

Advanced Health Research Ethics Workshop for Investigators

MANDEL TRAINING CENTRE, HARARE, ZIMBABWE

8th - 9th February 2018

THE UNIVERSITY OF EDINBURGH

NHS
National Institute for Health Research

Introduction



Professors Chimbari (Co-Dep Director, TIBA) & Ndebele (Director, MRCZ) at the start of the workshop

The NIHR Global Health Research Unit Tackling Infections to Benefit Africa at the University of Edinburgh (TIBA), in collaboration with the Medical Research Council of Zimbabwe (MRCZ), through the BBSRC-GCRF Impact Acceleration Award to the University of Edinburgh, organised a two day Advanced Health Research Ethics workshop in Harare, Zimbabwe, primarily for health investigators within the TIBA partnership and secondarily for Ethics Committee members and policy makers.

The high disease burden of African countries, the emergence of new diseases and the efforts to address the 10/90 gap, have led to an unprecedented increase in health research activities in Africa. In light of the generally poor health delivery system, the lower levels of education and the poverty of communities and governments, it has become imperative that health research ethics in Africa be strengthened in order to minimize the risk of unethical research being conducted on the poor populations.

Historically, research participants have been exposed to potential abuse and currently researchers, institutions and research ethics committees may be inadequately prepared to handle complexities that characterize justice and beneficence desirable for research involving human participants and communities. With increased focus on target oriented



research i.e. in affected human and animal populations, there is need to ensure research institutions, researchers and policy makers are fully equipped with the knowledge to conduct both human and animal research in terms of the moral and ethical expectations, regulatory systems, procedures and applicable laws.

Workshop aim

The main aim of the workshop was to strengthen understanding of ethics processes across all TIBA partner countries and examine the context for responsible research and innovation. The workshop flagged topical ethical issues that are relevant to health research in developing country settings, and explored various schools of thought with the aim of coming up with well thought out positions and/or recommendations. Various examples and case studies pertinent to Africa were used. The workshop applied participatory approaches including overviews, case studies, discussion groups, role plays, panel discussions and participants' presentations and other interactive and adult teaching/learning methods. Facilitators were drawn from Africa and the United Kingdom.



Participants

The TIBA-MRCZ Ethics workshop which was hosted by Professor Paul Ndebele (Director, MRCZ) attracted forty-seven participants from all ten TIBA partner countries (Botswana, Ghana, Kenya, South Africa, Sudan, Rwanda, Tanzania, Uganda, UK and Zimbabwe) as well as stakeholders and associates from the NEPAD Agency (Dr. Janet Byaruhanga), The Lancet HIV Journal (Peter Hayward), and the MRCZ. Also present were the co-Deputy Directors of TIBA (Professors Francisca Mutapi and Moses Chimbari), the three TIBA Principal Investigators from Zimbabwe (Professors Paul Ndebele, Simbarashe Rusakaniko and Elopy Sibanda) and TIBA Principal Investigators from Botswana and Uganda, Professors Nthabi Phaladze and Charles Waiswa.



Participants at the workshop

Welcome address by TIBA co-Deputy Director

In his welcome remarks Professor Moses Chimbari thanked all the delegates and stakeholders for coming, and the organising committee as well as the TIBA secretariat for the work they put into organizing this event. He introduced Dr. Shungu Munyati, Chairperson of the MRCZ, who delivered the keynote address.

Chairperson's remarks

Dr. Munyati welcomed all participants from the 10 countries and said "The MRCZ is a specialize Council of the Research Council of Zimbabwe (RCZ) established in 1974 under the Research Act of 1959 and Government notice of 225 of 1974. The MRCZ reports directly to the Minister of Health and Child Care and its mandate, besides coordinating and promoting research, is primarily to provide an independent ethical oversight of all research conducted in



Dr Munyati (Chairperson, MRCZ) delivering the keynote address

Zimbabwe. We serve as the gate keepers of research." She thanked the funders of the workshop, the UK BBSRC GCRF Impact Acceleration Award that was awarded to the University of Edinburgh in collaboration with TIBA. Dr. Munyati also thanked Prof Moses Chimbari and UKZN for all logistical arrangements including flight arrangements for regional participants.

Professor Ndebele gave an overview of the workshop objectives, and this was followed by introductions by the delegates.

Workshop topics

Topics presented at the workshop were wide ranging and included ethical principles and their application in health research in humans, vulnerable groups and animals. Speakers were from South Africa, the United Kingdom and Zimbabwe. The list of the topics, speakers and their affiliations and a brief description of each presentation are on the following pages.



