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Workshop proceeding

Ethics and Responsible Conduct of Research: Workshop Report

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ABSTRACT

The Center for Population and Reproductive Health, College of Medicine, University of Ibadan, Ibadan, Nigeria , with support from its NIH Planning Grant organized a two Day workshop on "Ethics and Responsible Conduct of Research" at the University of Ibadan Centre for Sustainable Development (CESDEV). There were 8 facilitators and 78 participants. The workshop concluded that responsible conduct of research (RCR) is the practice of scientific investigation or research with integrity involving but not limited to the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

Keywords: *Workshop report, responsible conduct of research*

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BACKGROUND TO THE WORKSHOP

Consequent upon increased importance of researches in growth and development of science and technology, the public support for researches increased dramatically over the course of the 20th century. However, for a long time, researches were not performed under carefully guided and regulated protocol and procedure. Today, with growing public awareness, there is understandable concern about the way research should be conducted with confidentiality and respect, yet with benefits. As public servants and also professionals, researchers have clear obligations to conduct their research in a responsible manner.

Recognizing in general terms that responsible conduct in research is simply good citizenship applied to professional life, the Center for Population and Reproductive Health, College of Medicine, University of Ibadan, Ibadan, Nigeria, with support from its NIH Planning Grant organized a two-day workshop on "Ethics and Responsible Conduct of Research" between 27th – 28th June 2018. The venue was University of Ibadan Centre for Sustainable Development (CESDEV), 20 Awolowo Road, Old Bodija Estate, Ibadan, Oyo State, Nigeria. There were 8 facilitators and 78 participants which included resident doctors, PhD students, post-doctoral fellows, postgraduate students and junior faculty. The course objective was to prepare potential trainees for quality research and provide guidelines to train faculty and students for NIH grants. All resource persons have sufficient experiences in the chosen subjects. Nine of the presentations are included in this publication.

The Universities of Ibadan (UI) and Chicago (UC) NIH FIC funded partnership training program entitled "International Partnership for Interdisciplinary Research Training in Chronic Non-Communicable Diseases and Disorders Across the Lifespan" commenced 2011. Since then, UI has identified priority areas for training and developed international partnerships for building strong postgraduate programs and research training capacity. Emphasis was placed on applying an interdisciplinary research approach, a "lateral shift", whereby trainees receive training in another health-related discipline such as behavioral research, bioethics, biostatistics, cancer biology, clinical pharmacology and pharmacogenetics, health services research, genetics, epigenetics, immunology and molecular pathology. This "lateral shift" was designed to expand trainees' knowledge and increase their capacity at various career levels to develop relevant hypotheses, plan appropriate study designs, operationalize research findings, nurture collaborations between scientists of different disciplines and in some trainees potentiate considerable shifts in thinking and approaches to prevent and cure diseases that affect populations in this region and continent.

The specific objectives of the NIH funded training program are:

1. To create and enhance opportunities for post-doctoral training in chronic non-communicable diseases across the Lifespan of high priority to Nigeria with the goal of providing trainees with necessary knowledge, skills and exposures to become independent researchers at the faculty level.
2. Formalize short-term, medium-term and long-term training in NCD research for nascent Nigerian physicians, non- physician scientists and allied health workers, thereby providing the skills necessary to bridge clinical medicine grounded in translational science.
3. Train a representative crop of healthcare professionals (HCPs) and biomedical researchers in the techniques and competencies of Good Clinical Practice and Good Laboratory Practice by developing Standard Operating Procedures (SOPs) in the different areas and levels of healthcare processes.
4. Disseminate novel research methodologies and opportunities to benefit other NIH-funded investigators and trainees at other institutions in Nigeria and Africa.

To achieve these objectives, University of Ibadan identified a robust pool of senior faculty and emerging global health leaders with international exposure who could both mentor others as well as undergo advanced training in specified focused areas of research. An NIH capacity sustaining planning grant was awarded to UI (D71) in 2017 as a vital next step that afforded the great opportunity to plan, organize and set the stage to competitively apply for in-country based D43, which will enable NIH stakeholder to consolidate and enhance the laudable achievement previously recorded by our team. Among the programmes scheduled for the D71 planning phase was the organization of workshops on protection of human subjects and responsible conduct of research for all potential research trainees. This was with a view to preparing for the establishment of sustainable yearly workshop on Responsible Conduct of Research modeled after the University of Chicago summer program. The workshop will not only aligned with NIH regulation, but also ensure opportunity for our postgraduate students and faculty to meet NIH requirement for prospective grantees.

The topics of presentations were Historical Perspective & Fundamentals of Clinical Research, Ethical Principles & Responsible Conduct in Research, Team Building and Responsible conduct of Research, Protocol and Research Relationship with IRB, Research Sponsoring/Financial Management and Conflict Of Interest, Responsible Conduct of Research: Human Subjects, Vulnerable Population, Animal Use and Care Research Ethics, Data Management in Clinical Research, and Authorship: Concept and Issues

OUTCOME OF THE WORKSHOP:

Training in responsible conduct of research was positively impactful on all participants based on responses to pre- and post-workshop evaluation. Most of the participants stated that they were better informed about: i). application of established professional norms and ethical principles in the performance of all activities related to scientific research, ii). prudent financial management and critical data analysis, iii). effectiveness of team work and the use of authorship criteria, iv) application of ethical and legal options in the face of conflicts involving scientific research, v). clarification of ethical controversies in animal research.

DISCUSSION AND CONCLUSIONS AT THE WORKSHOP:

The training in responsible conduct of research was designed to discourage research misconduct, questionable research practices and moving towards doing good science. It was clarified at this workshop that RCR is a scientific investigation with integrity which involves awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Apart from the fact that RCR is an essential component of research training, it also involves prudent financial management and critical data analysis, team work and authorship criteria, ethical and legal choices in the face of conflicts involving scientific research.

The papers delivered during the workshop added that supervisors should be approachable, assessable and supportive, keep integrity of teams and data, prevent misunderstanding and be ready to solve problems relating to misconduct. Processes for authorship dispute resolution pointed out were direct dialogue, mediation and peer panel. The workshop pointed out that author should have original idea, planning and input in the study, be active in the supervision of the project and experimental work be involved in drafting of manuscript. Provision of fund, reading through the manuscript and provision of reagents, funds or patients warrant acknowledgement only.

Animal research using non-human vertebrates such as primates, dogs, cats, rabbits, hamsters, birds, rats, and mice has improved understanding disease mechanisms, genetic manipulation and pharmacological/toxicological testing, reagent preparation with the subsequent development of new medicines and treatments. However, both animal-rights extremists and anti-vivisectionist groups believe that animal

experimentation is cruel and unnecessary, regardless of its purpose or benefit due to distress, pain, injury and eventual death. The lecture in this aspect during the workshop clarified ethical controversies and moral issues in animal researches. The lecture emphasised that researches involving the use of animals must have detail of procedures, experiments, numbers and types of animals. Moreso, experimental animal users should always realise that animals do feel pain, thus the use of the 3Rs is crucial to continuously reduce the suffering of animals in research.

The workshop concluded that responsible conduct of research (RCR) is the practice of scientific investigation or research with integrity involving but not limited to the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Ethical and responsible conduct of research is important for excellence, as well as public trust. Proper training and grapping the concept of RCR is considered essential in the preparation of future researchers. This workshop on RCR also provides framework for preventing research misconduct, managing research data/materials, publishing and disseminating research findings, including proper attribution of authorship, proper handling of laboratory animals, conducting effective peer review and managing conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.