

REPORT OF THE 10TH NIGERIA QUALITY ASSURANCE CONFERENCE (NQAC)/5TH EASTERN NIGERIA RESEARCH ETHICS FORUM (ENREF) BIOETHICS WORKSHOP.

Date: Wednesday 16th – Friday 18th November 2022.

Venue: Enugu State University of Science and Technology, College of Medicine Auditorium/School of Midwifery Hall.

Theme: Implementation of Bioethics & Quality Assurance Programs in University & Hospital Settings.

BACKGROUND:

The **Nigerian Quality Assurance Conference (NQAC)** started in 2011 as a National event introduced by the Nigerian Regional Chapter Society of Quality Assurance (NRCSQA) and other Quality Assurance 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 Neutra Klinical and Bethari Systems. The NQAC held for 3 years in Abuja (hosted at NIPRD), 2 years in Lagos (at the Nigerian Institute for Medical Research – NIMR), and 3 years in Enugu (Godfrey Okoye University, Chiolive International Medical Research Organization, and lastly at the College of Medicine/Teaching Hospital of Enugu State University of Science and Technology).

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. The decision and motivation to have the ESUT College of Medicine and the Teaching Hospital co-host this 2023 NQAC/ENREF Bioethics Workshop were:

1. To enable the College of Medicine and the University to key into the new project designed to help Nigerian Universities to set up Research Integrity & Compliance Offices in their institutions.
2. To ensure the Teaching Hospital and the College nominate people to be trained as Ethics Committee members, who would handle not just research ethics review, but other aspects of Bioethics including clinical and environmental ethics.
3. To help individual attendees to learn about the Quality Assurance profession and Bioethics as an emerging field of study, and benefit from the available academic and training programmes in these areas.

ATTENDEES/PARTICIPANTS:

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

1. College of Medicine, Enugu State University of Science and Technology; the Provost nominated ten (10) participants for the conference/workshop.
2. Enugu State University of Science and Technology Teaching Hospital: The Chief Medical Director nominated twenty (20) participants for the conference/workshop.
3. Chiolive International Medical Research Organization (CIMRO): The Director nominated six (6) participants for the conference/workshop.

4. Society for Quality Assurance in Nigeria (SQAN).
5. ZETA-12 Contract Research Organization.

FACILITATORS

The following persons facilitated the conference/workshop.

1. Ms. Gwen Kocher, RQAP-GLP. Director of Quality Assurance; Experimental Surgical Services; University of Minnesota & Chair, Society of Quality Assurance University Specialty Section
2. Dr. John Moses Maduabuchi: Executive Director SQAN
3. Prof. Chukwunkeke Felix: Dean Faculty of Dentistry/Chairman, College of Medicine Ethics Committee, University of Nigeria, Ituku-Ozalla Campus
4. Mr. Samuel Adesola Adeyemo, B.Ed, M.Ed. Research Associate and Program Coordinator, SURER Project Center for Bioethics and Research, Ibadan.
5. Mr. Joseph Ikedi O: MD, Xtrim Research Ltd. Aba
6. Dr. Uzoma Ajegbo: M&E Officer, WHO, Enugu State
7. Mr. Aminu Yakubu. Associate Research Fellow, Center for Bioethics and Research, Ibadan. Nigeria.

PROCEEDINGS:

The event was divided into a pre-conference workshop, conference, and post-conference workshop facilitated as a hybrid meeting. It was a 3-day event from the 16th to the 18th of November 2022. All the Bioethics trainees and some facilitators participated on-site, while some facilitators participated online. The online facilitators were from the SQA USA, Center for Bioethics and Research, Ibadan, Lagos, Xtrim Research Ltd. Aba, and the University of Jos Teaching Hospital. The workshop involved presentations, plenary discussions, group break-out discussions, and non-structured interpersonal interactions.

A. Pre-Conference Workshop.

The workshop started with the compulsory enrolment of all the trainees for the online Collaborative Institutional Training Initiative (CITI) training program. This is a compulsory program by the Center for Bioethics and Research, Nigeria for all Health Research Ethics Committee (HREC) Members, in addition to the onsite training before the listing/registration, certification, or accreditation of the institution HREC by the National Health Research Ethics Committee (NHRE). Some of the modules include: **What makes Research Ethical; Research ethics regulations in Nigeria; Introduction to Responsible Conduct of Research (RCR).**

B. Conference.

The conference started with goodwill messages shared on behalf of the Provost, College of Medicine, Prof. Frank Ezugwu, the Chief Medical Director, ESUT Teaching Hospital, Prof. H. Onah, and Dr. Orjioke, the Ethics Committee Chairman and Governance officer of the Teaching Hospital. They encouraged full participation by the participants and pledged their support in sustaining the activities of the HREC when fully inaugurated.

