

WAB Newsletter



West African Bioethics

funded by: the Fogarty International Center of the
United States' National Institute of Health

A Newsletter of West African Bioethics Training Programme

About WAB

The West African Bioethics is program for teaching, service and research in International Bioethics

The West African Bioethics training program is unique because it uses the opportunity afforded by its location in West Africa to research and train in Bioethics in English and French languages, both of which are widely spoken in the West African subregion.

INSIDE NEWSLETTER

BeOnline® Journal of the West African Bioethics Training Program Now in PubMed Central

Life as a National Institute of Health - Institutional Review Board Trainee

12th Annual Fogarty International Center Administrators' Meeting

Closing Remark



BeOnline® Journal of the West African Bioethics Training Program Now in PubMed Central

BeOnline® Journal of the West African Bioethics Training Program seeks to increase the contribution of African bioethicists to the international discourse on bioethics and increase discussions about bioethics issues as they relate to Africa. It mobilizes research that speaks to a range of scholars in bioethics and welcomes supplemental submissions from the fields of public health, political communication, sociology, political science, law, communications, media, literature, philosophy and history. Given that bioethical issues arise at all levels of society, the journal encourages multi-disciplinary debate on such issues and aims to shed light on research ethics concerns.



While BeOnline Journal embraces submissions across a range of research perspectives, it especially encourages work that employs empirical research methods to enhance critical understandings of bioethical theory and practice. BeOnline Journal seeks innovative, creative perspectives and forms of writing, and welcomes new challenges.

The journal welcomes the following types of submissions.

- (1) Full research articles incorporating substantive findings and promoting critical scholarship. BeOnline Journal is especially open to articles that encourage or incorporate new ways of thinking about theory, research policy, and practice in health care. Because we publish online, there is no page limitation.
- (2) Full length conceptual essays and diverse literary forms of writing in relating to bioethics
- (3) Short theoretical essays addressing current issues, topics, and debates.
- (4) Media Review Articles/Book Reviews.

The journal will also publish occasional special issues devoted to a particular theme or topic. Papers are accepted in either English or French, Times New Roman font, size 12 and formatted in NEJM style. They should not have been published already, nor be currently under consideration elsewhere.

The journal will take advantage of recent developments in information technology not only to enhance communication but also to improve the development, acceptance, review and publication of the manuscripts.



BeOnline® Journal of the West African Bioethics Training Program Now in PubMed Central contd.

We would like to invite students and established scholars to submit Op-ed and other writings to our on-line journal, BeOnline® Journal of the West African Bioethics Training Program (WAB). You can see our first issue here: <http://www.bioethicscenter.net/journal/index.php/journal1/issue/current/showToc>

It has received thousands of unique visitors and is now indexed on PubMed Central thereby giving contributors lots of on-line presence and impact. To contribute, please visit:

<http://www.bioethicscenter.net/journal/index.php/journal1/about/submissions#onlineSubmissions>



Life as a National Institute of Health - Institutional Review Board Trainee



Members of the Department of Bioethics, National Institute of Health. Second person seated in front from the right is Ms Olubusola Onasile (WAB Program Assistant)

The National Institute of Health (NIH) is the United States medical research agency and the largest source of funding for medical research in the world. It has 27 institutes and centers that conduct research in different disciplines of biomedical science. NIH both conducts its own scientific research through its Intramural Research Program (IRP) and provides research funding to non-NIH research facilities through its Extramural Research Program (ERP). NIH has 12 Institutional Review Boards (IRBs) that review and approve research conducted in the Intramural Research Program

The Institutional Review Board (IRB) annual training program is offered by the Department of Bioethics, National Institutes of Health, in cooperation with the NIH Combined Neuroscience IRB and the National Human Genome Research Institute (NHGRI) Education and Community Involvement Branch. The four months fully sponsored program targets applicants from developing countries with an interest in learning more about U.S. Federal human subjects' protections, IRB administration and function, and bioethics, with the goal of enhancing involvement in these activities at the applicant's home institution.