Emilia Choto receiving her certificate of participation from Dr Munyati

Topics Presented

Topic	Presenter	Affiliation
Workshop objectives & introductions	Paul Ndebele	MRCZ
Keynote address	Shungu Munyati	MRCZ
Ethical principles and their application in health research and ethical review processes	Paul Ndebele	MRCZ
TIBA, neglected diseases and the 10/90 gap	Francisca Mutapi	Univ of Edinburgh
Ethical issues in international collaborative health research	Takafira Mduluza	Univ of Zimbabwe
African Union agenda for health research and research ethics capacity building	Janet Byaruhanga	African Union/ NEPAD
International guidance documents, research oversight governance harmonization and TIBA partner country legislations	Rose Musesengwa	Univ of Zimbabwe
Research with vulnerable persons and groups	Lynda-Stranix-Chibanda	MRCZ, Univ of Zimbabwe
The ethics of research designs and methods	Simbarashe Rusakaniko	Univ of Zimbabwe
Models and practicalities of community engagement	Moses Chimbari Rose Musesengwa	UKZN Univ of Zimbabwe
Responsibilities in health research	Paul Ndebele	MRCZ
The ethics of research specimens and data sharing	Takafira Mduluza	Univ of Zimbabwe
Ethical issues in social and behavioral research	Paul Ndebele	MRCZ
Ethical issues in genetics and genomics research	Sam Mukaratirwa	UKZN

Animal research ethics	Linda Bester	UKZN
Inclusion of pregnant women in clinical trials	Stephen Munjanja	Univ of Zimbabwe
Responsible publication practices	Peter Hayward	The Lancet HIV
Award of certificates	Shungu Munyati	MRCZ

Brief description of the workshop presentations

• Ethical principles and their application in health research and ethical review processes

The presentation was aimed at providing a basic foundation for the workshop and described the ethical principles of research for persons, beneficence, nonmaleficence and justice and how they are applied in research. The presentation also focused on the role of Research Ethics Committees in ensuring that researchers consider the ethical principles during design of research protocols and during implementation of research.

• TIBA, neglected diseases and the 10/90 gap

The presentation highlighted the role of TIBA in addressing the 10/90 gap and neglected diseases affecting Africa. The presenter emphasized on the roles of TIBA Partners in addressing these challenging issues.

• Ethical issues in international collaborative health research

The presenter discussed the various ethical issues associated with international collaborative research including those relating to the selection of study topics, sharing of specimens and data and what research team leaders could do to ensure fairness in international collaborative research.

• African Union agenda for health research and research ethics capacity building

The presenter described the role of the African Union in strengthening capacities in Health Research as well as Health Research Oversight across the African continent. The presenter highlighted some of the complex studies being conducted in Africa and how these necessitated the intervention by the AU.

• International guidance documents, research oversight governance harmonization and TIBA partner country legislations

The presenter described the main international guidance documents including Declaration of Helsinki, CIOMS Guidelines and Good Clinical Practice Guidelines including the history surrounding the development of each guidance document.

• Research with vulnerable persons and groups
The presenter described various groups that are labeled as vulnerable, including children, prisoners, minority groups, refugee populations and others. The presenter also described some of the strategies that researchers can use to ensure that these vulnerable groups are not abused and unnecessarily excluded in research including issues of obtaining informed consent and permission from relevant authorities.

• The ethics of research designs and methods
The presenter described the link between science and ethics and the various ways in which research designs influenced the ethics of research studies. Other discussions centered on the various research designs and the ethical issues associated with them as well as adaptive designs as a way of ensuring flexibility in research.

• Models and practicalities of community engagement
The presenters highlighted the need for community engagement and the different strategies that researchers can use in community engagement. An interesting and stimulating aspect of the presentation was the role play by delegates on the models and practicalities of community engagements. In this exercise delegates were grouped into four and tasked with the responsibility of introducing their research projects to communities or districts and opinion leaders in a manner that highlights the challenges of such engagement processes and getting buy-ins and acceptance by the communities.

• Responsibilities in health research
The presenter described the main players in health research including research institutions, principal investigators and their teams, sponsors, research ethics committees, drug regulatory authorities, Ministries of Health and host community structures.

• The ethics of research specimens and data sharing
The presenter highlighted the increase in exchange of specimens and data in international collaborative research and the weak position of African scientists and institutions in international partnerships. The presenter emphasized on the need for ensuring fairness and the usage of material transfer agreements to ensure that African researchers are not disadvantaged.

