



South African Unit of  
the UNESCO  
International  
Network in Bioethics

# Steve Biko

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## Centre for Bioethics

Implementation of the DoH: Perspectives from the  
Developing World

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**Celebrating 50 years of the DoH: Helsinki, Finland. November 2014**



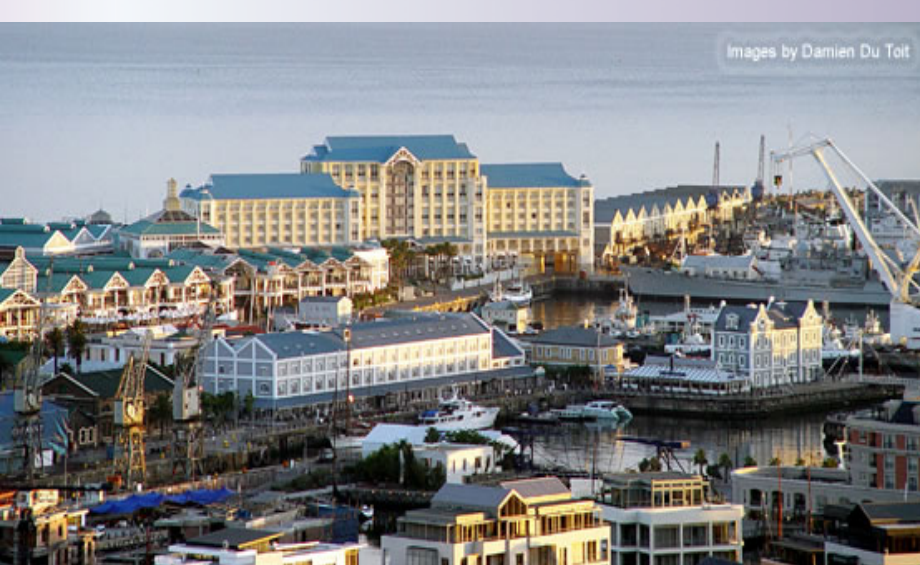
*“ The Declaration, through the past 50 years, has not only maintained its position as the most widely accepted guidance on health research involving human subjects, but has also notably influenced international and national laws and regulations on biomedical research. Many countries in Africa have developed ethical and legal instruments for health research with the spirit and principles of the Declaration shaping both their foundation and core. ....  
The Declaration of Helsinki ... creates a sensitive balance in which progress in science and health research is reconciled with protecting the rights and dignities of the vulnerable that participate in research.”*

# Context



# Vast Disparities

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# Protections of Rights and Dignities

- Recurring refrain throughout DoH (similar to Bill of Rights of SA Constitution)
- General principles – textual bedrock of national ethico-regulatory instruments in SA:
  - National Health Act
  - Ethics in Health Research: Principles, Structures and Processes (Department of Health)
  - General Ethical Guidelines for Health Researchers (HPCSA – basic standard to adjudicate complaints)
  - Quasi-legal status of guidelines

# Specific Aspects of DoH 2013

- 15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.
- 19, 20. Vulnerable Groups and Individuals
- 23. Research Ethics Committees
- 32. Research using identifiable human materials and data such as in biobanks or similar repositories
- 37. Unproven Interventions in Clinical Practice

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

A typical statement from an informed consent document for an NIH-sponsored clinical trial:

*“If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost of this treatment will be provided by the Department of Health in a referral hospital or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health. The investigators will provide you with reasonable medical care as is available at the . . . hospital”.*

Cleaton-Jones PC. Research injury in clinical trials in South Africa. *The Lancet*. 2006; 367 (9509): 447 – 540.

# 19, 20. Vulnerable Groups and Individuals

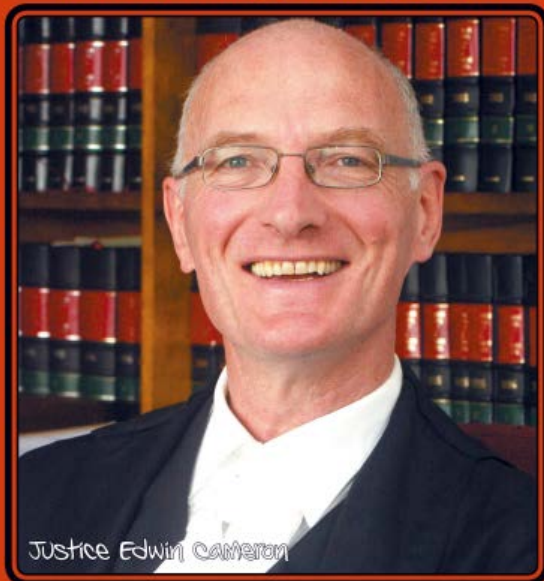
- 19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.  
All vulnerable groups and individuals should receive specifically considered protection.



