Updates To Helsinki and Potential impact for Research in Uganda and the Region

Dr Nakwagala Frederick Nelson

Senior Consultant Physician

Mulago National Refferal Hospital

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WHAT IS THIS DECLARATION

- Developed by The World Medical Association (WMA)
- The declaration of Helsinki as a statement of ethical principles for medical research involving human participants, including research using identifiable human material or data.

AMENDMENTS

- *Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:*
  29th WMA General Assembly, Tokyo, Japan, October 1975
  35th WMA General Assembly, Venice, Italy, October 1983
  41st WMA General Assembly, Hong Kong, September 1989
  48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
  52nd WMA General Assembly, Edinburgh, Scotland, October 2000
  53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
  55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
  59th WMA General Assembly, Seoul, Republic of Korea, October 2008
  64th WMA General Assembly, Fortaleza, Brazil, October 2013
  and by the 75th WMA General Assembly, Helsinki, Finland, October 2024

TITLE CHANGE

- WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS
- FROM INVOLVING HUMAN SUBJECTS
- ***THIS MEANS HUMANS ARE TO BE RESPECTED AND INVOLVED AS CRITICAL STAKEHOLDERS NOT MERE SUBJECTS***
- *NOTE THAT UGANDA ADOPTED THIS CHANGE DECADES AGO!*

PREAMBLE AND SCOPE

- **Section 1:** "Using identifiable human material ***and*** data" has been changed to "using identifiable human material ***or*** **data."**

- **Section 2:** The wording has been updated to emphasize that all individuals, teams, and organizations involved in medical research should uphold the principles of the Declaration, not just physicians**.**

- ***THIS IS THE FIRST TIME THIS DOCUMENT IS TO APPLY TO ALL CADRES INVOLVED IN RESEARCH. THIS WILL BUILD TEAM RESPOSIBILITYAND WIDEN SCOPE OF APPLICATION BEYOND PHYSICIANS.***

GENERAL PRINCIPLES NUMBER 3

- Changed from responsibility for Health of patient to ‘HEALTH AND WELLBEING.”

- ***THIS MEANS THAT EMPHASIS SHOULD BE ON HOLISTIC TREATMENT OF THE PARTICIPANT CARING FOR ISSUES BEYOND HEALTH CARE LIKE MEALS, REFRESHMENTS, COMPSATION FOR TIME LOST AND INCONVINIENCES AND CATERING FOR PSYCHOLOGIC AND SOCIA ECONOMIC WELLBEING WHERE APPROPRIATE***

- **UGANDAN REGULATORY SYSTEMS ALREADYIMPLEMENTING THIS.**

COMMUNITY ENGAGEMENT AND PARTICIPATION

- There is now profound emphasis on community engagement and participation
- Guideline number six provides for
  - Meaningful engagement with individuals and their communities before, during and after research (WHOLE LIFECYCLE OF RESEARCH)
  - Research participants to be enabled to share their priorities and values
  - They should participate in research design, implementation and results dissemination.
- ***THIS MEANS PROTOCOL APPLICATIONS WILL BE REQUIRED TO PRESENT DOCUMENTATION OF THE PROCESS HITHERTO AND FUTURE PLANS FOR COMMUNITY INVOLVEMENT.***

Continued research on proven interventions General Principle 5

- This has been updated to include the recommendation that even well-proven interventions should be continually evaluated through research for their safety, effectiveness, efficiency, accessibility, and quality.

- ***REGULATORS AND POLICY MAKERS TO REQUIRE CONTINUED RE-EVALUATIONS OF ALL PRODUCTS KNOWN OR PRESUMED TO WORK.***

UPHOLDING ETHICAL PRINSCIPLES DURING PUBLICH HEALTH EMERGENCES

- **Section 8:** This new section emphasizes the importance of upholding ethical principles during public health emergencies. *"**While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies**."*

- ***UGANDA ALREADY IMPLEMENTED THIS IN OLDER VERSIONS OF GUIDELINES AND SPECIFICALLY IN NATIONAL GUIDELINES FOR THE CONDUCT OF RESEARCH DURING COVID 19.***
- ***ETHICAL AND REGULATORY RIGOUR SHALL NOT BE DISPENSED OF DURING PUBLIC HEALTH EMERGENCIES.***

MINIMIZING HARM TO THE ENVIRONMENT

- **Section 11:** The wording has been updated to state that medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.

