REPORT OF THE 2\textsuperscript{ND} BIOETHICS TRAINING ORGANISED BY THE INSTITUTE OF PUBLIC HEALTH IN COLLABORATION WITH THE NEW HIV VACCINE AND MICROBICIDE ADVOCACY SOCIETY AND THE NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

Organised by

The Institute of Public Health, Obafemi Awolowo University, Ile-Ife

In collaboration with

New HIV Vaccine and Microbicide Advocacy Society

And certified by

The National Health Research Ethics Committee

(NHREC/TR/16/02/2013)
Facilitators

Morenike Ukpong: Served as the lead facilitator for the training. She is a trained paediatric dentist and holds a Fellowship of the West African College of Surgeons and a Bachelor’s degree in Dentistry, as well as a Master’s in Business Administration. Her particular expertise is in the development of curricula and implementation of capacity-building training and workshops including those on research literacy. She works with New HIV Vaccine and Microbicide Advocacy Society and the Institute of Public Health, Obafemi Awolowo University to develop and implement multiple capacity building training curricula one of which is the building of the capacity of laypersons on research protocol review and research monitoring. She has been involved with the teaching of bioethics for researchers, teachers, ethics committee members, project staff and community members since 2008. She current holds a Level 5 Fellowship of the Global Health Trials Network, Oxford University, UK.

Oliver Ezechi: He served as the co-lead facilitator for the training. He is a WHO accredited Clinical Trial Monitor with a high level of competency when it comes to clinical trial monitoring. He combines this efficiently with his work as a Senior Research and Head of Department of Clinical Services at the Nigeria Medical Institute of Research, Lagos, a lecturer at a University in Sweden, an examiner with the West African College of Obstetrics and Gynaecology, and a HIV physician.

Prof Oluwagbemiga Adeodu: Dr. Oluwagbemiga Oyewole Adeodu is a Professor in the Paediatric Haematology and Oncology Unit of the Department of Paediatrics and Child Health of the Obafemi Awolowo University (OAU) Ile-Ife. He is also a Consultant Paediatrician to the Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC) Ile-Ife. He had his University education at the Medical School of the prestigious University of Ibadan, graduating in June 1976. He became a Fellow of the West African College of Physicians, Faculty of Paediatrics in 1986 and a Professor of Paediatrics in the year 2002. At various times in his professional career he has been Head of the Department of Paediatrics and Child Health, OAU Ile-Ife, Chairman Postgraduate Training Committee OAUTHC, Ile-Ife, Chairman, Medical Advisory Committee, OAUTHC, Ile-Ife and Chief Examiner of the West African College of Physicians, Faculty of Paediatrics. He is the current Chair of the Health Research Ethics Committee of the Institute of Public Health, OAU, Ile-Ife. So far, he has supervised the dissertations of 15 resident doctors who have become Fellows of either the West African or National Postgraduate Medical Colleges. He has over 50 publications in learned journals, books and monographs. He took part in the 1st Annual IPH-NHVMAS bioethics training as well as attended a 2 weeks course on bioethics at the University of Harvard, USA.

Prof Olawunmi Fatusi: Prof Fatusi is an Oral and Maxillofacial Surgeon by training. She however is a trained fellow of the SARETI ethics programme, South Africa with ongoing plans to complete her Master’s program in Bioethics from SARETI’s host institution in South Africa. She has a long history of engagement in Bioethics being a constant resource person to take bioethics topics for the biannual Monitoring and Evaluation programme and the Adolescent health programmes held at the Institute of Public Health, Obafemi Awolowo University. She has a number of ethics related abstract presentations
including on that pushed for reconceptualising study participants engagement in clinical trial as a contractual labour.

BRIEF OVERVIEW OF THE TRAINING PROGRAMME

Seventeen participants representing members of ethics committees and researchers from across Nigeria participated in a three days training that addressed ethical and regulatory aspects of clinical trials. There were 15 participants present for the training that ran between the 18th and 20th of February, 2013. Two participants from the Federal Medical Centre, Kebbi however showed up on the 25th of March 2013 (they were not aware of the change of date of the training programme). The two had a crashed 2 days programme organized for them.