# 19, 20. Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.

"HIV medical treatment works: it works in rural areas, urban areas, poor areas, resource rich areas, on black, white, male, female, gay and straight people."



Justice Edwin Cameron

HIV...  
share your journey

See [www.aidsconsortium.org.za](http://www.aidsconsortium.org.za) for video clip



## Vulnerable groups

- Minors
- Adolescents
- Women
- Pregnant women
- Fetuses
- Those requiring emergency care
- Prisoners
- Vulnerable communities
- Persons highly dependent on medical care
- Patients in intensive care units
- Neonates
- Those at the end of life requiring terminal care
- Those with impaired capacity to communicate
- The unconscious person
- Other special groups.

## Dependent Relationships

- Older persons and their caregivers
- Persons with chronic conditions or disabilities and their caregivers
- Wards of State and guardians
- Patients and health-care professionals
- Students and teachers
- Prisoners and prison authorities
- Persons with life-threatening illness
- Employees and employers, including farm workers and their employers, and members of uniformed services and hospital laboratory staff and their employers.

Vulnerable groups		International		National		
	A	B	C	D	E	F
Patients	X	x		X		X
Patients with incurable diseases		x				
Those with serious life-threatening diseases		x		X		X
Those at the end of life requiring terminal care				X		X
The unconscious/comatose				X		X
Those requiring emergency care		x				X
Persons with chronic conditions or disabilities						X
Persons highly dependent on medical care						X
Patients in intensive care units						X
Challenges with informed consent	X		x			X
Consenting under duress	X					
Coercion or undue influence				X	x	
Elderly persons with limited capacity to consent		x				X
Those with impaired capacity to communicate				X		X
Mentally disabled persons				X	x	
Children				X	X	X
Wards of State						X
Neonates					x	X
Women						X
Pregnant women					X	X
Fetuses					x	X
Groups with hierarchical structuring			x			
Juniors / subordinates		x				
Students		x				X
Employees						X
Persons in dependant relationships	X					X
Persons confined to institutions				X		
Residents of nursing homes		x				
Prisoners		x		X	x	X
Those on welfare/social assistance		x		X		
Those that are unemployed		x				
Unfamiliar with modern medical concepts		x				
Those at risk of harm: physical, legal, social, economic		x		X		
Ethnic / Racial minority groups		x		X		
Homeless persons		x				
Refugees/displaced persons		x				
Nomads		x				
Disadvantaged rural black men				X		
Racial and ethnic minorities		x				
Politically powerless		x				
Economically disadvantaged persons				X	X	
Educationally disadvantaged persons					X	
Vulnerable communities						X
Other			x			X

## 23. Research Ethics Committees

- “This committee must be *transparent* in its functioning ... and must be *duly qualified*.”
- “After the end of the study, the researchers must submit a final report to the committee containing a summary of the study’s findings and conclusions.”
- Will enhance local guideline documents once incorporated.
- Currently many poorly functioning RECs : structures merely smokescreen / rubberstamping committees.

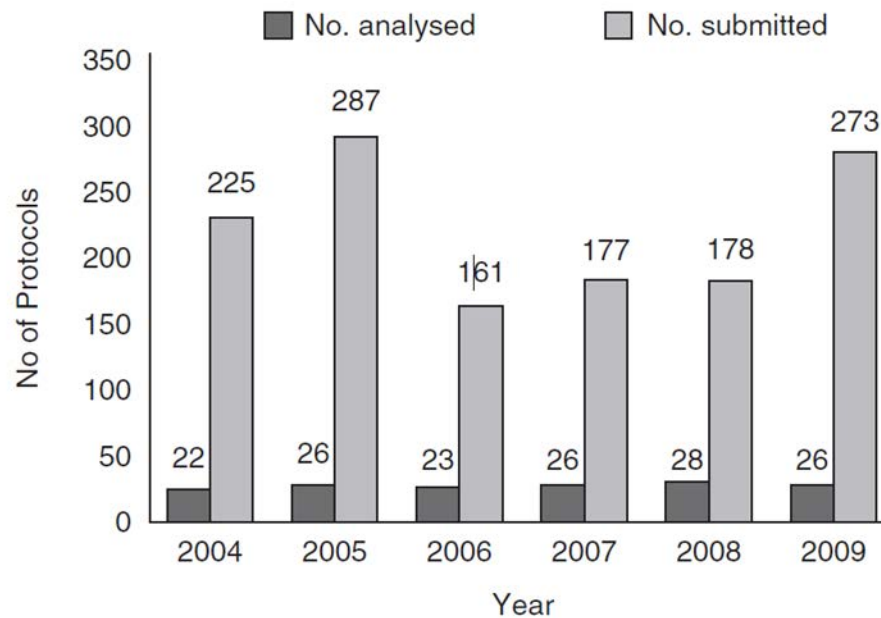
Moodley K, Myer L. Health Research Ethics Committees in South Africa 12 years into democracy. *BMC Medical Ethics* 2007; 8(1)

Dhai A, Mcquoid-Mason DJ. What is the function of Research Ethics Committees? *SAJBL* 2010; 3(1):2-3.