- ***CORE COMPONENTS OF ENVIRONEMENTAL ISSUES TO BE CATERED FOR DURING RESEARCH REGULATION***

COMMEMORATE MY BIRTH DAY 21/10/1965

REQUIREMENT FOR SCIENTIFIC INTEGRITY

- ***Section 13:*** *The wording has been updated to include "****Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.****"*

- *Uganda already established a national Office for Research integrity and now mandates training in Responsible conduct of research.*

- ***THERE IS URGENT NEED TO EQUIP INSTITUTIONS WITH A CULTURE OF PROMOTING RESEARCH INTEGRITY AND MANAGING MISCONDUCT.***

RETHINKING ETHICAL APPROACHES TO VULNERABLE POPULATIONS

- **Section 19:** The wording has been updated to consider the harms of exclusion weighed against the harms of inclusion in a trial of vulnerable individuals, groups, and communities.
- **Section 20:** This section now states, "Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, ***or when excluding them would perpetuate or exacerbate their disparities.***

- ***THIS IS TO STEM UNDUE PROTECTIONINSM THAT INSTEAD HARMS VULNERABLE POPULATIONS BY UNJUSTIFIABLY EXCLUDING THEM FROM RESEARCH.***

FREE AND INFORMED CONSENT

- **Section 25:** The wording has been updated to emphasize "***free*** and informed consent" instead of merely "informed consent."
- **Section 29:** For participants who cannot give informed consent, the researcher must consider any ***preferences and values expressed by the potential participant,*** *and the potential subject's dissent should be respected.*

- ***UGANDA ALREADY PROVIDES FOR EXCLUSION OF CHILDREN NOT ASSENTING TO RESEARCH.***

POST-TRIAL PROVISIONS.

- ***Section 34:*** *The wording has been updated to state that it was "arranged by sponsors and researchers to be provided by themselves,* ***healthcare systems****, or governments for all participants who still need an intervention identified as beneficial* ***and reasonably safe*** *in the trial."*
- *It now also requires that "****exceptions to this requirement must be approved by a research ethics committee****."*

- ***RIGOROUS PROVISION OF POST TRIAL ACCESS TO BE REQUIRED OF THE SPONSOR.***

RESEARCH REGISTRATION, PUBLICATION, AND DISSEMINATION OF RESULTS

- **Section 36:** The wording has been updated to emphasize the **timeliness** of results disclosure: “Researchers have a duty to make publicly available the results of their research on human participants and are accountable for ***the timeliness***, completeness, and accuracy of their reports.

- **JUSTICE DELAYED IS JUSTICE DENIED. SAME TO DELAYED DISCLOSURE OF STUDY RESULTS.**

- **REGULATORS WILL NEED TO PUT SPECIFIC TIME CONFINES IN WHICH THIS IS TO BE DONE.**

USE OF UNPROVEN INTERVENTIONS IN CLINICAL PRACTICE

- **Section 37:**. The bar is now set higher, requires inadequate/ineffective approved options
- Clinical trial enrollment not being possible.
- A stronger emphasis on subsequent research obligations.
- Clear prohibitions against using these interventions to circumvent normal research protections.

- ***UGANDA HAS EXPERIENCE OF USING UNPROVEN INTERVENTION FOR RESEARCH BUT BEING APPROVED BY DGHS MOH***

CONCLUSIONS

- THE 2024 UPDATES PROVIDE FOR SIGNIFICANT CHANGES TO EARLIER PROVISIONS.
- INTERESTINGLY MANY HAD ALREADY BEEN ADOPTED AND IMPLEMENTED BY UGANDA'S REGULATORY SYSTEMS.
- THESE CHANGES WILL NEED TO BE INCOPORATED IN NEWER REVISIONS OF OUR GUIDELINES BUT MORE SO IN THE ACTUAL PRACTICE.
- EACH NATION WILL NEED TO DO SELF INTROSPECTION TO ADAPT TO THESE CHANGES