Day 1: History, Guidance, and Framework for Ethical Clinical Research

Participants learnt about the history of research abuses, the development of ethical guidelines, how the ethical guidelines apply to biomedical research, and the development of the history of the development of the National Health Research Ethics Code. Participants were introduced to the 10 ethical framework of biomedical research as well as the three principles of biomedical research. These issues were discussed extensively. Later in the day, participants were divided into four groups. Each group spent 45 minutes discussing four different case studies. These included the Trovan trial, a case on conflict of interest, the case on export of adverse events, and the case of the Nevirapine trial in children. All the case studies were derived from the WHO case study book.

Day 2: IRB review, Risks and Benefits, and Investigator perspectives

Participants started the day off by spending an hour reviewing basic principles of biomedical research. The ‘who wants to be a millionaire game’ was used to take participants through the basics of HIV research, GCP, standard of care, clinical trial design and principles of biomedical research once again. Participants also learnt some fundamentals about operationalizing an IRB. Following this, participants had facilitated sessions on how to objectively evaluate for risk and benefit and how to assess the risk-benefit ratio for researches, the place of ancillary care in research and its perception as a study benefit, ethical considerations in conduct of research in children and those with impaired decision making. Finally, participants were broken up into four groups and asked to review and give feedback on a research protocol.

Day 3: Placebo controls, Subject Selection, Use of Stored Data and Tissue

Participants once again reviewed the content of the prior day’s training and raised questions to clarify concepts that were not clear. The day was spent discussing the role and function of HRECs, fair participant selection thereby addressing the principle of justice, informed consent, and conflict in research. Ethical issues in the use of stored tissue and data were also extensively discussed. Participants wanted the session to close early and so the session on ethical implications of placebo trials and the mock HREC session could not be taken. The session came to an end with presentation of certificates, award of CPD points for the training and the sharing of the CDs with the lecture notes.
EVALUATION OF THE TRAINING

The training was evaluated using multiple methods

1. Pre and post-test analysis to assess knowledge acquired: Participants took a 10 question pre and post test assessment on the first and last day of the training. Fifteen people took the pre-test and only nine persons took the post-test. The pretest analysis showed an average test score of 53.4 ± 20.6%. Eighty percent of those who took the test scored above 50%. However, 77.8% of those who took the post-test scored above 50% with the average post test score been 43.7 ± 16.1%. There was no significant difference between the pre and post test score (p=0.18). A t-test analysis could not be done as most of the participants did not put codes on their test papers and so matching of test results was not possible for most of the respondents.

2. Daily evaluation: A daily evaluation of the training was conducted. This enabled the facilitators make real time changes to programme implementation. This included the effort to provide meal at site for participants on day 2 and 3 and changes in level of participant interaction. See appendix 1 for report on daily evaluation.

3. Daily Facilitators' meeting: The lead and co-lead facilitator met daily to discuss observations and changes that needed to be made to programme implementations. Changes were made on day 2 and day 3 lectures in view of the need for co-facilitators to attend to official duties. Lectures on those days were therefore switched. Also, facilitators were able to identify those who were not participating well as well as concern about poor background knowledge of basic ethical principles. This necessitated the need for the ‘who wants to be a millionaire’ game. Active effort was made to engage those who were noticed not to be actively participatory in the sessions as well as the need to simplify terminologies in view of the differing level of competency of participants to understand medical jargons. The facilitators concluded that the training met the needs of participants though the feeding arrangement was a big distraction that needed to be addressed at subsequent sessions. Also, future trainings should devote day I to basics of biomedical ethics always. Next training should address Standard of care debates in biomedical research.

4. Programme evaluation: Participants evaluated the programme on the last day. The session with the highest rating was that on conflict of interest. The only session with a poor rating was the session on history, scandals and tragedies. All participants felt the workshop was a good use of their time and that the facilitation style was effective for learning. Eighty-six percent of participants felt the workshop was well organized. Thirteen percent of participant felt that there was inadequate time allocated for informal discussions among workshop participants. See appendix II for more details.

