Chapter 1
Ethics Dumping: Introduction

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Abstract Achieving equity in international research is a pressing concern. Exploitation in any scenario, whether of human research participants, institutions, local communities, animals or the environment, raises the overarching question of how to avoid such exploitation. Agreed principles can be universally applied to research in any discipline or geographical area, whatever methodologies are employed. This chapter introduces a collection of case studies, presenting a range of up-to-date examples of exploitation in North-South research collaborations, in order to raise awareness of ethics dumping.

Keywords Research ethics · Responsible research and innovation
Ethics dumping · North South collaborations · Exploitation

Introduction

Achieving equity in international research is a pressing concern. Exploitative North-South research collaborations often follow patterns established in colonial times. Whether the objects of exploitation are human research participants, institutions, local communities, animals or the environment, this raises questions about how such exploitation can be avoided.

"Dumping" is a term used in economics to describe predatory pricing policies in international trade (Investopedia nd). Dumping usually involves substantial export

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D. Schroeder et al. (eds.), *Ethics Dumping*, SpringerBriefs in Research and Innovation Governance, https://doi.org/10.1007/978-3-319-64731-9_1

volumes of a product and often has the effect of endangering the financial viability of manufacturers of the product in the importing nation.

"Ethics dumping"[1] occurs mainly in two areas. First, when research participants and/or resources in low- and middle-income countries (LMICs) are exploited *intentionally*, for instance because research can be undertaken in an LMIC that would be prohibited in a high-income country. Second, exploitation can occur due to insufficient ethics awareness on the part of the researcher, or low research governance capacity in the host nation.

This book provides 14 case studies of ethics dumping and one case of good practice. Its purpose is to address the second cause of ethics dumping by reducing researchers' lack of awareness.

Background to Ethics Dumping

Jeffrey Sachs, one of the world's leading experts on economic development, noted:

> Technology has been the main force behind the long-term increases in income in the rich world, not exploitation of the poor. That news is very good indeed because it suggests that all of the world … has a reasonable hope of reaping the benefits of technological advance (Sachs 2005: 31).

It is essential that the progress of science and technology is not accompanied by reasonable claims of exploitation of the poor and vulnerable. This is not easy to achieve, as both moderate poverty[2] and extreme[3] poverty increase the likelihood that communities and individuals will be exploited.

Unevenness in ethical and legal standards has led to the exploitation of human research participants and resources in LMICs that could have been avoided. The international debate on bioethics has noted the existence of "double standards" (Macklin 2004).

Vulnerable populations and research participants worldwide have been protected for decades by research ethics committees (ECs), but their success depends on three conditions. First, a relevant EC must exist with the capability, resources and independence to deal with ethics applications. Second, such committees must be able to recognize culturally sensitive ethical issues in complex settings. Third, a

[1]The term was introduced by the Science with and for Society Unit of the European Commission: "Due to the progressive globalisation of research activities, the risk is higher that research with sensitive ethical issues is conducted by European organisations outside the EU in a way that would not be accepted in Europe from an ethical point of view. This exportation of these non-compliant research practices is called ethics dumping" (European Commission nd).

[2]Households can only just meet basic needs for survival, with little left for the education of their children.

[3]Households cannot meet basic needs for survival (e.g. chronic hunger, no access to health care).

compliance mechanism must be in place. As these conditions cannot be guaranteed in LMICs, there is always the risk of an implementation gap.

