

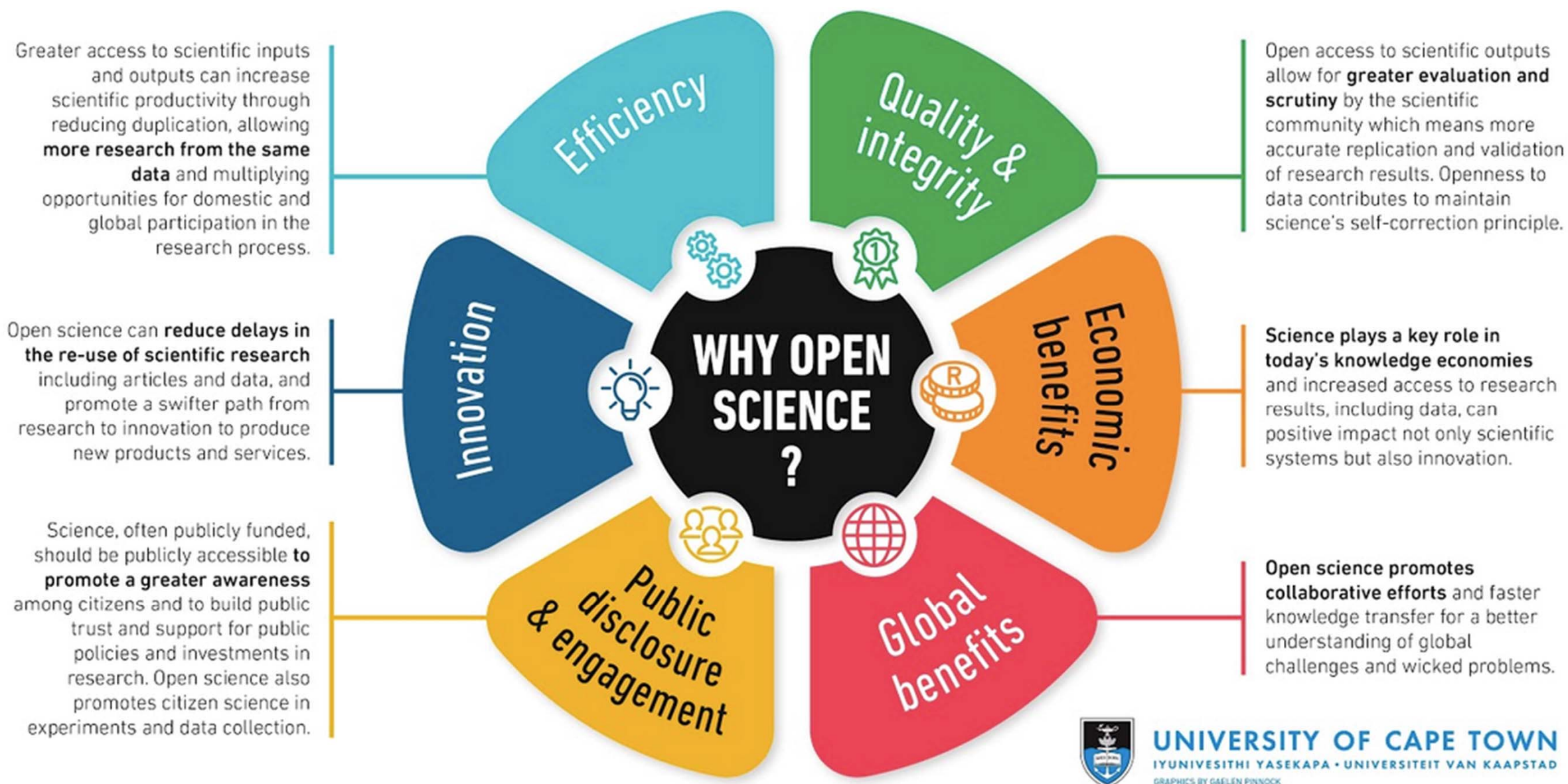


# Ethical constraints to open data in a [South] African Health Research context

## The Push and Pull

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University of Cape Town  
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- **‘Open’ science is good science:** transparent, replicable, verifiable influence policy, public access to findings etc
- Promotion of the ‘common good’
- Funder driven (especially if public funds)-utilitarian-maximize the utility gained from a funded project and the resulting data set
- Large research collaborations and consortia, need to transfer data across borders
- Biobanks and data repositories
  - Retention of identifiable ‘real-time’ data attached to biological samples



## African Principles for Open Access in Scholarly Communication

We, the undersigned, declare to adhere to the following Principles for Open Access in Scholarly Communication in and about Africa:

- 1) Academic Research and knowledge from and about Africa should be **freely available** to all who wish to access, use or reuse it while at the same time being **protected from misuse and misappropriation**.
- 2) African scientists and scientists working on African topics and/or territory will make their research achievements including underlying datasets available in a **digital Open Access repository or journal** and an explicit **Open Access license** is applied.
- 3) African research output should be made available in the principle common language of the global science community as well as in one or more **local African languages** – at least in summary.
- 4) It is important to take into consideration in the discussions **indigenous and traditional knowledge** in its various forms

**The African Principles for Open Access in Scholarly Communication are based on the following principles and guidelines:**

- Dakar Declaration on Open Access Publishing in Africa and the Global South (2016) | [codesria.org/spip.php?article2595](https://codesria.org/spip.php?article2595)
- Invest in Open Infrastructure | [investinopen.org](https://investinopen.org)
- FAIR Open Access Principles by the FAIR Open Access Alliance (FOAA) | [fairopenaccess.org/the-fair-open-access-principles/](https://fairopenaccess.org/the-fair-open-access-principles/)
- Scholarly Commons Principles | [force11.org/scholarly-commons/principles](https://force11.org/scholarly-commons/principles)
- Vienna Principles | [viennaprinciples.org](https://viennaprinciples.org)
- AmeliCA Principles and Values | [amelica.org/en/index.php/principios-y-valores/](https://amelica.org/en/index.php/principios-y-valores/)
- Jussieuu Appell | [jussieucall.org/jussieu-appell](https://jussieucall.org/jussieu-appell)

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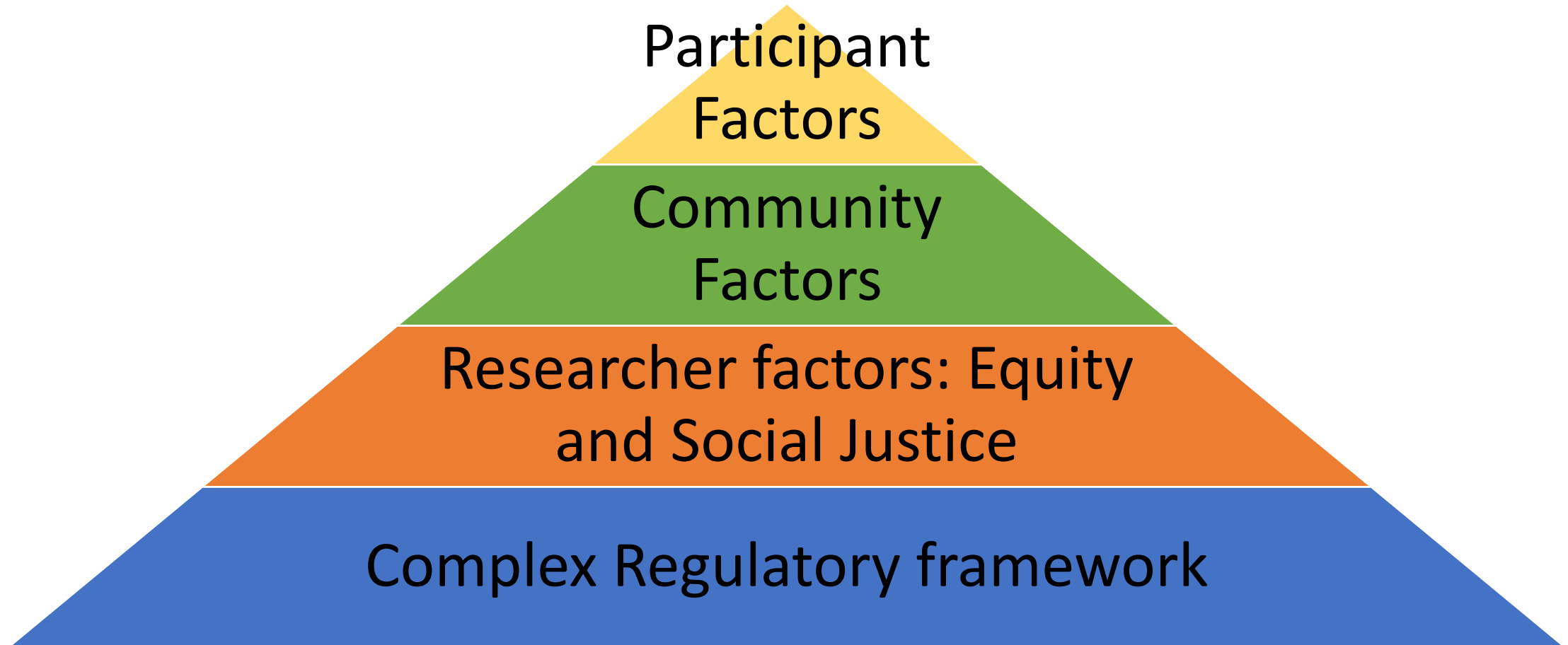
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# Local[SA] Drivers for Data Sharing