LESSON LEARNT: (i) the dates for the trainings should not be changed once announced (ii) training should go on as planned independent of initial registration figures. 13 persons attended this training without prior registration (iii) we need to put in measures to address the challenges of participants to access food during lunch hours.
APPENDIX 1

DAILY EVALUATION DAY I

Which session did you like most today?
- Clinical Research because of the presentation provided
- History, scandals and tragedies because it showed where we are coming from and the preparation made so far, some experiments were weird and because participant learnt about the consequences of the absence of human ethical review
- Case studies because they were very practical
- Clinical research ethics because it set out clearly the difference between clinical practise and clinical research and because of the adequate interaction

Which session did you like least today?
- Ethics placebo controlled trial because the topic wasn’t well presented
- “Do the codes apply in my research?” Because of the presentations of the different reports, there was insufficient time to discuss the codes and because of the medical terms
- Case reports because adequate information on what we needed to do was not given

How do you think each session can be improved?
- By revision of the topic after presentation
- By introducing more case studies
- By keeping questions and discussions till the end of the presentation

What did you like most about the entire programme?
- History, scandals and tragedies
- It was interactive
- The simple language of the presentations
- The competence of the facilitators
- The facilitator really took time to explain to the level of participants comprehension
- Group participation

What did you like least about the entire programme?
- Ethics placebo controlled trial
- Scouting for where to eat in an unknown terrain
- Participants should be encouraged to keep to time
- The meal was outside of the training venue
- No refreshment was provided
- Tea and lunch not provided

Did you have any logistic challenges?
- No

Any other comments?
- The workshop was well organised
- Great job
- Proper conference bags would make life easier
DAILY EVALUATION DAY II

Which session did you like most today?
- IRB review, risk and benefits and investigator perspectives because the session was presented in a logical order
- Ethic issues on research with children because of the emphasis of the child saying yes or no despite parental consent
- Mock IRB because it exposed participant to real life evaluation and it was very interactive
- All because they all addressed participants desired needs and they were all participatory
- Ethical issues in the use of stored tissue and data because it was very clear and it opened a whole new of knowledge, possibilities and ethical dilemma for participant
- Ethics of risk-benefit judgment because it revealed a lot about weighing risks and benefits to know whether a study can go on or not

Which session did you like least today?
- Ancillary care in clinical research
- Fair subject selection because it was not as interesting as the others

How do you think each session can be improved?
- By revision of topics after each presentation
- Some of the issues raised should be evaluated, probably in a wider context to accommodate the concerns of participants with respect to our their local circumstances without compromising the rights of humans used for research

What did you like most about the entire programme?
- The topics were interesting and well presented
- Sharing of experience
- The readiness of the facilitators to go out of their way to see that participants understand each sessions before going to another
- It was participatory
- The facilitators were very good
- The great level of contribution by the participants
- The ability to stop and ask questions
- The style of presentation was excellent

What did you like least about the entire programme?
- There was a bit of distraction due to repair work that was going on just beneath the workshop room
- Meals were served in a different venue
- The feeding arrangement
- Participant’s welfare

Any other comments?
- Well coordinated
- It was interesting
DAILY EVALUATION DAY III

Which session did you like most today?
• All session because they were interesting
• Purpose and function of HREC because it was well presented and showed participant his role as a member of HREC and it was detailed and systematic
• Informed consent because it explains explicitly the circumstances and methodology for giving consent and because it deals with protection and confidentiality of research volunteers
• Ancillary care in clinical research because it was well explained and it taught participant to understand the moral objectives to meet the patients needs and also to build trust in them
• Conflict of interest because the session basically was referring to drug trials

Which session did you like least today?
• Fair selection of research participants because of the inadequate time for the session
• Ancillary care in clinical research because of the inadequate time for session

How do you think each session can be improved?
• Allow participants to ask questions more often
• Introduced more practical sessions
• Frequent energizers should be introduced
• There should be more facilitators

What did you like most about the entire programme?
• The friendliness of the facilitator and participants
• It was highly educative
• It was an eye opener
• The presentation style
• Experiences sharred with participants by the facilitators
• Patience of the facilitators to entertain questions
• The arrival of Professor Gbenga enlightened the program
• Good materials provided
• The facilitators were marvellous

