

# ETHICS DUMPING

---

Dr. Nandini Kumar

Dr. Urmila Thatte

FERCI

# Ethics of North South Collaboration

---

Highlights

New technologies

---

of Case

Ethical governance/ process

---

Study

Vulnerable population

---

Book

Animal research

---

Clinical trials

---

Benefit sharing

---



## Genetic research involving the San Community



---

2010 project - Complete Khoisan and Bantu genomes from southern Africa published in *Nature*

---

To compare genetics of 'hunter-gatherer people' of Namibia to Bantu tribe of SA including 4 eldest in San communities

---

Many correlations & differences described – some unacceptable to San

---

Namibian authors questioned about prior permission & informed consent

---

Authors – Refuse to give details, EC approval from 3 countries & compliance with relevant requirements stated

---

San response – San Code of Ethics

## Accountability of Contractors



2009-2011 – MNC Double Blind Placebo  
Controlled Phase III trial in COPD

Multi-country (LMICs) sites – 10 in India

Private physician for 1 site in India misled – **free Rx  
with imported drug for respiratory illness**

No informed consent, no risk stated.

Unethical approval:  
Restrospective study  
in Liberia



---

Biomedical & health service related research  
increasing in Africa

---

Improvement in research oversight through IRBs  
& national regulatory mechanism lacking

---

Ebola outbreak in Liberia in 2014

**Retrospective IRB approval** sought  
under cover of “**emergency research**”

## Cervical cancer Study in India



---

3 internationally funded clinical trials (1998 - 2015)

---

Visual Inspection with Acetic Acid (VIA) for screening by primary health care workers

---

Cervical screening available in India since 1970s

**Control arm no screening**

Baboon  
Research in  
Kenya



---

Regulations

Tight in the EU

---

Decline in use of non-primates in research

---

Collaboration

Exploitation

---

Collaboration:

equivalence in ethical standards

avoid this exploitation.

Compensation  
for research  
related injury:  
China



---

78 year-old Chinese  
woman

SAE

---

---

Sponsor paid

Cost of medical care

---

Refused to provide  
compensation

---

Exploitation:  
Immature legal system and  
research participants with  
limited resources



GM 'vitamin-enriched' food



---

Banana enriched with the Vitamin A precursor, beta-carotene

**Exploitation:**

Research priorities determined by Northern researchers and philanthropic organisations, involvement of the affected LMICs.

Healthy  
volunteers in  
multiple trials  
for money



---

Healthy volunteers no direct benefits.

---

Resource  
poor sites

---

Poor people

---

Low literacy levels

---

May not understand the risks

---

No position to refuse financial incentives

---

Participation in CT source of income.

---

Conceal their involvement in studies

---

Compulsory national databases  
for healthy volunteers, funded by  
sponsors

No benefit sharing:  
Community research

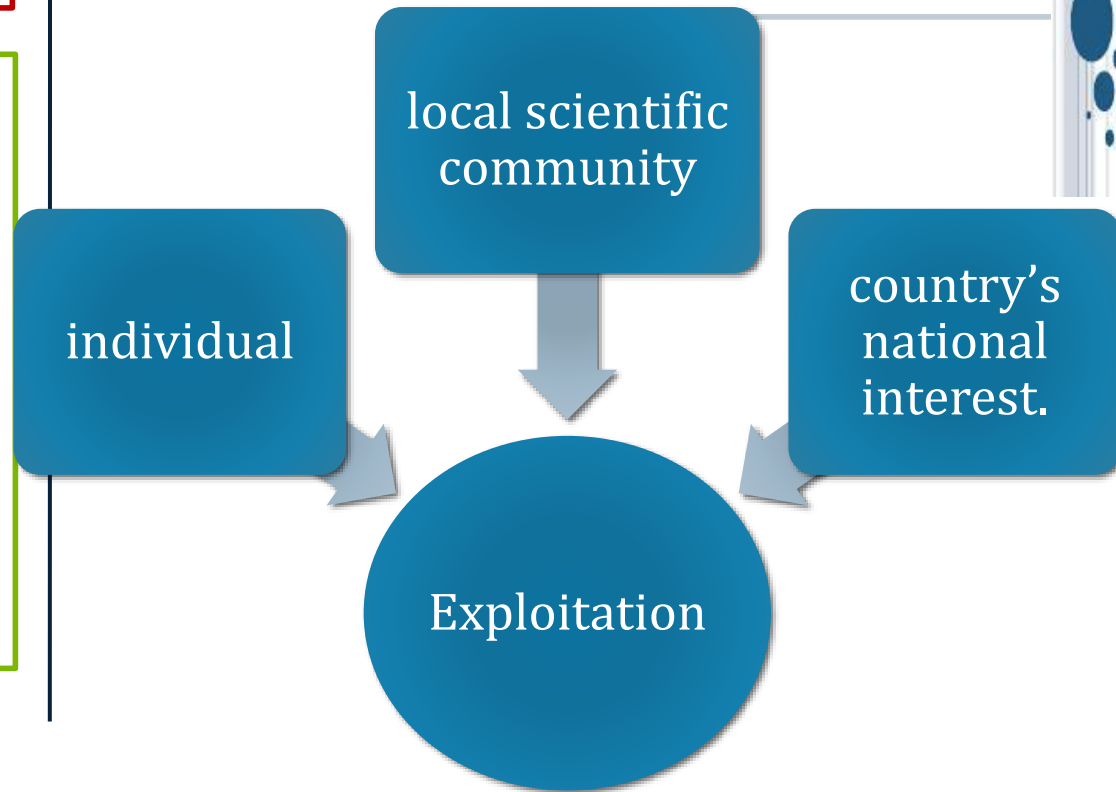
- Strengthen institutional arrangements
- Improve cooperation mechanisms

US University

Blood samples from villagers in Anhui, China

Information to participants

Incomplete



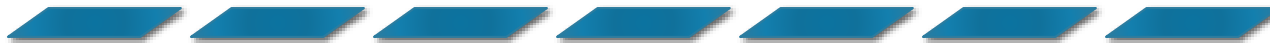
# North South Collaboration



No exploitation



Local centres should function as equal partners



Free flow of knowledge and capacity.



Research should be relevant



Communication between Ethics Committees and partners