Life as a National Institute of Health - Institutional Review Board Trainee **contd.**

I work as a program assistant at the West African Bioethics Training Program, Centre for Bioethics in Nigeria – an NIH funded centre for training biomedical researchers, Research Ethics Committees and the public on modern research ethics. In addition to planning and coordinating of workshops and trainings for health research ethics committees, I am also involved in the writing of protocols for research projects carried out by the organisation and development of recommendations for the ethical and regulatory issues that the organisation might face during the planning and implementation of research projects. I also ensure that the rights and welfare of the human subject participants of the project are put into consideration during the implementation of the program. I was nominated to participate in the NIH-IRB training program as part of the staff capacity building initiative of my organisation to strengthen my skills in these areas so the organisation can implement research projects of international standards.

Upon arrival at the Institute, I was taken aback at the size of the campus; occupying vast acres of land in an affluent city called Bethesda, Maryland. The Institute is large enough to be called a community because it contains apartments for guests, campus shuttle service, libraries, cafeteria, gyms, farmers market for fresh produce, chapel, mosque etc. I kept telling myself it will take me the whole four months to explore the Institute. The Institute is not only big, but lovely, serene and safe.

For the training program this year, candidates were selected from Kenya, Nigeria, Tajikistan and Uganda. On arrival at the bioethics department where we were to be hosted, we were welcomed and introduced to the faculty and other members within the department. We were then handed a list of the program of activities drawn up the training.



@ The Mormon Temple; from L-R Ms Noranjon Ayombekova (Trainee from Tajikistan), Ms Everlyne Ombati (trainee from Kenya), Mrs Hong Troung (Research fellow at NIH), Mrs Winifred Nazziwa Badanga (Trainee from Uganda), Ms Olubusola Onasile (WAB Program Assistant)



Life as a National Institute of Health - Institutional Review Board Trainee contd.

The activities include:

- IRB meeting attendance – We attended one to two different IRB meetings per week observing the functioning and protocol review processes of the IRB. Relevant documentation (e.g. protocols, consent forms, minutes etc.) to be used during the meeting were sent to us to review in advance of the meeting.
- Shadowing of IRB administrative staff – We spent time with IRB staff to observe the process involved in preparation for IRB meetings. Some of the major activities we learned included protocol pre-review, agenda development, minute taking and review of investigators' responses to stipulations. We also participated in the trainings conducted by the IRB administrative staff for the investigators to enable them understand the functioning of the IRB, the review processes, protocol development and reporting.
- Department of Bioethics' activities – As part of the activities of the program we participated in a broad range of departmental activities including:
 - (i) Taking the intensive six weeks "Ethical and Regulatory Aspects of Clinical Research" Course (<http://bioethics.nih.gov/hsrc/>). Lectures were held once a week for four hours. The course was facilitated by faculty members of the department of bioethics and other invited guest speakers from different institutions all over the United States. Some of the guest speakers were invited from other departments within NIH such as NIH Office for Human Subjects Research Protections. In addition we had guest speakers from universities and other federal bodies like the US Food and Drug Administration Agency (FDA).
 - (ii) Attending bi-weekly "works-in-progress" seminars by the faculty and fellows making presentations about their respective past and on-going projects. These were highly interactive sessions that presented a great opportunity for the presenters to get feedback from their colleagues on how to improve their projects especially those that were still under protocol development stage. Through these presentations we learned outcomes of projects that are already been completed.
 - (iii) Monthly bioethics journal club is a meeting where the journal club members meet with all the members of the department to review research ethics articles that have been published to date.
 - (iv) IRB Meetings: We had an opportunity to attend several IRB meetings, among them are the Combined Neuroscience (CNS), National Institute of Allergy and Infectious Diseases (NIAID), National Heart, Lung and Blood Institute (NHLBI), National Human Genome Research Institute (NHGRI)...



