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Site Office: ZETA-12 CRO/CIMRO Research Organisation, 26 Emeka Abalu Crescent, Trans Ekulu Enugu.

**REPORT OF THE 12TH NIGERIA QUALITY ASSURANCE CONFERENCE (NQAC)/
6TH EASTERN NIGERIA RESEARCH ETHICS FORUM (ENREF) BIOETHICS WORKSHOP.**

Theme: "From Compliance to Excellence: Advancing Quality in Healthcare Delivery and Ethical Leadership in Regulated and Clinical Research".

Date: Tuesday 11th – Thursday 13th November 2025.

Venue: University of Nigeria Teaching Hospital/ College of Medicine, University of Nigeria

BACKGROUND:

The Nigerian Quality Assurance Conference (NQAC) started in 2011 as a National project introduced by the Nigerian Regional Chapter, Society of Quality Assurance (NRCSQA) and other Quality Assurance and Regulatory Affairs Stakeholders including the Standards Organization of Nigeria (SON), National Agency for Food and Drug Administration and Control (NAFDAC), National Environmental Standards and Regulations Enforcement Agency (NESREA), National Biotechnology Development Agency (NABDA), National Institute for Pharmaceutical Research and Development (NIPRD) and several other organizations including Contract Research Organizations like ZETA-12, AHP-Africa Health Project, NestraKlinical and Bethari& DataSystems. The NQAC held for three (3) years in Abuja (hosted at NIPRD), two (2) years in Lagos (hosted at the Nigerian Institute for Medical Research – NIMR), and four (4) years in Enugu (Godfrey Okoye University, Chiolive International Medical Research Organization, Enugu State University of Science & Technology Teaching Hospital/College of Medicine), and lastly at the University of Nigeria Teaching Hospital Old Site.

The Eastern Nigeria Research Ethics Forum (ENREF) was created by Regional Stakeholders including Teaching Hospitals, Research Ethics Committees, and Individual Researchers in 2012. The first ENREF Bioethics Training Workshop was hosted in 2013 by the National Orthopaedic Hospital, Enugu. The decision to run the ENREF Bioethics Workshop as one of the NQAC Quality College workshops was for convenience sake, in order to reduce the time and work commitment for the same set of Bioethics Faculty members who run the ENREF Workshop and the NQAC Bioethics Quality College yearly. Considering the giant strides taken by the Management of the University Teaching Hospital, Ituku-Ozalla, in the area of Quality Improvement, we resolved to request the Hospital to host the 2025 NQAC/ENREF Bioethics Workshop:

STAKEHOLDERS/PARTICIPANTS:

The Conference drew attendees from these below-mentioned stakeholders, who also gave financial and other logistical support for the event.

1. Over (50) participants from the Departments/Units of University of Nigeria Teaching Hospital Ituku-Ozalla, Enugu Nigeria.
2. Health Research Ethics Committee (HREC) of Irrua Specialist Teaching Hospital, Edo State.
3. Health Research Ethics Committee (HREC) of University of Nigeria Teaching Hospital, Ituku-Ozalla.
4. Health Research Ethics Committee (HREC)/Research Education Training Department of National Orthopaedic Hospital, Enugu.
5. Quality Improvement (QI) Committee of University of Nigeria Teaching Hospital, Ituku-Ozalla.
6. Chiolive International Medical Research Organization (CIMRO).
7. Eastern Nigeria Research Ethics Training (ENRICH) Program.
8. Society for Quality Assurance in Nigeria (SQAN).
9. ZETA-12 Contract Research Organization.

