



# College of Medicine

School of Public Health & Family Medicine

Department of Health Systems & Policy

## ETHICAL & REGULATORY OVERVIEW IN MALAWI: WHO DECIDES?

A PRESENTATION AT MALAWI STAKEHOLDER MEETINGS ON DELIVER AND B-PROTECTED STUDIES

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# Outline of Presentation

- History: Milestones in research oversight in Malawi
- Situation analysis
- Strengths
- Opportunities
- Research Oversight System in Malawi
- Research integrity and moral capital
- Conclusion



# What are the country-specific regulations and guidelines that can affect research?

- Malawi Constitution Article 5
  - Academic freedom ( a right to be free to research and study and teach)
  - The duty to seek informed consent
  - Respect of privacy and confidentiality
  - National commission of science and technology Act
  - HIV Law (data protection)
  - Child protection Act
  - Anatomy amendment Bill
  - National Health Sciences Research Committee, Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi (Sept 2012)
  - Bio-banking guidelines in Africa
  - [AFRICA BIOBANKING GUIDELINES.docx](#)



# Situational analysis: Strengths

- One of the first ethics and research committees in the world
- By 1994 Malawi was one of the first 6 ethics existing ethics committee in existence in Africa.
- 2007 the first country in Africa with funding of ECDPT to move from informal ethics committee into professionalization of ethics committees
- By replacing the elected secretary of the committee by IRB administrator
- Introducing the post of ethics compliant officer to monitor the compliance by members of the committee and researchers
- Having COMREC Administrative secretary



# Situational analysis: Strengths

- Hosting the prestigious conference
  1. 2001 Fair benefit framework
  2. Amendment to zik Emmanuel ethics benchmark
  3. Cape Town and Blantyre are the only Africa countries who have hosted the prestigious Global forum of Bioethics.
  4. Blantyre hosted the global forum of bioethics in 2005
- Malawi is the first country in Africa to establish the National Committee on Bioethics (NACOB) to advise government on all bioethical issues in all sectors in line to UNESCO declaration on Bioethics and Human rights 2005
- Malawi together with South Africa in 2004 were among the first two countries in the world to receive Fogarty prestigious research ethics training grants. These grants led to establishment of the first bioethics centers on Africa
- Malawi through National Commission of Science and Technology pioneered no fault insurance on Africa continent



# Situational analysis: Strengths

- National interest studies-resolving the jurisdiction issues between local and national ethics committee
  1. All vaccines trials
  2. Stem cell research
  3. Cloning research
  4. All genetic studies
  5. All drug trials where safety issues are unknown and where patent issues
  6. National healthy surveys
- This national interest framework has received enquiries from many Africa countries including Uganda, Botswana
- Malawi introduced National research agenda this is also one of social innovation which has been copied by other countries like Kenya



# Situational analysis: Opportunity to reform and strengthen

- In Malawian research is academic right
- The limitation of that right is all research have a duty to ensure that informed consent is provided
- Globally pregnant woman has been considered as part of vulnerable population
- The classical understanding of the word “vulnerable”
- Vulnerable according to ethics means someone with diminished capacity or competence e.g., ultra poor, the prisoners, children, people with mental disability



# Are all pregnant women vulnerable

- The answer can be yes or no
- Not all pregnant women fit to be classified as vulnerable
- All pregnant women are becoming vulnerable because recently there have few studies have included pregnant women because it was considered risky.
- As results many women have become actually more vulnerable to diseases because there are few drugs that are meant for pregnant women
- Due to this scenario regulatory bodies like FDA, EMEA, WHO have moved from unwarranted overprotection
- The philosophy was all inclusion of pregnant women should have a strong justification
- Now all exclusion should be strongly be justified
- All inclusion in clinical trial should be responsive to their health needs
- Any trial that is not responsive
- Community voices and women rights groups are demanding the right for the pregnant woman to participate in clinical research
- The safety of pregnant women remain important but not at expense of women health.





# Research Oversight System in Malawi

- Health Research issues in Malawi are co-coordinated by the Division of Health, Social Sciences and Humanities of the National Commission for Science and Technology
- The Division is supported by committees at national and institutional level with legislative anchorage
  - National Committee on Bioethics (Advisory and policy making)
  - Drug Regulatory Authority (PMPB)
  - National Health Sciences Research Committee (NHSRC)
  - National Social Sciences
  
  - College of Medicine Research and Ethics Committee (COMREC)



# What are the means to do research oversight systems?

- Independent scientific review
- Independent ethical review
- Independent manuscript review

What are the tools we use?

- International codes
- Ethical frameworks
- National Laws
- National codes
- EC Guidelines
- SOPs

YET all these are just tools & not enough – there is one tool in the tool box which is often overlooked NAMELY: Moral capital based on moral reasoning



# Why moral capital transcends rule of law?

- ✓ Behavior change and acting correctly based on fear of the law alone is not sustainable.
- ✓ **Good skills and knowledge alone without investment in right attitude (moral character) are not enough for sustainable Research integrity and professional ethics** **Complete social control** is **not** possible in a democracy that respects **human rights**  
=> Democracy must be complemented with an investment in moral capital for it to function e.g., a technically competent German pilot who crashed passenger plane in Alps.



# Three pillars of moral capital:

## KAS Pillars

# Moral capital

expected  
knowledge

right  
Attitude  
= a combination  
of virtues  
appropriate for a  
particular socio-  
economic context

expected  
skills

# Conclusion

- *“Most people say that it is the intellect which makes a great scientist. They are wrong: it is character.”* Albert Einstein