- **UCT institutional policy**
  - Open by default; recognises that there are “limits to openness”
  - Must motivate for two year data embargo if needed
- **South African National Research Foundation**
  - Open data policy; students and researchers who receive funding must commit to sharing data sets, uploading to data repository
- **International funders:** NIH, EDCTP, Wellcome Trust etc- data sharing built in to funding contracts
- **Journals** require supporting data to be uploaded to a data platform that is accessible to reviewers and readers

# Hurdles and challenges to data sharing (the 'pull in the opposite direction'!)



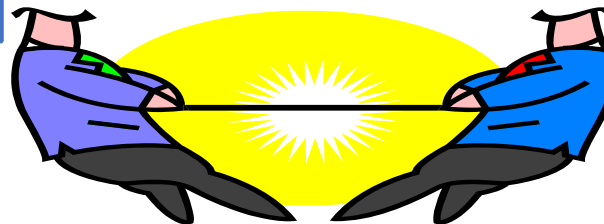
# Ethical/Legal Regulatory Framework

## CLASH OF COMPETING VALUES AND PRINCIPLES IN A HEALTH RESEARCH ETHICS DATA SHARING CONTEXT

- **Deontological**
- **Rights Based**
- Primacy to individual autonomy
- Privacy rights/ Avoiding exploitation of individuals
- Avoiding exploitation of Communities
- Protectionist approach
- MTAs

VS

- Public health ethics; **Utilitarian**
- Maximizing benefit from publicly funded research
- Open science
- Promotion of the Common good
- **Communitarian** ethic
- Solidarity, Reciprocity, Stewardship





# Ethical/Legal Regulatory Framework in SA

- **South Africa: National Department of Health**
- Ethics Guideline 2015; July 2018 published an MTA template: A step back from UCT 'default=open' RDMP and from NRF push for open science/data

*Where data or materials are shared with researchers in other institutions, the recipient institution should agree to comply with the requirements of the donor institution.*

*Furthermore, use of the data or material should comply also with any additional requirements of the recipient institution.*

*Inter-institutional sharing agreements should be confirmed in writing. (p.53)*

- NB Genomic data considered always identifiable

# Ethical/Legal Regulatory Framework in SA

## **EU- GDPR**

- SA/African researchers receiving funding from EU are subject to the GDPR via contracts
- Many researchers scrambling to understand implications for collaborations and data management processes
- LMIC institutions often poorly equipped to provide adequate systems and support

## **SA Protection of Personal Information Act (POPIA)**

- Based on earlier version of GDPR, similarities and differences
- 8 Conditions for lawful processing of information
- May not transfer PHI data across border unless equivalent data protection laws exist in receiving country ( implications for Africa and US collaborators)

# Researcher factors: Equity and Social Justice

1. See Global Forum on Bioethics in Research background paper : The ethics of data sharing and biobanking in health research. Meeting in Cape Town 13-14 Nov 2018

2. Bull, Susan (2016) Ensuring global equity in open research. Wellcome Trust. <https://dx.doi.org/10.6084/m9.figshare.4055181>

- Global North-South Collaborations still often very uneven
- Presumption that data will be uploaded and managed by data centers at the institutions of 'global north partners' – (practice ubiquitous with EU funded clinical research)
- LMICs may have limited capacity to curate, share or access/analyse data; even data they have collected
- Secondary analysis of primary data may not address research priorities of the country in which the data was collected