FACILITATORS

1. Prof. Chioli Pascal Chijioke, Principal Investigator Chiolive International Medical Research Organisation (CIMRO)/Dietary Intervention Research Group UNTH Enugu.
2. Dr. Yemihan Ogbetere, Administrator, HREC & Sponsor Representative, INTGRATE Lassa Fever Therapeutic Trial, Irrua Specialist Teaching Hospital, Irrua Edo State.
3. Mr. Chinonso Adolphus Ugwu, Administrator, Eastern Nigeria Research Ethics Training (ENRICH) Program, Bioethics Unit, Institute of Public Health, UNN.
4. Dr. Pamela Ukeoma, Secretary, Quality Improvement Committee, UNTH Ituku-Ozalla.
5. Mr. Umame Evans Oseremen, Quality Assurance/Quality Improvement Focal Person, Irrua Specialist Teaching Hospital, Irrua, Edo State.
6. Dr. Chidiebere Promise Ndubueze, Quality Implementor/Consultant, Laboratory Medicine, UNTH Ituku-Ozalla.
7. Dr. Chinenye Cynthia Akwolu, Research Officer, Liverpool Women's NHS Foundation Trust, UK.
8. Mr. Ado Danladi, Desk Officer, National Health Research Ethics Committee, Abuja, Nigeria.
9. Dr. John-Moses Maduabuchi, Executive Director, Society for Quality Assurance Nigeria (SQAN).
10. Mr. Christopher Both, SQA US Executive Representative & International Liaison for SQAN.

PROCEEDINGS:

The 2025 event which was designed as per our tradition into a pre-conference quality college, conference, and post-conference quality college was delivered as a hybrid meeting (the presenters from the United Kingdom and United States of America and several others participated virtually). Both the pre- and post-conference workshops were about the quality assurance activities of the Bioethics Specialty Section of the Nigeria Regional Chapter, SQA.

A. Pre-Conference Workshop.

Trainees were coached on how to register and commence the free online Collaborative Institutional Training Initiative (CITI) Training Program via the Centre for Bioethics and Research portal. For the practice of Research Ethics and ethical conduct of Research in Nigeria, the Nigeria Health Research Ethics Committee (NHREC) has minimum online CITI Training requirements that everyone must comply with. The CITI Training in addition to the onsite training is also compulsory for the listing/registration, certification, or accreditation of the institutional HRECs in Nigeria. Some of the CITI modules include: Research ethics regulation in Nigeria; what makes Research Ethical; & Introduction to Responsible Conduct of Research (RCR). Many participants heard about the CITI Training during that Workshop for the first time and signed up same day. (See the Appendix for more information about CITI Online Training for Bioethics). The other aspect of this workshop was the training on *Introduction to Responsible Conduct of Research* featuring both the modules from United States Office of Human Research Protections and CITI.

B. Conference Proper.

The conference started with opening Remarks from the Chief Medical Director (CMD), University of Nigeria Teaching Hospital, Prof. Obinna D. Onodugo who attended in person, and also accompanied by the Chairman, Medical Advisory Committee (CMAC) of UNTH, Dr. Charles Nonyelu. The CMD commended the Society for Quality Assurance in Nigeria for introducing this QA Conference in Nigeria and for choosing UNTH as the host institution in 2025. He commended Prof. C.P. Chijioke who actually made him understand the need for this Conference in UNTH at this point in time, in view of the several efforts being made by Hospital Management to improve the quality delivery of medical care and ethical conduct of research in the institution. The CMD pledged future substantial support for the NQAC and urged the participating Staff members of UNTH to take advantage of the opportunity to improve their capacity in Bioethics and Quality Assurance education and practice. He also appreciated all Guest participants especially the team from Irrua Specialist Teaching Hospital led by Dr. Ogbetere Yemihan and the facilitators/Local Organizing Committee as well.

The CMAC, Dr. Charles Nonyelu, on his part commended the Conference organizers and contributed appreciably to the discussion about Clinical Trials in Nigeria, stating that with this kind of concerted efforts from the Stakeholders of the NQAC, good awareness would be created about Nigeria being ready for global clinical trials, having enough stakeholders like QA Auditors and trained clinical trial sites so that International Sponsors would have confidence to domicile their trials in Nigeria, considering the huge drug-naïve population we have. He harped on the importance and relevance of Bridging studies which almost non-existent in our environment.