• Ethical issues in social and behavioral research
The presenter highlighted the role of social behavioural research in supporting clinical trials as well as the various ethical issues that researchers need to consider during protocol development and research conduct.

• Ethical issues in genetics and genomics research
The presenter highlighted the growth in genetics and genomics research across Africa and the various ethical issues associated with such research including issues of confidentiality, incidental findings, dissemination of findings and others.

• Animal research ethics
The presenter described the role of animals in human health research as well as the expectations on researchers regarding the use of animals in research. The presenter described the roles of institutional animal care and use committees in ensuring responsible use of animals in research as well as the international guidance documents on the use of animals in research.

• Inclusion of pregnant women in clinical trials
The presenter discussed the history surrounding the exclusion of pregnant women from research and the resultant disadvantages for this sub-population in terms of limited treatment options. He proceeded to describe current efforts aimed at ensuring that pregnant women were not unnecessarily excluded from research and the various ways in which data on safety of drugs or interventions can be gathered including the usage of pregnancy registers.

• Responsible publication practices
The presenter discussed pitfalls in manuscript preparation and best practices in publishing. The presentation raised numerous questions relating to journal editors expectations from some of the participants who trying to develop into accomplished authors.



Professor Mutapi (Co-Dep Director, TIBA) presenting TIBA, NTDs & the 10/90 gap

List of participants and their affiliations

Name	Affiliation
Phaladze Nthabi	University of Botswana
Makobu Kimani	KEMRI-WT, Kenya
Nadia Tagoe	KEMRI-WT, Kenya
Nuhu Assuman	University of Rwanda
Janet Byaruhanga	The NEPAD Agency, South Africa
Linda Bester	Univ of KwaZulu-Natal, South Africa
Nathan Chanhanga	Univ of KwaZulu-Natal, South Africa
Moses Chimbari	Univ of KwaZulu-Natal, South Africa
Lonestar Gonde	Univ of KwaZulu-Natal, South Africa
Nokwanda Majola	Univ of KwaZulu-Natal, South Africa
Samson Mukaratirwa	Univ of KwaZulu-Natal, South Africa
Pisirai Ndarwkwa	Univ of KwaZulu-Natal, South Africa
Vuyelwa Ndlovu	NUST/Univ of KwaZulu-Natal, South Africa
Bernard Ngara	Univ of KwaZulu-Natal, South Africa
Ndarukwa Pisirai	Univ of KwaZulu-Natal, South Africa
Faiza M. Osman	University of Khartoum, Sudan
Cecilia Uisso	NIMR, Tanzania
Charles Waiswa	COCTU, Uganda
Seth Amanfo	University of Edinburgh, UK
Danny Cosgrove	University of Edinburgh, UK
Francisca Mutapi	University of Edinburgh, UK
Janice Murray	University of Edinburgh, UK
Derick Osakunor	University of Edinburgh, UK
Peter Hayward	The Lancet HIV, UK
Lynda Stranix-Chibanda	MRCZ, Zimbabwe
Lowence Gomo	MRCZ, Zimbabwe
Shungu Munyati	MRCZ, Zimbabwe

Paul Ndebele	MRCZ, Zimbabwe
Melody Shana	MRCZ, Zimbabwe
Mazuita Chakawa	University of Zimbabwe
Caroline Chasara	University of Zimbabwe
Theresa Chimponda	University of Zimbabwe
Emilia Choto	University of Zimbabwe
Maritha Kasambala	University of Zimbabwe
Tafadzwa Madanhire	University of Zimbabwe
Ian Makupe	University of Zimbabwe
Takafira Mduluza	University of Zimbabwe
Rosemary Musesengwa	University of Zimbabwe
Caroline Mushayi	University of Zimbabwe
Lorraine Pfavayi	University of Zimbabwe
Simbarashe Rusakaniko	University of Zimbabwe
Melody Shana	University of Zimbabwe
Paradzayi Tagwireyi	University of Zimbabwe
Arthur Vengesa	University of Zimbabwe
Elopy Sibanda	Asthma, Allergy & Immune Dysfunction Clinic, Zimbabwe
Collen Masimirembwa	AIBST, Zimbabwe
Lovejoy Nlema	AIBST, Zimbabwe

Acknowledgement

We acknowledge the financial support of the BBSRC Global Challenge Research Fund Impact Acceleration Account Extension Award 2017 (Grant no. GCRF-IAA 2017) to the University of Edinburgh.



tiba



info@tiba-partnership.org

tiba-partnership.org

@TibaPartnership

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