What did you like least about the entire programme?
• Participants welfare

Any other comments?
• I suggest that when next the organisation are planning a programme like this, they should put into consideration welfare services like entertainment
APPENDIX II: PROGRAMME EVALUATION

<table>
<thead>
<tr>
<th>Module</th>
<th>Very Good (%)</th>
<th>Good (%)</th>
<th>Fair (%)</th>
<th>Poor (%)</th>
<th>Very Poor (%)</th>
<th>No Response (%)</th>
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<td>Session 1: History, Guidance and Framework for Ethical Research</td>
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<td>What makes clinical research ethical?</td>
<td>53</td>
<td>40</td>
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<td>History, Scandals and Tragedies</td>
<td>47</td>
<td>40</td>
<td>-</td>
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<tr>
<td>Do the codes Apply to my research? (Nuremberg, Helsinki, The Belmont Report, CIOMS, the Common Rule)</td>
<td>47</td>
<td>47</td>
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<td>7</td>
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<tr>
<td>Case studies</td>
<td>60</td>
<td>13</td>
<td>20</td>
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<td>Session II: IRB review, Risk and Benefits, and Investigator Perspectives</td>
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<td>Purpose and Function of IRBs: Success and Current Challenges</td>
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<tr>
<td>The Ethics in Risk-Benefit Judgments</td>
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<td>33</td>
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<td>Conflicts of Interest</td>
<td>80</td>
<td>13</td>
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<td>Ancillary care in clinical research</td>
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<td>MOCK IRB</td>
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<td>20</td>
<td>13</td>
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<td>Session III: Placebo controls, Subject Selection, Use of Stored Data and Tissues</td>
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<td>Ethics of Placebo Controlled Trials</td>
<td>27</td>
<td>40</td>
<td>-</td>
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<td>Fair Subject Selection</td>
<td>33</td>
<td>53</td>
<td>7</td>
<td>-</td>
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<td>7</td>
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<tr>
<td>Ethical issues in research with children</td>
<td>60</td>
<td>33</td>
<td>7</td>
<td>-</td>
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<td></td>
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<tr>
<td>Ethical issues in the use of stored tissue and data</td>
<td>27</td>
<td>40</td>
<td>13</td>
<td>-</td>
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<td>20</td>
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<tr>
<td>Research involving persons at risk for Impaired decision-Making</td>
<td>27</td>
<td>27</td>
<td>7</td>
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<td>Informed Consent</td>
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<td>7</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>33</td>
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</table>
Please provide us with some feedback on your experience of the workshop

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<tr>
<th>Please indicate your agreement with the following statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
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<tbody>
<tr>
<td>This workshop provided me with new insights about HIV prevention technologies</td>
<td>33</td>
<td>27</td>
<td>20</td>
<td>7</td>
<td>-</td>
<td>13</td>
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<tr>
<td>Participating in this workshop was a good use of my time</td>
<td>80</td>
<td>20</td>
<td>-</td>
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<td>I will be able to apply the content of this workshop to my daily work</td>
<td>53</td>
<td>47</td>
<td>-</td>
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<tr>
<td>I made new contacts which will be helpful in my daily work or everyday life</td>
<td>47</td>
<td>33</td>
<td>20</td>
<td>-</td>
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<tr>
<td>Overall, the facilitation style was effective</td>
<td>60</td>
<td>40</td>
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<tr>
<td>There was adequate time allocated for informal discussions among workshop participants</td>
<td>47</td>
<td>40</td>
<td>-</td>
<td>13</td>
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<td>-</td>
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<tr>
<td>The workshop was well organized</td>
<td>53</td>
<td>33</td>
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</tr>
</tbody>
</table>

What changes will you recommend to make this workshop better?

- A change in date should not be sudden
- Appropriate arrangement for tea break and lunch should be made
- Banners and posters should be placed at strategic places to enable participants locate the hall/venue easily
- Inclusion of conference bags and lunch in course fee
- Improve on welfare of the participants please
- There should be more facilitators
- Training should be made residential
## PARTICIPANTS LIST

<table>
<thead>
<tr>
<th>S/N</th>
<th>NAME</th>
<th>INSTITUTION/ORGANISATION</th>
<th>EMAIL ADDRESS</th>
<th>GSM NO(s)</th>
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