In response to the CMD, the Executive Director of SQAN, Dr. Maduabuchi John-Moses on behalf of all attendees appreciated the UNTH Management especially for hosting and financially supporting the Conference. He remarked part of the Conference Hallmarks would be deliberations on how the design and implementation of Quality Management Systems (QMS) could help improve service delivery especially starting with the Accident and Emergency Department, and the need to set up Clinical Ethics Committees that would use Clinical and Professional Ethics code to ensure ethical conduct of healthcare workers among other roles.

C. Post-Conference Workshop.

This segment, also promoted by the Bioethics Specialty Section of SQAN, featured presentations about the creation of the regional Human Research Protection Programme (HRPP) introduced last year in Nigeria. To start with, the HRPP Forum focused on the Eastern Region with stakeholders including Health Research Ethics Committees (HRECs)/IRBs most of which have been certified by the Regulatory Body, National Health Research Ethics Committee (NHREC); the Groups that provide Education and training in the fields of Research Ethics and Quality Assurance, like ENRICH and the Society for Quality Assurance in Nigeria; experienced and committed individual researchers and institutions/research organisations committed to responsible conduct of research.

The components and scope of activities of this regional Joint HRPP Forum (the first of its kind in Africa) include the traditional Education Programme, relevant Local/State Laws, Institutional Policies, Quality Improvement (QI) Programmes, Ethics Committee Reviews, Reliance Agreements, Privacy Issues, and Ancillary Committees. Other local peculiarities and needs would also be considered moving forwards.

PLENARY PRESENTATIONS

Dr. Ogbetere Yemihan, Public Health Physician/Administrator HREC, Irrua Specialist Teaching Hospital HREC.

Lecture Topic: *Operationalizing Quality and Ethics in Clinical Research Oversight: The Irrua Specialist Teaching Hospital HREC Model*

This lecture presented the progress made by the Irrua Specialist Teaching Hospital HREC in strengthening

protocol review, monitoring, and audits. The speaker discussed challenges in protocol compliance, reviewer capacity, and investigator engagement. He outlined lessons from their model and stressed the importance of institutional support, standardized SOPs, and improved reviewer training to enhance efficiency and quality.

Mr. Ado Danladi, Desk Officer, National Health Research Ethics Committee (NHREC).

Lecture Topic: *Regulatory Oversight and Strengthening National Research Ethics Governance*

Mr. Danladi provided an overview of NHREC's mandate, national guidelines, accreditation processes, and monitoring activities. He explained the current gaps in Nigeria's research ethics system and ongoing reforms to improve compliance, communication, and integrity. He called for stronger HREC capacity building, improved NHREC–HREC collaboration, and adoption of digital tools for protocol review and reporting.

Prof. C. P. Chijioke, Principal Investigator, CIMRO/DIRG

Lecture Topic: *DIRG – Nutritoxico-epigenetics Study: An Investigator-Initiated Clinical Trial*

Prof. Chijioke presented the scientific basis of nutritoxico-epigenetics and its relevance for Nigeria. He highlighted the methodological and regulatory considerations required for investigator-initiated clinical trials and discussed the potential impact of this research on genetics and nutrition. He stressed the need for increased funding, Teaching Hospital collaborations, and capacity building in epigenetic research.

Mr. Chinonso Adolphus Ugwu, Administrator, ENRICH Programme.

Lecture Topic: *ENRICH – A Model for Strengthening Ethical Leadership and Research Oversight*

This presentation highlighted the ENRICH Project's focus, achievements, including training outputs, institutional collaborations, and contributions to the strengthening of Bioethics Education and HRPP Systems in Nigeria. Mr. Ugwu discussed current challenges, emerging opportunities, and the next phase of ENRICH activities. He advocated for program expansion, sustained funding mechanisms, and mentorship pathways for upcoming Bioethics professionals.

Dr. Pamela Ukeoma, Secretary, UNTH Quality Improvement Committee.