The first condition (a capable EC) cannot be taken for granted, as in this list of constraints on African ECs:

- Insufficient resources
- Lack of or insufficient expertise on ethical review
- Pressure from researchers
- Lack of active or consistent participation of EC members
- Lack of recognition of the importance of EC functions
- No or poor support from the EC's institution
- Lack of independence
- Pressure from sponsors
- Unequal treatment of applicants in review (Nyika et al. 2009: 193)

The importance of cultural sensitivity is demonstrated in Chap. 4, which describes a study that was granted ethics approval in both a high-income *and* a middle-income country, but failed to consider culturally relevant ethical concerns. The third condition (a compliance mechanism) exceeds the remit of this book, but will be considered further in the TRUST project.[4]

The Cases[5]

Cases of exploitation in research have been used to illustrate unacceptable practices since the mid twentieth century. However, infamous medical experiments, as cited in many textbooks—for example, diabolical Nazi experimentation and the Tuskegee study (Emanuel et al. 2011)—are not always a suitable sole learning source for twenty-first-century researchers.

The case studies in this book will help researchers understand better how exploitation can occur in the context of contemporary North-South collaborations. These are genuine cases, assembled from four sources. TRUST experts contributed case studies. Two non-governmental organizations (NGOs) each contributed a case study. Indian bioethicists were invited to a workshop in Mumbai in 2016 to share their ideas, and a case study competition launched through TRUST sourced additional material from LMICs.

[4] http://trust-project.eu/.

[5] Responsibility for the accuracy of each case study, the integrity of the information cited and the legitimacy of its acquisition rests with the respective authors. This disclaimer is especially relevant to those cases where the editors could not verify publicly available sources.

The selected case studies have been grouped into six themes:

- Vulnerable populations
- Clinical trials
- Benefit sharing
- Animal research
- New and emerging technologies
- Ethical governance and processes

Vulnerable Populations

"Social Science Research in a Humanitarian Emergency Context", by Gwenaëlle Luc and Chiara Altare, describes conflicts for an international NGO in an African village. The community felt betrayed when unexpected findings about health-seeking behaviours that revealed illegal female genital mutilation (FGM) were shared publicly and contributed to cultural stigmatization. The NGO performed a dual role as assistance provider and researcher, which endangered the neutrality of the data collection and, in the end, the acceptability of its assistance.

Roger Chennells and Andries Steenkamp criticize an international research project, which aimed to examine the genetic structure of "indigenous hunter-gatherer peoples" from Namibia and compare the results with "Bantu from southern Africa". A supplementary document published with the study contained conclusions and details that the San regarded as pejorative and discriminatory; "International Genomics Research Involving the San People" details the perceived exploitation and the San response.

In "Sex Workers Involved in HIV/AIDS Research", Anthony Tukai tells the personal story of supporting a vulnerable and stigmatized population in a Nairobi slum. In a demonstration of good practice, the case outlines empowerment mechanisms that reduced the potential for exploitation.

In "Cervical Cancer Screening Trials on Poor and Illiterate Women in India", Sandhya Srinivasan, Veena Johari and Amar Jesani describe three internationally funded clinical trials that took place between 1998 and 2015 to determine whether primary healthcare workers could conduct cervical cancer screening using cheap visual inspection. These non-drug trials did not require regulatory permission, and the existing standard of care was misconstrued. According to the authors, known and effective methods of cervical cancer screening (by Pap smear) were withheld from 141,000 women even though they have represented the standard of care in India since the 1970s. Two hundred and fifty-four women in the no-screening arm died from cervical cancer.

Clinical Trials

Godfrey Tangwa questions clinical trials in "A Match to Local Health Needs? Ebola Vaccine Trials". The Ebola epidemic of 2013 in West Africa which affected three countries had been brought under reasonable control by 2015. This case study is about a phase I/II clinical trial (testing for safety and immunogenicity) of a candidate Ebola virus vaccine in 2015 in a sub-Saharan country which had not registered any cases of Ebola. The study was sponsored and funded by one of the biggest northern multinational pharmaceutical companies and had government support. But public concerns about the risk of a public health disaster meant the trial was suspended. A commentary by Katharine Browne and Doris Schroeder discusses the importance of trust, highlighting differences from a 2014 phase I Ebola vaccine trial in Canada.

