

Compliance, Research Integrity and Bioethics Capacity-Building for University-based Research: An Assessment of the Nigerian Situation.

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(www.nrcsqa.org)

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The Background

- Nigeria is the most populous Country in Africa, and has the World's largest drug naïve black population.
- There are **170 Universities in Nigeria**, but discussions about University-based Research in Nigeria are arguably an unfamiliar research/academic activity for many people.
- Though there are many **public and private universities, none is a clear cut Research University**, as we know it that: "Research universities can be public and non-profit private universities, which are regarded as doctorate degree-granting institutions that spend millions in research expenditures and have high research activities."
[1]
- Several cases of **research misconducts** had been insinuated across Nigerian institutions and tertiary Hospitals. Much more could be unknown or undocumented.

The Background

- Concerns about the ethical conduct of research, and debates about **adequacy of relevant regulations, compliance and oversight** of research abound.
- Responsible Conduct of Research (RCR) deal with issues of falsification, fabrication and plagiarism mainly, but more could be involved in our setting.
- Much needs to be done in promoting **Responsible Conduct of Research (RCR) and Research/Scientific Integrity (RSI)** particularly in Low and Middle Income Countries (LMIC).
- Despite the concerns about Research Misconduct, **low level of regulated research in Nigeria**, is largely responsible for the relatively low capacity of both regulators and researchers.

The Background

- Several Organizations and conferences within Nigeria focused on research capacity building in the past, and even currently.
- Unfortunately this has not improved the output of regulated research in Nigeria.
- Information about Clinical Trials in Nigeria, are not much in the public domain. **Hospitals do not have or place adverts about CTs anywhere.**
- The Academic Institutions as well, generally do not have **Offices of Research Compliance or Integrity**, and as such do not have a centralized portal for documenting on-going or completed Research projects. [2]

The Nigerian QA & Research Frameworks

► Regulatory Authorities

► Standards Organization of Nigeria - SON <https://son.gov.ng/>

- The apex Standardization Body in Nigeria; the Government Regulator focused on improving life through standards and quality assurance.

► National Agency for Food, Drugs, Administration and Control - NAFDAC <https://www.nafdac.gov.ng/>.

- Apart from Drugs, NAFDAC has a role to ensure food hygiene & safety but there is a huge and unmet need in the society herein.

► National Environmental Standards, and Regulations Enforcement Agency - NESREA <https://www.nesrea.gov.ng/>

- responsible for the protection and development of the environment, biodiversity conservation and sustainable development...regulations, rules, laws, policies and guidelines.

The Nigerian QA & Research Frameworks

- **Regulatory Authorities continued.**

- **National Biotechnology Development Agency - NABDA**

- <https://nabda.gov.ng/> established to implement the Government policy that is aimed at conducting research, promotion, coordination and development of biotechnology for Nigeria.

- **National Health Research Ethics Committee - NHREC**

- <https://nhrec.net/> “Promoting Highest Ethical and Scientific Standards for Health Research in Nigeria.” NHREC has the mandate to regulate and audit Health Research Ethics Committees in Nigeria. [3,4,5]

QA Professional Society in Nigeria/Africa.

- ▶ **NRCSQA - Nigerian Regional Chapter, Society of Quality Assurance.** (www.nrcsqa.org; www.sqa.org)
 - ▶ The **Nigerian Quality Assurance Conference (NQAC)** started in 2011 as a National event introduced by the Society for Quality Assurance in Nigeria (SQAN) and Quality Assurance Stakeholders (SON, NAFDAC, NABDA, NESREA, NIPRD, NIMR, CROs like ZETA-12 etc).
 - ▶ The **Eastern Nigeria Research Ethics Forum (ENREF)**, was created in 2012 by Regional Stakeholders including SQAN, ZETA-12 CRO Teaching Hospitals, Research Ethics Committees, and Individual Researchers . The first **ENREF Bioethics Training Workshop** was hosted in 2013 by the National Orthopaedic Hospital, Enugu.
 - ▶ Highlights of the (last) **10th Nigeria Quality Assurance Conference** will be discussed later.

