

CONDUCTING MEDICAL RESEARCH IN LOW-RESOURCED SETTINGS UNDER THE DOH.





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Presented by:

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At the WMA DoH Revision Session



Venue: Aula Vecchia del Sinodo, Vatican City.

Date: Thursday, January 18, 2024.

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SETTING THE SCENE

- ❖ Research is not new to humans.
- ❖ Benefits not in doubt.
- ❖ Troubling reality of disparities in conduct of medical research across countries.
- ❖ This conversation is a welcome idea, especially as Research has great impact on population health and the DoH.



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DEFINITION

Research

"A process of systematic inquiry or study of the materials and behaviours of the physical and natural world through observation, experimentation, and testing of theories against evidence."

It involves the collection of data through defined methodologies, analysis, and interpretation of the data to generate findings



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HISTORY AND GAINS OF RESEARCH

- Observations of trends by humans.
- Advances in Modern Biology.
- 19th Century: Cellular Biology.
- 20th and 21st Century: Advanced Scientific discoveries and Technological developments.



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HISTORY AND GAINS OF RESEARCH



- Genetic engineering and advances in Cloning technologies
- Genetically Modified Organisms (GMOs): GM crops
- The Human Genome Project
- AI and Big Data.
- mRNA Technologies/Vaccines.
- Antimicrobials.
- Space travels/holidays.
- Renewable Energy.



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POSSIBLE INTERVENTIONS IN 2050

(Credit to Nikhil Adithyan)

- AI-enabled Human Robots and Reincarnation or Rebirth of People.
- Superhuman Clothing.
- Entire Dependency on Renewable Energy.
- Space Vacations.
- Drone Solutions.
- Hyperloop.



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New/Improved Diagnostic methods, Therapeutics & Vaccines



New/Improved medical devices/ Health infrastructure



Better patient experience/ quality of care



Improved health outcome/Life Expectancy



Better job satisfaction/reduction Of burnout



BENEFITS OF RESEARCH






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THE CASE OF LOW RESOURCED SETTINGS



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WMA

DEFINITION

LMICs

Countries with a GNI per Capita of between \$1, 045 and \$4, 095.

- World Bank

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LADEN WITH OPPORTUNITIES

WMA

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BUFFETED WITH CHALLENGES

- Poor Priority.
- Inadequate Funding.
- Resource/Logistical Constraints.
- Political interference/views.
- Poor awareness/Perception.
- Trust deficit/ Opposition.
- Legal/Regulatory framework.
- Ethical challenges/Misuse/Breach.



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RESEARCH CHALLENGES

- **Unfair access to the benefits of Research/inequitable allocation.**
- **Cultural/Religious dogmas/superstitions/myths.**
 - ✓ Disruption of socio-cultural ethos.
- **Deliberate distortions by ideologues/conspiracy theorists.**
 - ✓ Infodemia/unregulated social media/amorphous advisers.



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DoH & ETHICAL CONSIDERATIONS

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DoH AND ETHICAL CONSIDERATIONS

❑ Research Ethics Committees--DoH 23

- ✓ Legal/ Reg/Policy framework (NHA).
- ✓ Provision of monitoring info to REC.
- ✓ **Capacity: Approvals & Monitoring.**
- ✓ Submission of final report to REC.

❑ Informed Consent---DoH 26

- ✓ Sufficient/Adequate information on the aims, methods, etc.
- ✓ Specific information needs of subjects.
- ✓ Information about the general outcome and results of the study.

❑ Vulnerable Groups--DoH 23

- ✓ Equity: DoH GP 13.
- ✓ Risk assessment & Mgt: DoH 18
- ✓ Post-trial provisions: DoH 22 & 34

❑ Rights & Interests of Individual research subjects--DoH GP 8

- ✓ Kano drug trials

❑ Privacy & Confidentiality--DoH GP9

- ✓ Physician's responsibility.
- ✓ Quality of Med Records Staff.
- ✓ Lack of EMR.

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DoH AND ETHICAL CONSIDERATIONS

❑ Risks, Burden, & Benefits--DoH 18

- ✓ Risk assessment.
- ✓ Guarantee that the risk can be satisfactorily managed.

❑ Compensation--DoH GP 15

- ✓ Appropriate compensation and treatment for subjects who are harmed as a result of participation in research.

❑ Regulatn/Mgt of Biosamples/BioBanks --DoH GP 32

- ✓ ???Approval by REC

❑ Research Publication/Dissemination. ---DoH 35

- ✓ Adherence to accepted guidelines on ethical reporting---News media:
- ✓ Publication of -ve, +ve, and inconclusive findings.

