ETHICS DUMPING: TRUST code for European Commission research funding

FATIMA ALVAREZ CASTILLO
UNDERSTANDING THE SOCIAL WORLD (USW): a research & consultancy group Inc.

TRUST

Equitable Research Partnerships

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TRUST PROJECT

landmark collaborative initiative among organisations in Europe, Africa and Asia, to

directly counter ‘ethics dumping’ which is the

- practice of exporting unethical research practices to low and middle income countries (LMICs)

- practice that would be ethically unacceptable in Europe but are done in LMICs where strong legal frameworks and ethics compliance mechanisms may be lacking

- practice of double standard (R Macklin, 2004)

Produced *Global Code of Conduct for Research in Resource-Poor Settings*

- the first comprehensive global code of conduct to guide researchers from high-income countries when they undertake work in low- and middle-income settings.
- drawn up thru extensive engagements with highly vulnerable populations (San community and sex workers from Majengo, a low-income neighbourhood of Nairobi), researchers, research councils, policy advisors, industry representatives and research funders.

Ethics Dumping : Case Studies from North South Research Collaborations

2018. Doris Schroeder · Julie Cook François Hirsch · Solveig Fenet Vasantha Muthuswamy   Editors. Springer Open.

The code emphasizes four values that are important for equitable research partnerships between researchers and funders from high income settings and communities, research participants and researchers from lower income settings. The values are: **Fairness, Respect, Care and Honesty**

- 23 articles on equitable research partnerships between high-income and low- and middle income settings.
- Some articles are substantial whilst others are procedural (e.g., requiring a clear mechanism for feedback, complaints or allegations of misconduct is available, which can also be accessed by illiterate or impoverished research participants)
- The code does not repeat standard requirements in ethical research

Code presented at

- meeting of the Leadership Council of the Sustainable Development Solutions Network in Stockholm on 15 May 2017
- to the European Parliament organized event on 29 June 2018 featuring keynote speaker professor Jeffrey Sachs.
- The European Commission’s Ethics and Research Integrity Sector in the Directorate-General for Research and Innovation intends to propose the code as a reference document for future research projects seeking funding under the EU’s Framework Programmes for research and innovation.

- ProGReSS

PROmoting Global REsponsible research and Social and Scientific Innovation

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TRUST
Creating and Enhancing Trustworthy, Responsible and Equitable Partnerships in International Research"
23rd to 25th May 2016

- The Constant Gardener

by John le Carre

Exploitative North-South research collaborations many times follow patterns established in colonial times

Not exactly research, but

- In 1949, Filipino doctor Abelardo Aguilar was testing micro-organisms he had isolated from soil samples in his back garden in Iloilo when he chanced upon bacteria that would later lead to the development of the antibiotic erythromycin.

  Aguilar was then working for the U.S. pharmaceutical giant Eli Lilly Co., which has since earned billions of dollars by marketing the drug under its brand-name, Ilosone.
- Aguilar tried but failed for 40 years to get some royalty for his work. He died 1993 at age 76. Even the help of Sen Flavier did not produce positive result for him.
- For Third World experts Aguilar is a symbol of the double- standards in international patent laws that let Western transnationals profit from patent laws derived from indigenous knowledge, scientific expertise or biodiversity found in developing countries — all in the name of intellectual property rights.

Source:http://www.ipsnews.net/1994/11/medicine-philippines-who-really-discovered-erythromycin-1-an-inter-press-service-feature/

Cervical cancer screening case in India

- Three clinical trials in India 1998 to 2015 to determine whether trained health care workers could conduct cervical cancer screening in a community using cheap methods of testing – primarily visual inspection with acetic acid
- Trials conducted on approximately 374,000 women, of whom about 141,000 were placed in the control arm (no screening).
- Although the standard of care for testing of the disease in India has been the Pap smear since the 1970s, screening for cervical cancer was not available universally under a government programme, and for the study purposes the standard of care was therefore misconstrued to be no screening.
- Known and effective methods of screening for cervical cancer were therefore withheld from 141,000 women in areas where it was known to be of high incidence and prevalence.
- 254 women in the no-screening arm died due to cervical cancer as per the latest published reports on the three trials.
- A no-screening control arm would not have been allowed in the USA, but was accepted by the US funders for clinical trials in India.

