

MEDICAL RESEARCH COUNCIL OF ZIMBABWE



NEWSLETTER

December 2015

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FROM THE EDITORIAL DESK

Greetings to our Readers! After some brief moment of inactivity, the MRCZ Newsletter is back on track. This time – hopefully the Newsletter is back to stay. As usual, in this publication we endeavor to keep you abreast with developments in the health research landscape including new and changing regulations in human research. Our main aim is to keep all stakeholders including researchers apprised.

In this issue, we report on the work of our National Research Ethics Committee, the work of our Compliance Unit, the training that we offer in Research Ethics and Good Clinical Practice; and our work in training existing as well as new institutional research ethics committees. We have also provided snippets from recently published researches that were conducted in Zimbabwe. For researchers who would like to present their work at national, regional and international forums, please check the section on upcoming events. Our Information and I.T team are currently working on updating all our forms. Please check our website regularly for new forms.

Any suggestions with regards to our functions are most welcome. Please feel free to write to us on mrcz@mrcz.org.zw. We promise you two things: We appreciate the feedback and we will do our best to accommodate your suggestions. Now – Happy Reading!

Research Ethics Committee Activities

The MRCZ Technical Committee (TC) is an operational arm of the MRCZ that serves as the National Research Ethics Committee. From January to Dec 2015, the TC received and reviewed 106 new applications from researchers. From, Fig 1 it can be noted that highest volume of research submitted was on Behavioral and Social Science studies followed by Epidemiological and Operations Research. Fig 2 below shows the categories of student research proposals that were reviewed in 2015.

Fig 1: Studies Reviewed by MRCZ in 2015

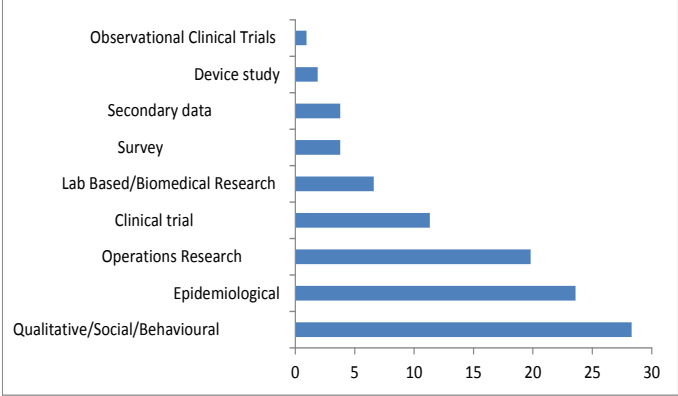
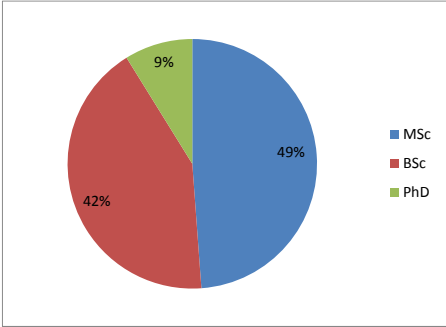
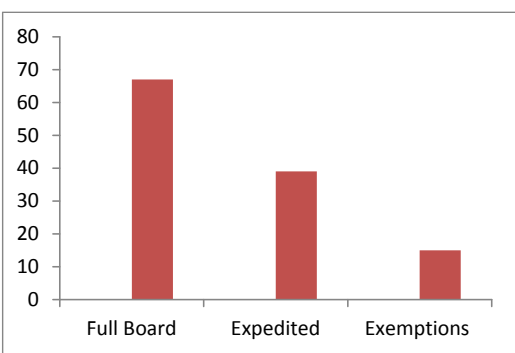


Fig 2: Student Studies Reviewed by MRCZ in 2015



The TC reviews studies using 3 different routes, either expedited (Minimal Risk Studies Only), full board review or exempt. In 2015 the majority of studies were reviewed through full board review.

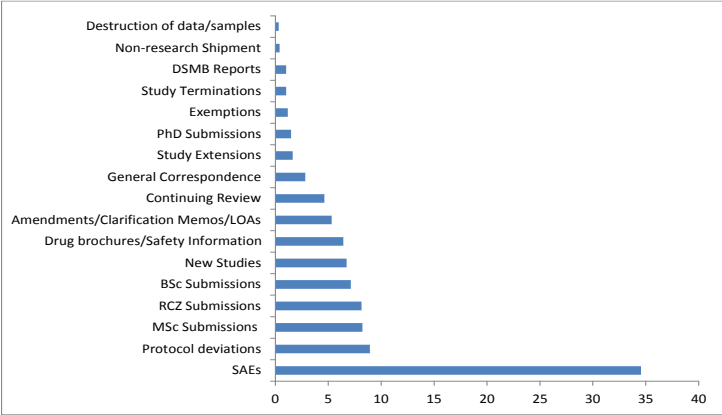
Fig 3: Types of Review



Compliance Unit

This unit does passive (desk) and active (inspections) monitoring of all approved research. Fig 4 shows the amount of work processed by the Secretariat in 2015.

Fig 4: Compliance Unit Statistics



The graph indicates that the Secretariat handled a large volume (35%) of Adverse events & Protocol Deviations related to research. This indicates an efficient reporting system by study coordinators and researchers.

