standard to Influence Research Protocols

Since its launch in 2018 the GCC has been translated into French, German, Spanish Portuguese, Mandarin, Hindi, Russian and Japanese. The availability of the GCC in multiple languages enables thousands of researchers to have access to the document. This allows a wider body of professionals to adopt the four core values of the code into their research practice.

The four values framework also forms the basis of the two new Oxford University Press Epigeum e-learning courses on being an ethical researcher, which also includes the GCC. The training is currently undertaken worldwide at 35 universities, in the UK, Australia, the Republic of Ireland, continental Europe and South East Asia [I]. The incorporation of the GCC in these training materials enables researchers to learn the importance and value of ethical research from the outset. This takes ethical practice beyond just a funding requirement and embeds it into the research process itself, ensuring that ‘ethics dumping’ is prevented at every opportunity.

Two books authored by the GCC developers [4, 5] are available from Springer through Gold Open Access. This provides another route through which researchers can engage with the core principles of the GCC and incorporate them within their research. The first book provides case studies of ethics dumping [4] and has received more than 133,000 downloads since January 2018. The second book [5] analyses the development of the GCC and has been downloaded 62,000 times since its publication in 2019.

Contributions to Widening Public Access to the GCC

Multiple avenues have been explored in order to expand the understanding of the GCC beyond a research funding context. This has enabled a wider public understanding of the values of fairness, respect, care and honesty exemplified in the GCC. The GCC was presented by invitation at the Vatican to delegates representing all major world religions, via the Ethics in Action initiative hosted by the Pontifical Academy of Sciences and supported by the Pope [H]. The focus of Ethics in Action was to discuss ethical and safe solutions to establish best practices and good standards for the beneficial development of Artificial Intelligence [H]. Promotion, awareness and uptake of the GCC has been facilitated through a series of media articles and blog posts in popular, publicly accessible, news streams. These include; *Nature* [C], *The Guardian*, *The Independent*, *The Economist*, *Economist Radio*, *Times Higher Ed.*, *The Conversation*, *The Biologist*, *Nature Masterclasses* and German national radio network *Deutschlandfunk*.

The creation of a stand-alone website enables anyone to access and download the GCC. Additionally, the website provides a hub for Open Access learning materials, including videos and academic publications.

The following diagram shows the countries where the GCC has been employed because the funder, the university or the project lead required it (European Commission data only for 2019) [J].

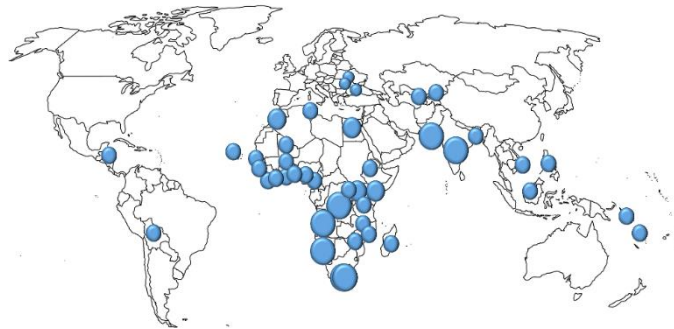


Figure 2 - Countries where the GCC has been employed

5. Sources to corroborate the impact (indicative maximum of 10 references)

- A. Transcript of the speech from Wolfgang Burtscher, Deputy Director-General of the Directorate-General for Research and Innovation of the European Commission, http://www.globalcodeofconduct.org/wp-content/uploads/2018/12/TRUSTNewsletter_2018_Issue5.pdf
- B. Statistics provided by EC Research Integrity and Ethics Sector.
- C. NATURE, Europe's biggest research fund cracks down on 'ethics dumping', 03 July 2018, <https://www.nature.com/articles/d41586-018-05616-w>.
- D. Tweet from Director General for Research and Innovation of the European Commission, Jean-Eric Paquet
- E. Letter from EDCTP Director Dr M Makanga, 18 November 2019.
- F. Dutch Research Council (NWO) call for proposals, January 2020
- G. Letter from UCT Associate Professor J de Vries, 22 October 2019.
- H. Programme for Ethics in Action 10, Pontifical Academy of Sciences, October 2018
- I. Email from OUP Epigeum, 29 October 2019
- J. Evidence list of countries with GCC use required by funder, university or PI.