The 2019 Annual International Bioethics Forum

STUDY PARTICIPANTS’ PROTECTION: TRANSLATING PRINCIPLES TO PRACTICE

Date: 12th & 13th December 2019

Venue: Amber Residence Hotel
What an event! brilliant and amazing speakers, stimulating and engaging moments and grand opportunities for networking.
KEY TAKE-AWAYS:
The 2019 Bioethics Forum themed, Study Participants’ Protection: Translating principles to practice, held at Amber Residence, GRA Ikeja, Lagos between December 12 & 13 and attracted about one-hundred participants.
KEY TAKE-AWAYS:
among which are over a 100 participants who are researchers, experts in various field of medicine, social anthropology, law, philosophy, science and humanities, ethicists, NGOs, programmers and community members from different institutions and regions: Nigeria, Sierra Leone, Ghana, Senegal, Burkina Faso, Cameroon, Australia, Switzerland, UK.
KEY TAKE-AWAYS: featured different informative learning sessions including four plenary sessions, two case presentations and three major panel discussions session among others.
KEY TAKE-AWAYS:
All stakeholders in research including researchers, research participants, institutions, Ethics Committees, regulatory bodies, policy makers and the Community need to focus on ensuring that the community is engaged throughout the research process.
KEY TAKE-AWAYS:
It is important that Institutions and HRECs develop and implement procedures, processes, guidelines and working documents that will promote the implementation of appropriate and culture-sensitive standard of care and general protection of participants interests in research.
KEY TAKE-AWAYS:
Participants' culture, perceptions and environment should form a cardinal part of the protection process and the process of protection should, among other virtues, demonstrate empathy.
KEY TAKE-AWAYS:
To ethics committees especially in Africa or in a multicultural society, should include socio-behavioural experts who can contribute to the review process. Participants should be involved from the protocol design stage through the implementation of the research.
The 2019 Annual International Bioethics Forum was a platform for networking for collaborations and for personal developments among researchers, ethics experts, ethics committee members, NGOs, research participants, Academic and Research Institutions.
In a serene environment at Amber Residence, Ikeja, BESON forum attendees enjoyed several opportunities to engage, reflect and relax. Participants had fun at the cocktail, lunch and tea break times. These times were also opportunities for building new networks and sharing of ideas.
Why Research Matters
The session described health-related research as activities designed to develop or contribute to generalizable health knowledge within the more classic realm of research with humans, such as observational research, clinical trials, biobanking and epidemiological studies.
He noted that clinical trial is only a small part of health research and also questioned if all clinical trials fall under the definition of research.
The speakers discussed the need for research to be tailored to progress and the good of the community but however it is optional and not all research lead to progress.
The concept of vulnerability should be perceived from the standpoint of the person, environment and circumstances. He also discussed the concept of research as a right, the researcher has the right to conduct research but there is need to strike a balance between the quest for innovation and the protection of the human participants. Protecting the dignity, rights of research participants’ should be a priority.
The role of research regulation in promoting research conduct and also protection the research participants was emphasized.
Key take-aways:
Research should be for progress and for the good of the community
Research for progress requires HREC put a system in place to ensure researchers’ institution ensures compliance
Research institutions should take the responsibility of monitoring research conducted by researchers in their institution.
Key take-aways:

Protecting the research participants is not solely about regulations or researcher’s education but should be an institution matter. Every stakeholder of researcher should be concerned about the consequence of research on the participants.
Case presentations
Title of Presentation 1: Ethical Issues in Genomic Research - A case of DELSUTH HREC

Speaker: Prof. Patrick Okonta
Session Chair: Prof. Ebun Oluwole
Rapporteur: Olufemi Hodefe
There is a global upsurge in genomic research to find cure to diseases among other health needs. Nigeria cannot be left out. However, genomic research is predisposed to so many ethical issues in Nigeria ranging from privacy, stigma, export of samples. The presentation focused on the case of DELSUTH HREC that had handled six genomic study related protocols.
Adequate protection of participants require understanding. The informed consent document was found to be usually quite comprehensive and lengthy and the question remains how comprehensible is it to participants? And also the consenting process, where is it done and by whom?
KEY TAKE-AWAYS:

Informed consent should be administered at the community to eliminate participants vulnerability imposed by the power play in the hospital environment.

Ethics Committees need to collaborate to address skill gaps in protocol review.