Life as a National Institute of Health - Institutional Review Board Trainee contd.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Child Health and Human Development (NICHD) IRBs respectively. This enabled us to observe the process involved in the review and approval of protocols submitted to the NIH IRBs. The review process is described below:

- Protocols are submitted electronically
- They must have first been reviewed by a scientific review committee (SRC) and have a letter of approval indicating that they have been reviewed and the PI adequately responded to issues raised at the SRC
- Once received at the IRB office, they are reviewed administratively for completeness and for minor issues like typos. The PI is then "informally" sent the comments which he responds to before the revised proposal can be forwarded to the IRB for review.
- Each protocol is assigned to 2 primary reviewers; each summarizes the protocol at the meeting and presents their comments
- At this level a protocol can be approved subject to the PI addressing the raised issues (stipulations) or it can be sent back to the SRC with stipulation for the PI to consider before it can be resubmitted again for review
- Once approved, the PI is required to submit continuous reviews annually
- Any amendments must also be submitted to IRB for review and approval before they can be implemented
- (v) Daily "tea-time" with members of the Department of Bioethics: this is an informal 30 minutes meeting where all members of the department come together to discuss everyday issues; politics, economics, business etc. over tea and snacks. This is also to encourage bonding among members of the departments to get to interact with one another, know about other members' background and culture as it is a very culturally diverse department.
- (vi) Monthly staff meetings is a meeting conducted by the chairman of the department where all members of the department gather to discuss issues relating to the welfare and working conditions of the members of the department.
- Intramural NIH IRB policy/oversight bodies: Trainees attended monthly meetings of various oversight entities including:
 - (Human Subjects Research Advisory Committee (HSRAC): HSRAC is an advisory committee that advises the governance arm of the NIH Human Research Protection Program.



Life as a National Institute of Health - Institutional Review Board Trainee **contd.**

(ii) Various AAHRPP implementation meetings: The Association for the Accreditation of Human Research Protection Programs (AAHRPP) promotes high quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs). NIH is in the pursuing accreditation of their IRBs and the AAHRPP implementation meetings held

discussed the benefits for accrediting a Human Research Protections Program (HRPP), describe the HRPP accreditation application process, discuss the current and future status of the NIH's application and describe the OHSRP resources available for staff.

(iii) Meetings with the staff of the NIH intramural Office of Human Subjects Research Protections (OHSRP): The OHSRP helps Intramural research program investigators, research staff, IRBs and others to understand and comply with the ethical guidelines, regulatory requirements, and NIH policies and procedures for research involving human subjects. Meetings had with the staff of OHSRP was to enable us understand the functioning of NIH-OHSRP and the role it plays in the human subject protection program of the NIH

Other activities trainees participated in include:

(i) The annual Public Responsibility in Medicine and Research (PRIM&R) meeting which took place at the Hynes Convention Centre in Boston, Massachusetts. PRIM&R was founded in 1974 to provide those charged with ensuring research protections, as well as those involved in the design and implementation of research protocols, with education, practical tools and cutting edge strategies for their careers. Hosting highly acclaimed conferences and short courses on the ethics, regulation and administration of research are some of the ways PRIM&R achieves this goal. This year's conference content reflects and addresses ongoing changes in research and their implications for regulatory and ethical oversight. Attending PRIM&R conference not only gave me the opportunity to be involved in lively discussions and debates about everything from best oversight practices to key ethical concepts but also provided network opportunities with other attendees involved in human research protection from all over the globe.



@ PRIM&R conference in Boston... from the L-R, M... Everlyne Ombati (trainee from Kenya), Mrs Winifred Nazziwa Badanga (trainee from Uganda) Ms Olubusola Onasile (WAB Program Assitant)



Life as a National Institute of Health - Institutional Review Board Trainee contd.

(ii) Webinar on Advancing Bioethics Education by the Presidential Commission for the Study of Bioethical Issues. The Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission) is an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering. The Bioethics Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Bioethics Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner. To support ethics education and facilitate the integration of bioethics into traditional and non-traditional educational and professional settings, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) has developed pedagogical materials to facilitate easy access to the material in its reports by professors, instructors, teachers, and professional leaders.

The educational modules provide foundational information, ethical reasoning, applications, questions, discussion points, and suggested additional readings. The featured reports illustrate relevant and current applications for each topic. These materials are not intended to be a lecture script or outline, but rather to support instructors in developing their own presentation(s).

The essence of the webinar was to introduce the educational modules now publicly available on the bioethics commission website. (<http://www.bioethics.gov>)

(iii) Each trainee gave a "work in progress" seminar to the department of bioethics to describe their local system and what lessons can be brought back from NIH.