In "Hepatitis B Study with Gender Inequities", Olga Kubar explores why a proposed internationally sponsored study in Russia was not approved by the local EC. Indications of exploitation consisted of inadequacies in the study's design compared with its announced purpose and the indirect inclusion of women in the trial without their informed consent. On the basis of non-compliance with national and international regulatory and ethical requirements, this trial was not approved, providing an example of successful research ethics governance.

In resource-limited settings, healthy volunteers are most often poor people with low literacy levels who might not understand the risks they are taking, and are in no position to refuse even small financial incentives. Participation in clinical trials is a critical source of income, and some volunteers covertly enrol in several studies simultaneously. This exposes them to medical risks (e.g. drug-drug interactions) and also potentially biases the study data; "Healthy Volunteers in Clinical Studies", by Klaus Leisinger, Karin Schmitt and Francois Bompart, provides a recommendation to protect healthy volunteers from such exploitation.

Benefit Sharing

In "An International Collaborative Genetic Research Project Conducted in China", Yandong Zhao and Wenxia Zhang describe how US university researchers collected blood samples from villagers with the cooperation of local research institutes and the government. The US team was later accused of violating research ethics principles by not adequately informing participants and not sharing benefits fairly. Subsequent investigations by American and Chinese media and authorities showed that the US research institute, its personnel and a pharmaceutical company were benefiting substantially from the project, while the Chinese research participants and the government were not.

Animal Research

In "The Use of Non-human Primates in Research", Kate Chatfield and David Morton show that since regulations on the use of non-human primates are tight in the European Union the number used has declined. However, the increase in numbers used elsewhere indicates that researchers from high-income countries are taking advantage of variations in standards, legislation and humane practices to conduct experiments through collaborative efforts in countries where regulation is less strict.

New and Emerging Technologies

Jaci van Niekerk and Rachel Wynberg present concerns about research to develop a genetically modified "vitamin-enriched" banana for cultivation in Uganda through a proposed trial with North American university students. "Human Food Trial of a Transgenic Fruit" explains how northern researchers and philanthropic organizations determine research priorities without necessarily involving affected LMICs. The case highlights differences between the concepts of food security and food sovereignty, illuminating different approaches to addressing poverty-induced hunger and malnutrition.

"mHealth" is the application of mobile phones or other remote monitoring devices to health care. Mobile phones that can run software applications are increasingly used to improve diagnosis, personalize care and expand access to information and services. But mobile phones also collect a wide range of personal information from users. In "ICT and Mobile Data for Health Research", David Coles, Jane Wathuta and Pamela Andanda focus on the potential ethical issues as researchers and clinicians attempt to minimize unintended harms in new digital territory.

Johannes Rath describes "Safety and Security Risks of CRISPR/Cas9" and other novel genome editing technologies. The case focuses on the unresolved ethical issues related to safety and security in the proliferation of a new and very powerful technology at a time when tailored ethical and legal frameworks at the international, national and local levels are missing.

Ethical Governance and Processes

In "Seeking Retrospective Approval for a Study in Resource-Constrained Liberia", Jemee Tegli describes an attempt to seek ethics approval for an anthropological study after it had been conducted. "Emergency research" was used as a cover to

avoid the review process, although emergency research regulations stipulated full disclosure of proposed research prior to implementation.

In "Legal and Ethical Issues of Justice: Global and Local Perspectives on Compensation for Serious Adverse Events in Clinical Trials", Yali Cong analyses a situation in which a major international pharmaceutical company sponsored clinical research in an LMIC and applied a double standard in dealing with serious adverse events (SAEs). A 78-year-old Chinese woman joined a clinical trial, and the sponsor paid the cost of medical care arising from an SAE, but refused the family's request for compensation. The family sued the company and the hospital in litigation that continued for nine years.

The editors of this collection hope that it contributes to raising awareness about the dangers of ethics dumping and unethical conduct in North-South research collaborations and promotes ever higher ethical standards in research conducted anywhere in the world.

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