Lecture Topic: *PharmaAccess' Role in Strengthening UNTH Systems for National Impact: Advancing Quality Healthcare through Collaboration.*

Dr. Ukeoma discussed the strategic partnership between PharmaAccess and UNTH and the Quality Improvement initiatives implemented under this collaboration. She highlighted the broader National relevance of these interventions and emphasized the importance of public-private partnerships. Her presentation called for sustained quality assurance programmes and the scaling up of successful innovations across Nigeria. She recommended the sustenance of the NQAC and for partnership between UNTH and SQAN to improve ethical conduct of research and quality service delivery.

Mr. Umane Evans Oseremen. Quality Assurance/Quality Improvement Focal Person.

Lecture Topic: *Quality Assurance as a Pillar for Ethical Conduct of Research in Nigeria.*

This lecture explored the need for QA systems and ethical research conduct. Mr. Umane discussed the gaps in existing QA structures, in the context of HREC Functions in Nigeria and stressed the need for institutional QA frameworks, regular audits, and integration of QA processes into all research stages. He underscored that quality systems are central to ensuring credibility and integrity in Human Subject Research.

Proposal Presentations – HRPP Session Proposal for PRIM&R and SQA USA Conference Abstract.

Presenters: *Dr. J.M Maduabuchi, C.A. Ugwu & Dr. C. Ndubueze.*

This session outlined and discussed a Session Proposal focused on the new Regional HRPP Forum in Nigeria which was submitted and accepted for the Public Responsibility in Medicine & Research (PRIMR - www.primr.org) Conference in the United States of America. This emerging model of running a Joint Human Research Protection Programs (HRPPs) for institutions and research sites starting with Eastern Nigeria is an innovative response to the persisting regulatory, operational, and resource pressures facing research oversight systems, in our region. Joint HRPPs were presented as structured inter-institutional collaborations that harmonize IRB/HREC reviews, standard operating procedures (SOPs), training, and quality assurance mechanisms to enhance efficiency, consistency, and participant protection.

Overall, the session concluded that despite contextual challenges, the new Joint HRPP represents a sustainable and scalable pathway toward strengthening ethical research oversight and protecting human research participants through collective responsibility and collaboration. The presenters also discussed an abstract on a research capacity assessment designed for UNTH and other tertiary Teaching Hospitals in the region. They highlighted gaps in institutional research infrastructure and opportunities for collaborative strengthening and Research.

SQAN & STAKEHOLDERS' BUSINESS MEETING

This held on the last day of the Conference at CIMRO for logistics reasons. The execution of the Conference was reviewed with subsequent strategic planning for future NQAC, HRPP and ENREF Activities. Elections of SQAN Executive Committees Members also held during the close-out meeting, successfully producing officials including the President, Vice President, Secretary, Treasurer, three (3) Directors and a Past President. Discussions and plans were also made about the QA activities slated for 2026, including the 42nd SQA Annual Meeting & Quality College in Maryland, USA, Seminars and Workshops to be organized by SQA in Nigeria.

RECOMMENDATIONS/RESOLUTIONS

1. All major Quality Assurance Stakeholders in Nigeria are hereby implored to collaborate in sustaining the objectives and aspirations of the NQAC, and the Regional HRPP Forum to strengthen ongoing and future partnerships for National Development.

2. The Unit of Society for Quality Assurance in Nigeria Members based in UNTH Ituku-Ozalla has been set up, ably led by Prof. Chioli P. Chijioke. It is recommended that the UNTH Management recognize and work with this Unit to support Quality Systems as she may deem fit. For any activities related to QA/QI that needs to be done in UNTH or any Institution/Hospital that comes into similar partnerships, the National and Global QA Resources in SQA (www.sqa.org) would be brought to bear on the efforts.