Research Institutions/Agencies

- **NIPRD – National Institute for Pharmaceutical Research and Development.** <https://www.niprd.gov.ng/>
 - NIPRD is statutorily charged with the responsibility for research and development of drugs, vaccines, phytomedicines, commodities, and diagnostics aimed at improving sustainable access to safe, affordable and high-quality healthcare. NIPRD also undertakes activities relating to capacity building, policymaking, data collation, drug distribution and the development of contextual partnerships that can expedite access to healthcare.
- **NIMR – Nigerian Institute for Medical Research.** <https://www.nimr.gov.ng/>
 - The Nation's foremost Institute of Medical Research engaged in human subject research to improve public health.

Research Institutions/Professional Societies

CBR - The Center for Bioethics and Research, Nigeria.

<https://bioethicscenter.net/>

- The Leading Nigerian Research Organization that attracts grants for Research Capacity Building.
 - Secured Grants to set up the **National Health Research Ethics Committee (NHREC)** in Abuja, Nigeria. NHREC regulates Research Ethics Practice in Nigeria, and registers institutional ethics committees.
 - Secured Grants for the running of Academic **Bioethics** programs in 3 Nigerian Universities.
 - Secured Grants to train and set up **Research Integrity** Units for at least 16 Nigerian Universities.
- **CIMRO - Chiolive International Medical Research Organization.**
 - Commenced an Investigator-Initiated Dietary intervention Clinical Trials one of which is "**Personalized food avoidance dietary intervention trials in psoriasis and hypertension**"

The Objectives

This study was initiated by the Nigerian Regional Chapter SQA, following the 2022 Nigeria Quality Assurance Conference (NQAC):

- To determine the perceptions of research respondents (non-attendees of the NQAC) about proper conduct of university-based research.
- To establish the need or otherwise of more capacity building projects/programmes for research in Nigeria.
- To determine the availability of resources to improve capacity building for Research Integrity, Compliance and Bioethics practice in Nigeria.

Justification

- Having been involved in both National and Regional efforts to promote Bioethics and Quality Assurance practice in Nigeria, we deemed it essential to report on the recent activities of the Nigerian Regional Chapter, SQA.
- And to initiate a multimethod research to study the level of Compliance, Research Integrity and Bioethics Capacity-Building for University-based Research in Nigeria especially because there has not been such.
- This paper will provide basic information for the Nigerian/African Research Community and also prime our Institutions to prepare to introduce QA Courses in their teaching Programs. It would also challenge the Regulatory Authorities to asses their level of impact.

The Design/Methodology

- This is a pilot study to document the awareness and the extent of Compliance, Research Integrity and Bioethics Capacity-Building for University-based Research in Nigeria.
- Data was gathered primarily from Focus Group Discussions, Key Informant and In-depth Interviews, and by review of current information shared online by Research Stakeholders in Nigeria.
- The recently concluded Nigeria QA Conference report and proceedings were also included as part of this presentation.
www.nrcsqa.org.

Result/Findings

Summary of Key Focus Group Discussion Results

- Most respondents had participated in **Researches and Clinical Trials** as both Researchers and Subjects (**though none did as a QA Auditor**). Part of their responses were that:
- Research is the collection of information from several people, like sampling of opinion about a particular subject.
- Research is like having an investigation or study to establish an already known fact or get a new idea on things...
- Most problems facing Research in Nigeria has to do with compliance because **the Regulatory Authorities are not up and doing.**
- There is a persisting problem of **lack of research feedback** in Nigeria.

Result/Findings

Summary of Key Focus Group Discussion Results

- ▶ About **Research Misconduct**, it is good for Nigerian researchers to look inwards, and check what is happening with their research projects.
- ▶ Some misconducts are not intentional and can be addressed with proper communication. **Nigeria is not immune to research misconduct.**
- ▶ The Trovan scandal is an old one that involved children with meningitis.
- ▶ **Mismanagement of Research Grants.** People were paid but the money was not used for the purpose of the study.