NHREC Code and documents - MTA, DTA – needs to be updated to address genomic research needs.
Title of Presentation 2: The Role of Capacity Building and Networking in Human Research Protection Program

Speaker: Dr. CHIEDOZIE Ike
Knowledge Sharing Method Case Presentation
Session Chair: Prof. Ebun Oluwole
Rapporteur: Olufemi Hodefe
To adequately protect the safety, rights and welfare of research participants, research institutions should invest in education, training and networking.

The case of Irrua Specialist Teaching Hospital efforts at building network and expertise in IRB management began in year 2015. It explored various training models to deepen IRB members' understanding of ethics and building on past history of shortfalls.
In area of networking and collaboration, ISTH HREC has been able to address complex and even controverted issues arising from International collaborative studies. These were made possible through local and International networks of experts in ethics and research.
KEY TAKE-AWAYS

Training in HRPP is imperative and should be continuous.

Collaborations among HRECs within and across national boundary are necessary for capacity building.

It's time Africa Bioethics societies and RECs develop a network that is African in context that is comparative to what is obtained in the West.
Title of Presentation 1

TOPIC: The Case for certificate of Confidentiality (CoC)

Speaker: Dr. Oliver Ezechi

Knowledge Sharing Method: Panel Discussion

Session Chair: Prof. Patrick Okonta

Rapporteur: Dr. Betiku Bamidele
CoC as a document that protect the privacy of research participants and that it primarily protects against compulsory legal disclosure through court orders and subpoenas, for identifying information of a research participant.

Coc does not, however, protect a participants where there is voluntary disclosure, a case of abuse and where Public Health Law requires a mandatory disclosure of certain diseases.
Coc in the United States is issued by the National Institutes of Health (NIH) and it is automatic following research approval. For Nigeria, it requires NHREC approval. Once COC has been issued, it is permanent throughout the course of the research but it must begin at the inception of the research. Information on CoC inclusion in any research should be discussed in the informed consent process.
KEY TAKE-AWAY:

Certificate of Confidentiality (coc) is central in the protection of participants of research especially with research with marginalized, stigmatized and other vulnerable groups.
Title of Presentation 2: The Realities of Men Having Sex with Men (MSM)

Speaker: Mr. Ekpo Godsgift
Session Chair: Prof. Patrick Okonta
Rapporteur: Dr. Betiku Bamidele
The realities of the MSM community:

Right-Constrained Environment: He lamented that Nigeria is a right-constrained environment for the MSM community especially with the promulgation of the law against MSM in 2014 which stipulates 14 years imprisonment for MSM.

There is gross human right violation such as unwarranted arrest, unfriendly attitudes and beliefs, and these drive the MSM community underground, thus, making them unwilling to participate in research.
The realities of the MSM community:

Informed Consent: This should be simple and written in clear language for participants to interpret. MSM should have the freedom to object to questions that are sensitive, and participation should be truly voluntary. Monetary reward should be de-emphasised.

Community Engagement and Ownership: This should be throughout the research process. MSM community should have input in all the process conceptualisation.

Data Management: There should be adequate management of data generated about the MSM community to prevent group harm especially as it may affect their insurability, employability and reputation.
KEY TAKE-AWAYS:

The Nigerian law should be modified in order to accommodate the MSM community. HRECs and all stakeholders of research should be conversant with the relevant laws and regulations especially the Law against same-sex marriage.
Title of Presentation 3

TOPIC: Realities of Persons who inject Drugs (PWID)

Speaker: Mr. Awosika Harold
Session Chair: Prof. Patrick Okonta
Rapporteur: Dr. Betiku Bamidele
Drug use cut across several individual groups including the compulsive consumption of soft drinks.

The realities of PWID include poverty, divorce and school dropout. PWID are vulnerable to unwarranted arrests, discrimination, illegal detention, and marginalization.
The effect of this vulnerability is the lack of motivation to participate in research. He passionately appealed that PWID should be educated, truly rehabilitated (not a recycled kind of rehabilitation as is currently practiced), they should be empowered (in terms of vocation), love, affection, and care.
**KEY TAKE-AWAY:**
To effectively engage the PWID in research, their basic needs must be identified and taken into consideration. Research with PWID should have social value.
Title of Presentation:
Community Engagement In Research is an Ethical Imperative

Speaker: Prof. A.J Ajuwon
Session Chair: Prof. Feyi Adepoju
Rapporteur: Dr O.A Ekun
What is community engagement: A process when a researcher INTERACTS with the member of the community on his/her research in the ways that the research can be conducted.
It is in the best interest of the researchers to be involved in community engagement prior, during and after research if they intend to achieve the best outcome from their research.