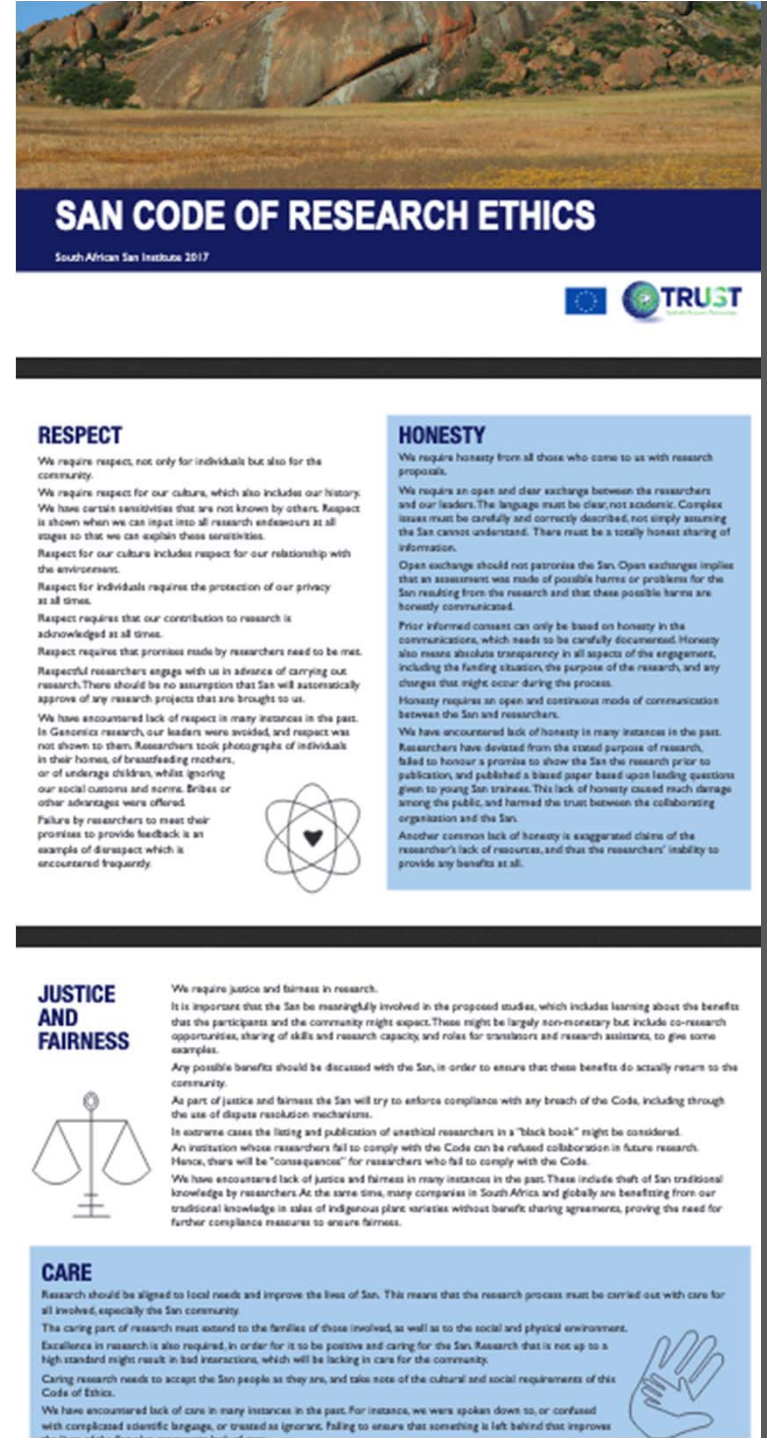
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- *“Although the majority of (Mahidol Oxford Tropical Medicine Research Unit) MORU research data is generated in LMICs, to date, no requests for access to MORU data have been received from institutions in LMICs. Instead, applicants tend to be from well-resourced groups in higher-income settings who have good IT infrastructure and the capacity to conduct complicated statistical analyses and mathematical modelling.” (Cheah et al, 2017)*
- *“ researcher and several others expressed concerns that without more exposure to global datasets and training in complex meta-analysis, scientists from non-endemic countries would be unable to join the “big data” era. They would be increasingly consigned to the data collection end of the research spectrum, their involvement in analytic collaborations such as study groups merely tokenistic.” (125, WWARN science group head) (Pisani and Botchway, 2017)*

# Community Factors

- Community and stake holder engagement critical if interests of communities are to be respected
- Parachute or safari research must be avoided at all cost!
- Discussions need to include
  - Potential risks to communities with sharing of data sets from specific geographical communities e.g. phylogenetic
  - Fair benefit sharing
  - Community research priorities etc





# Participant Factors

- Genomic data cannot be fully anonymized
- Vulnerable research populations ( low literacy level levels, poor understanding of biomedical concepts)
- Privacy concerns especially with sharing of health records in longitudinal data repositories and biobanks
- Broad Consent- now used extensively in Africa but is broad consent fully legal or an acceptable standard in terms of both EU-GDPR and POPIA?- matter is still being debated.
- Photo credit: Creative Commons Lisence

<https://photobucket.com/gallery/user/biopact3/media/bWVkaWFJZDoxNjA0MjM0Mw==/?ref=>



# Conclusion



- There is much value in the promotion of data access and sharing.
- However, international funders, publication houses and research consortia and collaborators need to be particularly sensitive to research contexts where there are both legal and ethical challenges to the widespread sharing of data that must be considered and accommodated.
- In particular, **factors relating to the promotion of equity** must be taken into consideration when researchers from Africa and other LMICs are made/requested to share data.





Thank you for listening!