Result/Findings

➤ Summary of Interview results

- Research means “finding an answer to a question that has not been answered; no question has been fully answered on Earth”.
- Research has been part of the medical school and other university programs curriculum *ab initio*. But there is **low level of regulated research in Nigeria**.
- “...there has been a lot of trumpeting about the setting up of all sorts of research institutes, HRECs, and regulatory bodies, agencies, legislation....”
- “Does this plethora of 'research capacity' actually function as it should, sustainably and reliably for the long haul? ...No”.

Result/Findings

Summary of Interview results

- One major frustration to research in Nigeria is the reluctance of some international journals to publish works done in Nigeria.
- Few respondents said that **University-based Research, to them means Academic Research**. One said “it is an absolute disaster” because it is just research aimed at getting degrees, with the exercise not even utilized for any further benefit.
- There is not enough capacity of trainers/mentors for Regulated Research in Nigeria.
- Huge Funding gaps and poor access to research equipment, poor social capital, like power supply affect research.

Result/Findings

Summary of Interview results

- Known Frameworks for Research: include what Universities do to teach and oversee research, as for instance in the Community Medicine Departments of Nigerian Universities that oversee Students' Research.
- We pioneered research on "Ivermectin, in the wake of Nodulectomy, HIV, River Blindness".
- Outcome of many Research Studies in Nigeria **are not used to benefit the trial subjects.**
- We have so many Epilepsy patients, but despite the development of many new drugs for this condition, **our Teaching Hospital has no clinical trials, not even Phase 4 studies on epilepsy patients.**

Lessons from the 10th NQAC.

- **Ms. Gwen Kocher, RQAP-GLP.** Director of Quality Assurance; Experimental Surgical Services; University of Minnesota & Chair, Society of Quality Assurance University Specialty Section.
- **Quality Assurance as A Career: Is it Right for You?** This lecture discussed the advantages of the QA Career for individuals and institutions and shared practical experiences and opportunities through which individuals and institutions could benefit from the QA profession by getting involved with the Society of Quality Assurance and through other US Universities that have academic programs in Quality Assurance.
- **Several Nigerians joined NRCSQA and SQA as Outreach Members because of this Keynote Speech.**

Lessons from the 10th NQAC.

- **Mr. Samuel Adesola Adeyemo, B.Ed, M.Ed.** Research Associate and Program Coordinator, Surer (Scaling Up Research Ethics and Research Integrity) Project (www.surerproject.net) Center for Bioethics and Research, Ibadan.
 - This Speaker talked about the new training project for Nigerian Universities with grants from the National Institute for Health, NIH US. **Already 12 Universities have been recruited for this project with only 2 from Eastern Nigeria.** This funded MSc project is open for all Universities, organizations, hospitals and individuals in Nigeria. People are encouraged to apply for this MSc program and other related training available at CBR. However only those nominated by Universities will get enrolled into the program, free of charge.

Lessons from the 10th NQAC.

- ▶ **Mr. Aminu Yakubu MSc (PhD in-view).** Associate Research Fellow, Center for Bioethics and Research (CBR), Ibadan.
 - ▶ This presentation was on the need and the ethical framework for setting up of Biobanks in Nigeria. He expounded all the considerations needed to be made, demonstrated how global resources could be sourced and made a cogent recommendation that individual facilities like Nigerian Teaching Hospitals should set up their own Biobanks and out in place the ethics and oversight frameworks for such and any research that could ensue there-from.
- ▶ **Nigerian Institutions and Hospitals were advised to make early efforts to set up Biobanks and develop guidance and frameworks for their operations.**

Resolutions from the 10th NQAC.

