

CULTURE MATTERS: AN APPROACH TO INTERNATIONAL RESEARCH AGREEMENTS

WEALTHY vs POOR UNDERDEVELOPED COUNTRIES : USING ETHICS IN DECISION-MAKING



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National Academies – Washington, August 2013

DIRECTIVE

- *How does or should research efforts differ in underdeveloped countries with significant financial resources as compared to those with very limited resources?*
- *How is research / science policy made when there are lots/limited resources?*
- *How does governance structure and principles differ?*

STRUCTURE

- *Research Governance*
 - Legal & Regulatory
 - Ethics
- *Social Responsibility*
 - Global
 - Country level
 - Industry
- *Trust and Trustworthiness*
- *Framework Convention Modified*

- *Legal and Regulatory*
 - Absent
 - Differing standards
- *Ethics*
 - Competent review
 - Post review responsibilities
 - Justice as dominant principle

- Justice as in fairness
- Distributive
 - Substantive – fair distribution of burdens / benefits of research
 - Procedural - fairness in process of decision-making
 - Consistency
 - Bias suppression
 - Accuracy
 - Correctability
 - Representativeness
 - Ethicality

IDENTIFICATION OF HEALTH RESEARCH PRIORITIES

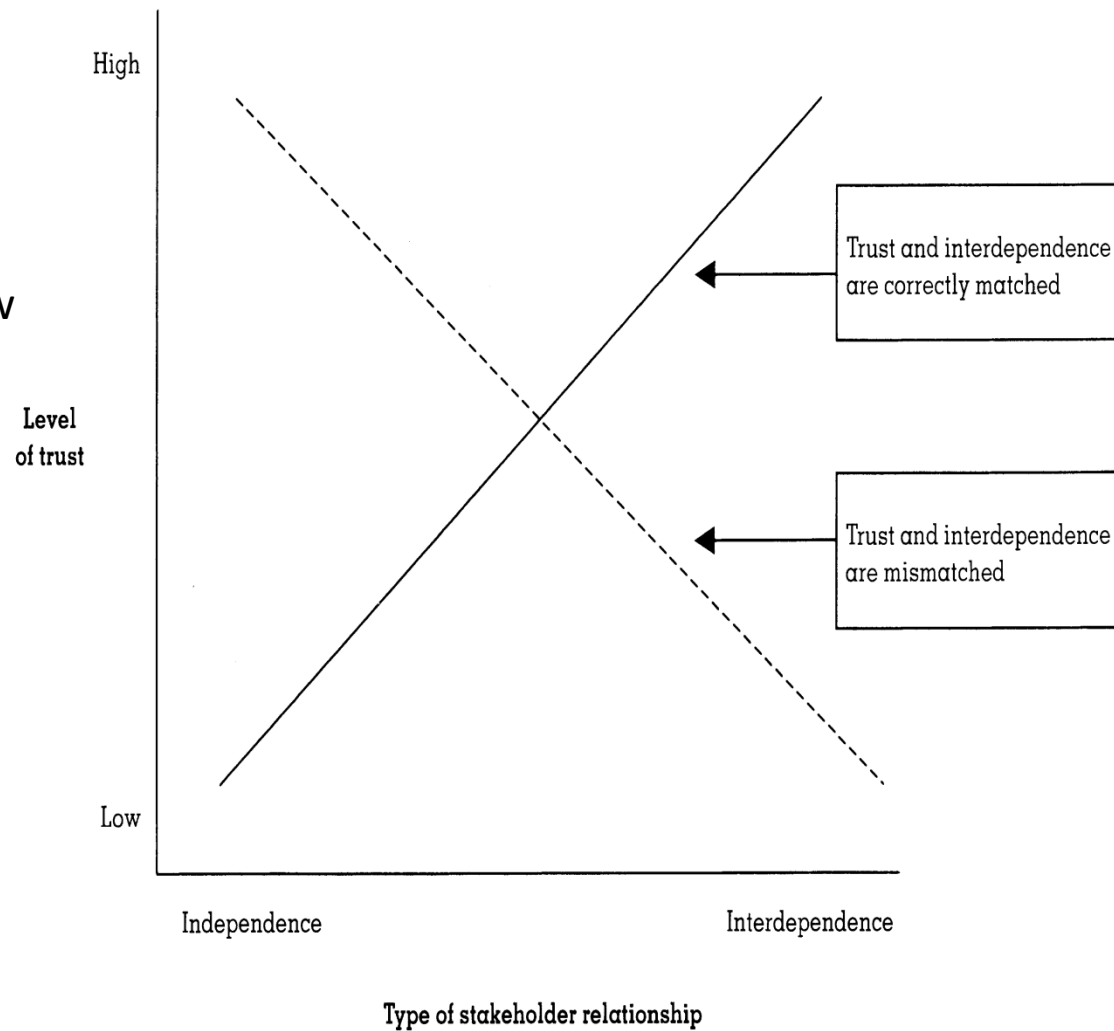
- National Health Act
- National Health Research Committee - identify and advise
- Must have regard to:
 - burden of disease;
 - cost-effectiveness of interventions aimed at reducing burden of disease;
 - availability of human and institutional resources for the implementation of intervention at level closest to the affected communities;
 - health needs of vulnerable groups such as woman, older persons, children and people with disabilities;
 - health needs of communities.