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Cervical cancer screening case in India

The Declaration of Helsinki is clear on this issue. Such studies are only allowed if the patients who receive no intervention will not be subject to serious or irreversible harm as a result of taking part in research

Cervical cancer screening case in India

- Some argue that the issue becomes less clear in settings where no medical care is available at all, studies sponsored by high-income countries may be the only access to healthcare poor patients have. Hence, half of the patients in a study with a no intervention control arm might still benefit.
- Illustrates Double Standard.

Genomic Sequencing of the San

- The San people of southern Africa are among the most-studied indigenous groups in the world. Unknown # of researchers have investigated their hunter-gatherer lifestyles, click languages and ancient rock art, and San individuals were some of the first from Africa to have their whole genomes sequenced

Genomic Sequencing of the San

- In 2017, 3 San communities in South Africa issued their own research-ethics code that could be the first from any indigenous group in Africa.
- The code was developed by traditional leaders of the !Xun, Khwe and !Khomani groups of San, which represent around 8,000 people in South Africa. This process was supported by TRUST.
- The impetus for the ethics code was the 2010 publication, in *Nature*[1], of the first human genome sequences from southern Africa: those of Archbishop Desmond Tutu, winner of the 1984 Nobel Peace Prize, and four San men from Namibia. The Namibian government and ethics committees at the scientists' universities in Australia, South Africa and the United States approved the study. The researchers also filmed the San men giving verbal consent with the help of a translator.

(. (https://www.nature.com/news/south-africa-s-san-people-issue-ethics-code-to-scientists-1.21684)

Genomic Sequencing of the San

- Issues:

- Consent
- Derogatory language in the article (e.g “Bushman”). *“No other recent research has been perceived as being so insulting and arrogant to San leaders*,” (Roger Chennells, lawyer of the San.)

Genomic Sequencing of the San

- While the code may carry no legal weight, the San hope that it will achieve the same influence as guidelines for working with Aboriginal communities in Australia where researchers must get approval from groups that represent local or regional indigenous communities. A 2011 study[2] reporting the first genome of an Aboriginal Australian (taken from an early-twentieth-century hair sample) was nearly scrapped because the scientists had not initially sought the endorsement of an Aboriginal group.

Andreis Steenkamp, well loved
San leader in the Kalahari

Members of the San Council, South Africa

Other common dumping practices

- lack of insurance in clinical trials to cover for potential harm of research participants
- Why unjust? research participants incur a harm when supporting the progress of science for all and are then left to fend for themselves. This is particularly worrying when they do not have access to quality health care as standard, which is likely if they were recruited from a low- or middle-income setting.

Other common dumping practices

- Paltry compensation for research participants
- Absence of technology transfer
- Unfair monetary compensation for local researchers
- Ignoring Relief of Oppression principle

2017 PHREB Guidelines **(ETHICAL GUIDELINES FOR INTERNATIONAL COLLABORATIVE RESEARCH)**

Some major ethical issues when developing countries are involved have constantly been raised like:

The standard of care that shall be used in research in developing countries

The “reasonable availability” of interventions that are proven to be beneficial during the conduct of research

The quality of the informed consent

Inequitable funding

PHREB Guidelines adopted framework of Commission for Research Partnerships with Developing Countries:

Set agenda together

Be accountable

Create transparency

Clarify responsibilities

Promote mutual learning

Enhance capacities

Share data and networks

Disseminate results

Pool profit and merits

Apply results

Secure outcomes

- Codes and guidelines have limited effectiveness for ensuring ethical collaborative research.
- Research funders may have some clout, but
- The best guarantees:

a. integrity of individuals and an ethical culture among persons involved
b. Enabled research participants & communities

Thank you for your time and attention.