32. Research using identifiable human materials and data such as in biobanks or similar repositories

- Substituted consent and safeguard role of REC.

Sathar A, Dhai A, Van De Linde S. Collaborative International Research: Ethical and Regulatory Issues Pertaining to Human Biological Materials at a South African Institutional Research Ethics Committee. *Developing World Bioethics* 2013.



*Figure 1. Number of protocols submitted over a 6 year period to the REC.*

Sathar A, Dhali A, Van De Linde S. Collaborative International Research: Ethical and Regulatory Issues Pertaining to Human Biological Materials at a South African Institutional Research Ethics Committee. *Developing World Bioethics* 2013.

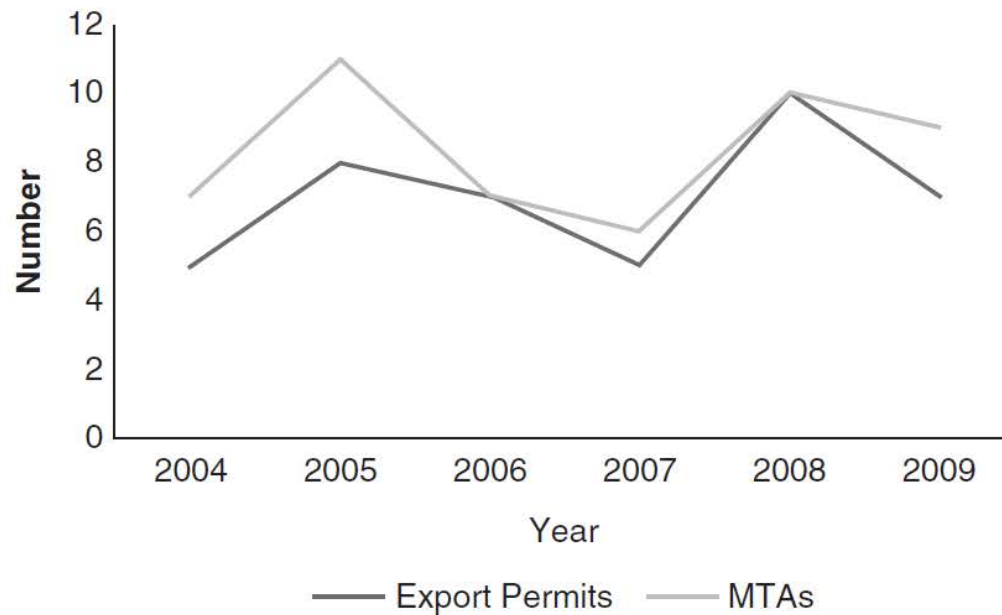


Figure 3. Number of Export permits and MTAs submitted over a 6 year period.

# The Ebola Crisis and the DoH

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# The Ebola Crisis and the DoH

- All articles of DoH applicable, in particular:
- 3. Declaration of Geneva “The health of my patient will be my first consideration”. International Code of Medical Ethics “A physician shall act in the patient’s best interests when providing medical care”
- 4. Duty of physician to promote and safeguard health, well-being and rights of patients, including those involved in medical research
- 7. Medical research – subject to ethical standards that respect and ensure respect and protection of health and rights
- 9. Duty of physicians involved in medical research to protect life, health dignity, integrity, right to self-determination, privacy, confidentiality of research subjects
- 12. Research to be conducted only by individuals with appropriate ethics, and scientific education, training and qualifications.
- 19, 20. Vulnerable Groups and Individuals
- 37. Unproven interventions in clinical practice.

- **37. “Unproven Interventions in Clinical Practice**

*In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.”*

# The Ebola Crisis and the DoH

- The EVD continues to spiral and external sources have now come forward to assist the affected countries. However, for as long as governments in these countries do not commit to strengthen their healthcare systems and improve the underlying social determinants of health attempts at combatting the Ebola crisis and other crises that follow could end up being ineffective.



*“The World Medical Association is to be congratulated for the success of this gem of an ethical guideline. Best wishes for another 50 years!”*

*Thank you*