- Global Corporate Social Responsibility Policies Project
 - *“Global corporate social responsibility ... business practices based on ethical values and respect for workers, communities and the environment”*
- World Business Council for Sustainable Development
 - *“... continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families as well as the local community and society at large.”*
- Ethics in Action Awards
 - *“... obligation to be accountable to all stakeholders, ... consider full scope of impact on communities and environment ... Balancing the needs of stakeholders with their need to make a profit.*

TRUST & TRUSTWORTHINESS

- *Trust*
 - Willingness to make oneself vulnerable to another based on belief that trusted person will behave trustworthily and not exploit vulnerability.
- *Trustworthiness of trustee dependant on 4 critical factors:*
 - Ability, benevolence, openness and integrity

FIGURE 1
Matching Trust and Interdependence Levels



Academy of
Management Review
(1999)

TRUST & TRUSTWORTHINESS: A TWO-WAY STREET

- **Pharma - Tops all other industries in total amount of fraud payments for contraventions under False Claims Act:*
 - 2012
 - \$3 billion settlement for off label promotion and failure to report safety data
 - \$60.2million settlement for bribing physicians, hospital administrators, regulators in several European and Asian countries including China – highlights global nature
- *Underdeveloped countries*
 - Corruption, inefficiencies, mismanagement

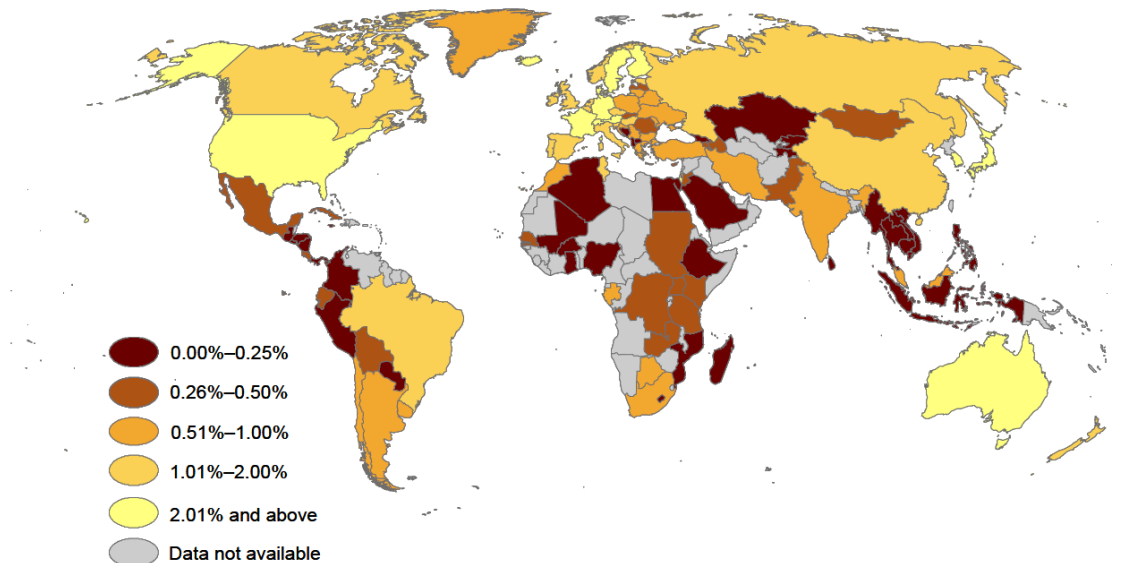
*Trudo Lemmens *Pharmaceutical Knowledge Governance: A human rights perspective*. Global Health and the Law (2013)

Source: UNESCO Institute for Statistics estimates, August 2010.

Figure 2 illustrates the distribution of R&D intensity in main regions/countries. This indicator reflects R&D intensity by presenting R&D expenditure relative to the size of the regional or national economy.

Figure 3. A snap-shot of R&D intensity

Gross domestic expenditure on R&D as a percentage of GDP,
2009 or latest available year




Source: UNESCO Institute for Statistics, July 2011.

ASSAF : REVITALISING CLINICAL RESEARCH IN SA₍₂₀₀₉₎

- *Barriers*

- Inadequate public engagement
- Lack of research planning, regulation, coordination
- Inadequate capacity for (human & infrastructural resources)
- Lack of adequate and appropriate funding
- Absence of monitoring and evaluation

- *Synergistic solutions*

- National strategic planning, regulation and coordination of clinical research
 - Human and infrastructural capacity
 - Creation of clinical research centres & institutes
 - National funding scheme for health research
 - Monitoring & evaluation
- 

GOSTIN'S FRAMEWORK CONVENTION MODIFIED

- *Transparency, accountability, enforcement:*
 - Active citizen participation to ensure transparency, collaboration, accountability & better resource mobilization for socially responsive research
 - Increased stakeholder accountability
 - Education initiatives to ensure well informed civil society to strengthen political accountability

CONCLUSION

Any initiative will unavoidably depend on mutual trust and actions of those who control power internationally and within individual nations