- A Joint **HRPP – Human Research Participants Protection Program** will be commenced for the Eastern Region (South-East and South-South Zones), to be based in Enugu and coordinated by the Enugu State University Ethics Committee.
- Efforts to be made to get the Universities in Eastern Nigeria to benefit from the available **Academic program in Bioethics and Research Integrity**.
- That further efforts be made in seeking guidance and partnership for the setting up of **indigenous Biobanks in Nigeria**.
- That NRCSSQA Members henceforth (post-Covid) would attend Conferences in the United States of America for better training and capacity building in Quality Assurance.

Discussion

Regulated Research projects exist in Nigeria, at a very low level. Sponsors are yet to give qualified Nigerians QA roles on the projects. Low level of awareness among the public.

- No information in the public domain about GLP Studies in Nigeria.
- Very few GCP Studies. In many hospitals and facilities, surprisingly, many clinicians do not have any past or current Phase 4 CT studies.
- Data on some ongoing CTs are available from Registries like US www.clinicaltrials.com and WHO www.pactr.org.
- The **Nigeria Clinical Trials Registry (NCTR)** has scanty records of CTs. NAFDAC and NHREC were said to have created it. <https://nctr.nhrec.net/about.php>. However NAFDAC has her own Clinical Trial Database, that is apparently not linked to NCTR and has different CTs listed.

Discussion

- ▶ The **Nigerian Regulatory Authorities (RAs)** are so uncoordinated in their oversight roles. As reported by one FGD respondent, they really do not oversee ongoing researches enough **but just wait to collect the results**. NAFDAC has inspected some GCP studies. NESREA has not overseen any known GLP Studies. NIPRD (not a Regulatory Authority) does little GLP studies.
- ▶ A good number of respondents in this pilot study were familiar with **ethical frameworks** for Research but not the **legal frameworks**.
- ▶ SON is supposed to design and insist that all the other RAs and Research Stakeholders run QMS as may be required.
- ▶ The **Nigeria Quality Assurance Conference (NQAC)**, was created in 2011 as a Stakeholder Forum which all the RAs subscribed to. But they are not committed to use it to provide Research Stakeholders their annual Regulatory Updates as in the US.

Discussion

- ▶ There is a huge patient base, among very poor populations who would benefit from **large scale or small scale Phase 4 studies especially for Epilepsy, Hepatitis, DM, Hypertension etc.**
- ▶ Research Subjects' concerns about how Clinical Trials are conducted are very germane, and they border on Misconducts on the part of the investigators. These are issues that can be addressed when Researchers and Research Institutions **form/join a Human Research Participants Protection (HRPP) Program.**
- ▶ The existing publication bias obviously deters grants and support for developing country scientists, with the consequence of the **negative impact on the quality and quantity of research output.** This needs to be addressed too.

Recommendations

- ▶ **University-based research** should be placed on the front-burner in Nigeria because of the myriads of the ethical, legal and societal issues associated with it.
- ▶ With respect to equitable sharing and dissemination of research benefits, the global Research Community should support the quest of Nigerian Researchers **to outsource Phase 2-4 Clinical Trials.**
- ▶ In particular, there is a dire need to improve the capacity and interest/focus of the Regulatory Authorities on Clinical Trials and other Regulated Research. There should be a Policy that will support Nigerians to get **QA roles in all Studies** within the Country.
- ▶ The Nigerian RAs and Government Agencies should fully embrace the **Nigeria Quality Assurance Conference** project and use this platform to drive this desired outcome each year.

Recommendations

- Nigeria needs **Academic Quality Assurance and Regulatory Science Programs** in her higher Institutions. Despite the past unsuccessful effort on our part, the Global and US QA Community/Network are still requested to assist Nigeria in this direction.
- The **Enugu State University** needs a stand-alone **Bioethics Program** or as part of her recently approved post-graduate Public Health Program, and also desires QA Programs.
- The **University of Nigeria**, has not jettisoned the need to partner with a US University for her **Regulatory Science Program**.
- We need help with **human and material resources/funds** that would be needed to set up our proposed **HRPP Project** and the execution of **Capacity building Training with the Nigerian RAs**.

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Thank you for listening!

Questions, if any.