The goodwill messages were followed by keynote lectures and guest speeches from presenters across the states and from the US.

1. **Ms. Gwen Kocher, RQAP-GLP.** Director of Quality Assurance; Experimental Surgical Services; University of Minnesota & Chair, Society of Quality Assurance University Specialty Section.

Lecture Topic: Quality Assurance as A Career: Is it Right for You? This lecture discussed the advantage 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 persons indicated interest to join SQA because of this lecture.

2. Mr. Samuel Adesola Adeyemo, B.Ed, M.Ed. Research Associate and Program Coordinator, SURER Project Center for Bioethics and Research, Ibadan.

Lecture Topic: Scaling Up Research Ethics and Research Integrity.

This Speaker talked about the new training project for Nigerian Universities with a Grant from the National Institute for Health, NIH US. The Principal Investigator for this Grant is Prof. Clement A. Adebamowo. Already 12 Universities have been recruited for this project with only 2 from Eastern Nigeria. This funded MSc project is open to 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. Upon graduation, trainees would be sponsored to create Research Integrity Units for their Universities.

3. Mr. Aminu Yakubu. Associate Research Fellow, Center for Bioethics and Research, Ibadan. Nigeria.

This presentation was on the need and the ethical frameworks 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 outlined the need for the ethics and oversight frameworks for such and any research that could ensue there-from.

C. Post-Conference Workshop.

The Workshop (training of Ethics Committee Members) continued after the Conference on the last day.

The post-conference modules handled include:

- Research – An Overview. Dr. Uzoma Ajegbo
- Monitoring and Evaluation: by Dr. Uzoma Ajegbo
- The Role of HRECS in Research Ethics Regulation & DSMB in Clinical Research; By Dr John-Moses
- Ethics Committees: Composition & Functions; by Dr John-Moses

The last day of the training provided the participants with ample opportunity to discuss on the nature and scope of the work expected of them. The deliberations were presided over by Dr. Maduabuchi John-Moses Uwanduoma, during which ample clarifications were made about the expectations of the CMD from the trainees. The participants were informed that the CMD, and Dr. Orjioke as well as the Chairman Medical Advisory Committee, expects all the nominated trainees to be available and render services to the hospital as ethics committee members. In view of the standard requirements to set up ethics committees, (which include a minimum of 5 members, and at least 2 officers), the trainees nominated the following

1. Dr. Anigbo Gideon (who represents Dr. Orjioke) as Chair of the Committee
2. Mrs. Agwagu Njideka as Secretary
3. Mrs. Agbo Ifeoma as Administrator.

The meeting ended on a merry note with a vote of thanks offered by Dr. Anigbo Gideon who also was the Chairman Local Organizing Committee.

RESOLUTIONS:

Considering that the National Health Research Ethics Committee (NHREC), at the moment has the sole mandate to register and accredit Health Research Ethics Committees, the ESUT College of Medicine and Teaching Hospital should be encouraged to put things in place for NHREC's visit (on invitation sooner than later).

The participants resolved to

1. Adjourn the training (for the constraint of time) and complete the remaining aspects online and during the Ethics Committee meetings. It was agreed that the scope of ethical review should go beyond Health Research Ethics, especially for the Hospital Bioethics Committee which should pioneer clinical ethics review in this part of the country.
2. Pay a visit to the CMD and Provost as a team to present the Conference report and also request further management support for the Ethics Committee work.
3. To secure meeting space for monthly meetings and to commence reviewing research protocols as a team without delay. Apart from having reviewers from both the Hospital and College, Bioethicists from the ENREF Forum and SQAN Bioethics Specialty Section can also be invited to the review meetings or requested to contribute to the review as may be needed.

RECOMMENDATION/PRAYERS:

1. That the Provost, College of Medicine and the CMD/ESUT Hospital Management would recognize the trained members of staff as the substantive members of the College and Hospital Ethics Committee and grant them any required subsequent support they may need to operate. That both Committees be allowed to sit jointly as may be required and also participate as stakeholders in the proposed regional Joint Human Research Participants Protection (HRPP) Program, to be coordinated from ESUT College of Medicine.
2. That the Provost of the College Medicine would nominate a mid-career level staff for the funded MSc Bioethics programme in Research Integrity and Compliance, based at the University of Ibadan. The nominee would be funded for the programme and his project would be to set up a Research Integrity Unit for the University.
3. The ESUT Teaching Hospital could also support a second staff member for this role by funding/sponsoring the MSc Programme.
4. The ESUT Teaching Hospital could consider seeking further guidance and partnership in setting up her own Biobank for Research purposes.

Signed:



Dr. Anigbo Gideon
Chairman LOC.



Ogbuka Janet
Rapporteur



Dr. Maduabuchi John-Moses U.
SQAN Executive Director