❑ Unproven interventions in Clinical practice---DoH 37

- ✓ If it offers hope of saving life, re-establishing health, or alleviating suffering.
- ✓ This intervention should be subsequently researched to evaluate its safety & efficacy---GNLD.



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RECOMMENDATIONS



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AWARENESS CREATION

- Political/Community/ Public engagement.
- Benefits of research.
- The imperatives of the DoH and other ethical norms and standards.



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RESEARCH SHOULD BE WELL FUNDED

- Adequate budgeting for research.
- Responsible investments in research.
- PPP support.



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ADVOCACY

- Political/Institutional commitment to research and its outcomes.
- Priority for research, its processes and outcomes.
- Establishment of legal and regulatory frameworks.



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RESEARCH SHOULD BE ETHICAL AND REGULATED

- Responsible & protects humanity.
- Upholds ethical and moral obligations - DoH
- Abhors compromise of its processes.
- Strict enforcement of ethical and regulatory codes.
- Monitors and evaluates its findings/developments.



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BUILD PUBLIC TRUST



Public interest Vs Interest Grp Approach

- Transparently communicates its results/developments
- Appreciates the Socio-cultural context.
- Discourages abuse of research/ Bad research.

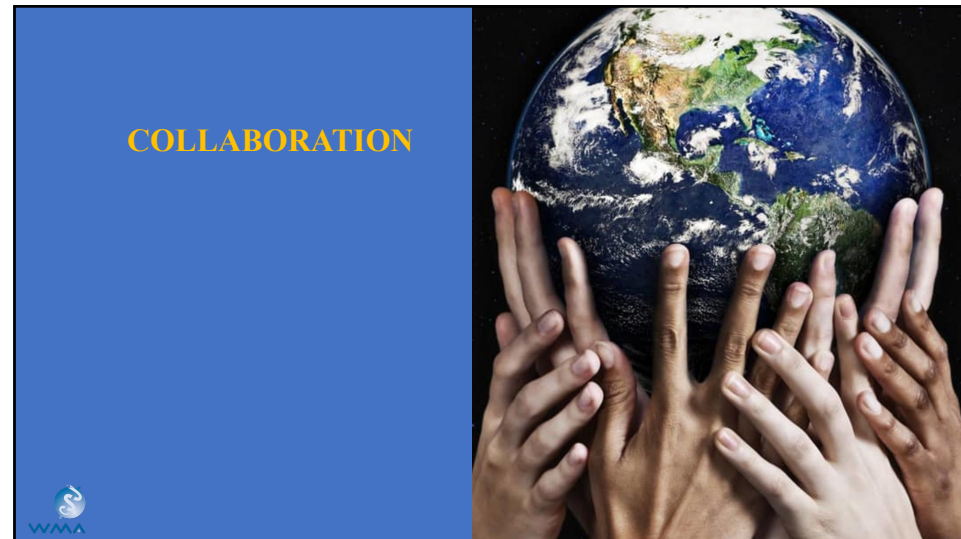
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CAPACITY BUILDING & MENTORSHIP



- Training and retraining.
- Curriculum development and review.
- Opportunities for mentorship.

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- Research that collaborates.
- Promotes equitable sharing of data/findings/ benefits.
- Responsive and delivers effective, affordable and equitable solutions.

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RESEARCH THAT SECURES THE LIVES OF RESEARCHERS:

A DEDICATION TO ALL PHYSICIANS AND RESEARCHERS



Quest for security of lives and welfare of Physicians: The First Anti-Kidnapping Street Protest March by Nigerian Physicians Conducted in Benin City, Edo State, Nigeria, on August 5, 2009, under the leadership of the then Chairman of Edo State branch of Nigerian Medical Association, Dr. Osahon Enabulele.

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CONCLUSION



The significance of research, particularly human research, and its discoveries in shaping human existence cannot be over-emphasized. It has been a major contributor to the reduction of morbidities and mortalities, and improvement in life expectancy in many countries of the world.

Despite the opportunities that abound for research in low resourced settings, they are still buffeted by challenges which have impacted on the pace and ethical integrity of the research processes and outcomes.

For the global population to maximally benefit from the research opportunities in low resourced settings, the identified barriers need to be addressed. In this regard, appropriate funding and logistical support, awareness creation on the benefits of research and the imperatives of the DoH, capacity building and North-South collaboration, as well as the emplacement of adequate legal and regulatory standards need to be given expression.

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APPRECIATION

- Our Creator.
- The WMA Leadership.
- The DoH Revision Team.
 - Ms. Sunny Parks.
- My Wife & Family.

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THANK YOU!

**DR. OSAHON
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