The speaker summarized the presentation by asking the following questions:

**Why is engagement an imperative in research?**
It shows respect to members of the community, it provides an insight into the workings and dynamics of the community, it also creates opportunity for members of the community to learn about the nature of the research.

**When is conducting community engagement needed?** Prior, during and after the completion of the research.
KEY- TAKE-AWAYS:
Researchers need initial education on importance of community engagement
- Researchers must learn from previous experience of community engagement
- It is in the best interest of the researchers to engage the community in any research study.
Title of Presentation

Community Engagement and determination of standard of care in research

Speaker: Florita Durueke
Session Chair: Prof. FeyiAdepoju
Rapporteur: Dr O.AEkun
KEY TAKE-AWAYS:

The regulatory agencies and stakeholders of research should be involved in ensuring that the appropriate standard of care based on the socio-economic setting should be implemented.

The National Ethics Code should include SoC requirements as part of the code.

Researchers have the moral obligations to offer participants the best during the research.

Research is not an emergency, so SoC should be adequately planned ahead of the research.
PLENARY 2
Title of Presentation
TOPIC: Ethics with Empathy: Bioethics and Translational Research Practices
Speaker: Dr. Ike Anya
Session Chair: Prof. Shalom Chinedu
Rapporteur: Dr. Betiku Bamidele
Ethics means principles, while empathy is the ability to sense other people’s emotions and translational research is a bi-directional process that involves a multidisciplinary approach. The goal of translational research is to speed up scientific discovery into patient and community benefit.

KEY TAKE-AWAYS:
There is need for empathy in ethics and to learn ethics outside the shores of Nigeria, but the learning must be domesticated in a bid to create our own version of ethics. Nigeria and indeed, Africa
DAY 2
Prof Cheikh Ibrahim Niang

The Practice of research bioethics theories during emergencies

Rapporteur: Dr. Grace Olasehinde.
KEY TAKE-AWAYS:
Bioethics should not be practiced without considering the environment and the culture of the people. Empathy should be a virtue that should be held high by stakeholders of research. The heart of cultural practices in Africa is one that shows empathy. Research practice in Africa should promote this show of empathy. This requires the need to include solidarity as an ethics principle for research conduct in Africa. Anthropologists and other socio-behavioural scientists should join to contribute to bioethics.
Yusuf Kabba: Research Participants during the Ebola Emergency: What Ethics Committees should know

Chairman of Session: Prof Sunday Omilabu
Rapporteur: Dr. Ekun Oloruntoba
The initial idea in the mind of survivors was that researchers were using them as guinea pigs. This led to the initial rejection of research. The presenter championed the rejection.

**KEY TAKE-WAY:**
There should be a plan to build the capacity of Ebola Survivors. Researchers should consider involving Ebola survivors as part of the research team.
Bridget Haire: Protocol review for multi-site clinical trials: Relation between DSMB and Ethics Committees
KEY TAKE-AWAYS:
The DSMB is the stewardship of Clinical Trial. Participant’s safety is the primary and overarching responsibility of the DSMB. DSMB can suggest the termination of a clinical trial for safety purposes.
Sybril Ossei
Research Practice and Regulation in West Africa: WAHO Guidelines
KEY TAKE-AWAYS:
HRECs in Africa should network and collaborate with WAHO. There are harmonized AVAREF documents available for HRECs and researchers.
Aminu Yakubu
Ethics and Genomics
KEY TAKE-AWAYS:
It is imperative for researchers to understand the different models of consent for genomic studies. Genomic studies are essential in patient’s care. NHREC should incorporate regulations about Genomic research in the coming updated CODE.
The Ethics of Everything: Looking beyond the Research in Humans

KEY TAKE AWAYS:
Ethics is relevant to all fields of research and not limited to biomedical research.
Not only biomedical approach should be used for the review process; innovative approaches relevant to each discipline should be developed.
• Title: Ethics of Animal Research
• Animals are also vulnerable participants in research and
• They deserve to be protected.
• Institutional Animal Care Committee should be properly
• Established in all institutions performing research with animals.
• Animal researchers should be aware of local and international regulations
  in the use of animals for research.
• If there is no animal ethics approval, the protocol should not be approved.
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The 2019 Bioethics Forum LOC

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Florita Dureke
It was the best of times in 2019 Bioethics
Thank You and Safe Journey
See you in 2020
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