Participating in the training program has improved my knowledge and understanding about the structure and functioning of an IRB, the IRB review process and the role of the IRB in Human Subject Protection in research. Also, working in the department of bioethics with the faculty members and fellows and observing their passion and drive in implementing their respective research projects has inspired me to want to pursue a career in research ethics to have an in depth knowledge of the field, to understand the role it plays in shaping the regulations and policies of a country which in turn impacts the health systems of a country. Finally, I am grateful to Prof Clement Adebamowo, the Director of West African Bioethics Training Program (WAB) and staff of the Department of Bioethics, NIH for giving me the opportunity to participate in this life changing training program and to all the staff of WAB for supporting me in this journey into the world of ethics.

Thank you!!

Olubusola Onasile, Program Assistant, West African Bioethics Training Program



12th Annual Fogarty International Center Administrators' Meeting



Participants at the 12th Annual FIC Administrators' meeting: Extreme left, sitting...Dr. Ogundipe (WAB Program Administrator)

The 12th annual Fogarty International Center (FIC) administrators' meeting was hosted by the University of Buffalo AIDS International Training and Research Program (AITRP), New York. It was a three-day well-packaged program from the 1st – 3rd of December, 2013. In attendance were Dr. Ogundipe (WAB program administrator), administrators from various FIC programs across the globe, as well as the Principal Investigator (PI) and Co-Director of the University of Buffalo-University of Zimbabwe AITRP (Dr. G. D Morse and Dr. Mtugang).

The first day featured a road trip to the Niagara Falls Park; a collective name for three waterfalls (American Falls, Bridal Veil Falls and the Horseshoe Falls) that straddle the international border between Canada and the United States, more specifically, between the province of Ontario and the state of New York. Participants took a walk round the park; some went on a boat ride in the cave and had the opportunity to take lovely pictures. It was an awesome experience! On return to the hotel, we had an opening dinner and Dr. Morse gave his welcome address while each participant introduced themselves and gave a briefing about their FIC programs.



12th Annual Fogarty International Center Administrators' Meeting

Day 2 program commenced at 8am at the University of Buffalo Center for Excellence in Bioinformatics and Life Sciences. Shuttle buses were made available to convey participants from the hotel to the venue. A total of eight plenary sessions were taken, which include FIC program updates, Making CareerTrac work for your program, supporting global health research-why training isn't enough, types of agreements: an overview, leadership in research administrations environment, Successful mentoring from a distance, Grants management updates and allowable costs. Following each plenary sessions, few minutes were spared for questions and answers as well as discussion. Two past trainees of the UB-UZ

AIDS International Training and Research Program, Tinashe Mudzviti and Martin Zende also shared their experiences as an AITRP scholar and expressed their gratitude for the opportunity given to them to take part in the program. They expressed the fact that it has helped them in their career path. The session ended at about 5pm and shuttle buses were provided to convey participants back to the hotel.

A dinner was held same night at the hotel. A Minstrel and a Musician were in attendance to entertain the guests. Games and other activities were also available as a means to socialize and interact with colleagues.

The third day began at 8am and about seven concurrent sessions were held. These include; Building your FIC budget, Harmonizing requirements of multiple ethics reviews, Administering an in-country training program, Day-to-day accounting for non-accountants, Targeted short-term training for long-term impact, Your trainee's professional development, Evaluating your program, Developing standard operating procedures for research administration and program management. Following each session there was room for question and answer and general discussion.

The meeting came to an end at about 1pm following launch and group photograph.



@ The Niagara Falls; From L-R: Dr. Kangwende (Director, Africa University Clinical Research Center, Zimbabwe), Ms. Mirembe (Program Administrator, Makerere University Joint Clinical Research Center, Uganda) and Dr. Ogundipe (Program Administrator, WAB, Nigeria).



CLOSING REMARKS

Thank you for taking your time to read the issue of the newsletter, Your comments about the current issue, and ideas for the next issue are what will keep the West African Bioethics Newsletter an interesting and lively newsletter!!

Please send contributions and suggestions to **admin@westafricanbioethics.net**

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