3. Publishing and circulation of this Report to all Stakeholders and early decision and planning for the 2026 NQAC.

DONATIONS AND FINANCIAL SUPPORT (SUMMARY)

On behalf of all of us, we thank Prof. Obinna D. Onodugo, CMD, UNTH, Ituku-Ozalla, Prof. Chioli P. Chijioke, Dr. Chibuzor Ndiokwelu and all others who supported the Conference financially. Other moral support from NHREC, Abuja, from the UNTH Hospital Management/Community, from the Conference Organizing Committee, the Caterer and anticipated donations from other Institutions are kindly acknowledged. They really impacted the successful outcome of this year's 12th Nigeria Quality Assurance Conference (NQAC).

CONCLUSION

In conclusion, the conference provided a valuable platform for strengthening knowledge, collaboration, and best practices in Quality Assurance, Bioethics and Human Research Participant Protection. The insights gained reinforce the importance of robust ethical oversight, capacity building, and adherence to national and international standards in health research and clinical practice.

All stakeholders and participants committed to supporting ethically sound, high-quality research that safeguards participants, promotes scientific integrity, and contributes meaningfully to national and global health priorities. Two stakeholders, the University of Nigeria Teaching Hospital (UNTH) and the Irrua Specialist Teaching Hospital (ISTH) which are foremost tertiary health institutions in the region reaffirmed their commitment in supporting/hosting future NQAC Events. For these and other stakeholders that tertiary Hospitals and Research Centres, it was agreed that local SQAN Units would be created for each Centre to facilitate Collaboration and institutionalizing the education and practice of regulatory quality assurance.

The leadership of the joint Human Research Participant Protection Program will adopt a dual-layered structure. While the core leadership will be institution-based to ensure accountability, sectional unit leadership will be maintained to promote the decentralization of roles. This is to enhance collaboration, streamline workflows, and improve overall participant safety outcomes.

The conference concluded with a clarion call for increased stakeholder awareness and active participation.

To actualize the outlined objectives, there is a recognized need to:

Align local protocols with international regulatory bodies to ensure that Nigerian research remains globally competitive and ethically sound.

Encourage broader stakeholder involvement to meet set targets in scientific integrity and public health priorities.

All participants departed with a shared commitment to safeguarding research participants and upholding the highest standards of scientific integrity, ensuring that health research contributes meaningfully to both national development and global medical advancement.

APPENDICES

1. PHOTO SPEAK



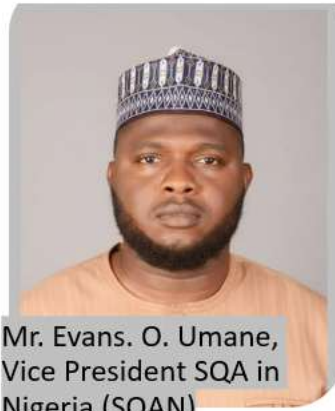
2. HOW TO REGISTER FOR CITI ONLINE TRAINING.

1. Visit <https://about.citiprogram.org/en/homepage/> and click Register on the menu at the left-top side of the page.
2. Click Register
3. Select your Organisation: type in: Center for Bioethics and Research (CBR), Nigeria.
4. Agree with the Terms of Service and affirm your affiliation by checking both small boxes on the left.
5. Proceed in completing the registration filling in your personal data.
6. For options about CE Credits Units, choose NO if you are not in US or can't process it.
7. Complete the registration.
8. You have to accept and sign the Assurance page before you access/begin any course.

3. NEW SQAN EXECUTIVE COMMITTEE MEMBERS.



Dr. Chidiebere P. Ndubueze, President SQA in Nigeria (SQAN)



Mr. Evans. O. Umane, Vice President SQA in Nigeria (SQAN)



Mr. Chinonso Adolphus Ugwu, Secretary SQA in Nigeria (SQAN)



Mr. Ijeoma Ugwu, Treasurer, SQA in Nigeria (SQAN)



Dr. Chinenye (Chinny) Akwolu, Director, SQA in Nigeria.



Prof Ejeatuluchukwu Obi Director, SQA in Nigeria.



Prof. Chioli Pascal Chijioko
Director, SQA in Nigeria

Signed:

Chinonso Adolphus Ugwu
Secretary, SQAN

Dr. Chidiebere Promise Ndubueze
President, SQAN