Non-research Determination

The MRCZ is also mandated to process the shipment of non-research biological specimens. In 2015 the MRCZ processed 8 applications for non-research shipments for individual DNA testing, proficiency testing and for clinical diagnosis.

Inspections

As part of its oversight activities, the MRCZ carries out site visits/inspections in collaboration with officers from the Medicines Control Authority of Zimbabwe and the Research Council. During the year 2015 the MRCZ managed to inspect 12 studies. An inspection checklist is available on our website for all researchers to access so that they are aware of what is required of them during and inspection.

The highlights of the inspection findings in 2015:

- Lack of GCP & Ethics training for study staff
- Unreported protocol deviations and non-compliances
- Not consenting participants
- Not giving participants copies of signed consent forms
- Issuing participants with wrong lab results
- Failure to obtain continuing review approval

These issues have been resolved via consultations between the Ethics Committee and the Principal Investigators.

Training Unit

The Secretariat offers a 3 day combined Research Ethics and Good Clinical Practices Course meant to familiarize researchers with Ethical and GCP standards of conducting research. Figure 5 below shows that the MRCZ trained 371 researchers from 6 research teams. The MRCZ also trained 16 Bindura University faculty members in Research Ethics & GCP.



IRB Mentorship & Recognition Programme

The MRCZ being the National Ethics Committee has the mandate to set up Ethics Committees (EC) in public and private academic and research institutions and mentor them to become internationally recognized ECs. In 2015 Bindura University initiated the process of establishing an Ethics Committee. The 16 potential EC members were trained in ICH-GCP, Research Ethics and IRB101 course. The EC members will be asked to attend at least 1 MRCZ meeting and the EC Administrator will attend a 2week internship with the MRCZ, before they can be issued with a letter of recognition by the MRCZ.



Upcoming Events

International Association of Bioethics (**IAB**) is hosting the 13th World Congress of Bioethics in Edinburgh from 14 – 17 June 2016

Theme: “*Individuals, Public Interests and Public Goods: What is the Contribution of Bioethics?*”

<http://iab2016.com/about-iab2016/>

ARESA will be hosting a seminar on the 20th of May 2016 at the Vineyard Hotel and Spa, Newlands, Cape Town. The seminar will cover the following topics:

- *Death in clinical trials*
- *Ethics and emerging technologies*
- *Data sharing in research*

<http://www.sun.ac.za/english/faculty/healthsciences/aresa>

South African Research Ethics Training Initiative (**SARETI**) will be hosting a course on: Institutionalising Ethical Review of Health Research at the University of KwaZuluNatal from the 15–19 Aug 2016

<http://sareti.ukzn.ac.za/Homepage.aspx>

Email: pettite@ukzn.ac.za

The Global Health Training Centre is offering two new free online courses that will be relevant to researchers in Zimbabwe:

Introduction to Good Clinical Laboratory Practice

This peer reviewed course provides an introduction to GCLP, summarises the principles of GCLP and offers an overview of the implementation of GCLP within a clinical trial.

<https://globalhealthtrainingcentre.tghn.org/good-clinical-laboratory-practice/>

Children and Clinical Research

This course aims to give researchers and members of ethics committees confidence in thinking through the challenges of carrying out research with children and young people.

<https://globalhealthtrainingcentre.tghn.org/children-clinical-research/>

Published Ethics Articles

Testing the waters: Ethical considerations for including PrEP in a phase IIb HIV vaccine efficacy trial.

Dawson L, Garner S, Anude C, Ndebele P, Karuna S, Holt R, Broder G, Handibode J, Hammer SM, Sobieszczyk ME; NIAID HIV Vaccine Trials Network.

The field of HIV prevention research has recently experienced some mixed results in efficacy trials of pre-exposure prophylaxis, vaginal microbicides, and HIV vaccines. While there have been positive trial results in some studies, in the near term, no single method will be sufficient to quell the epidemic. Improved HIV prevention methods, choices among methods, and coverage for all at-risk populations will be needed. The emergence of partially effective prevention methods that are not uniformly available raises complex ethical and scientific questions regarding the design of ongoing prevention trials. We present here an ethical analysis regarding inclusion of pre-exposure prophylaxis in an ongoing phase IIb vaccine efficacy trial, HVTN 505. This is the first large vaccine efficacy trial to address the issue of pre-exposure prophylaxis, and the decisions made by the protocol team were informed by extensive stakeholder consultations. The key ethical concerns are analyzed here, and the process of stakeholder engagement and decision-making described. This discussion and analysis will be useful as current and future research teams grapple with ethical and scientific study design questions emerging with the rapidly expanding evidence base for HIV prevention.

Codes of Conduct

P. Ndebele

Encyclopedia of Global Bioethics 10.1007/978-3-319-05544-2_97-1

A code of conduct is a set of rules that guide the conduct of individuals who are members of a particular profession, institution or group. This entry focuses on codes of conduct that relate to professionals in the two main areas that deal with human life; healthcare and human health research. The entry discusses the development of codes of conduct in health and highlights present day codes that guide the conduct of professionals involved in health care and health research. Codes apply to three main parties' namely professional associations or institutions, professionals who provide a service and the citizens. To each of these parties, the code of conduct holds a different meaning. Whilst there are numerous codes that have been issued by institutions and national authorities or professional associations involved in healthcare and health research, this entry mainly discusses codes that are international in scope including the World Medical Association (WMA) Declaration of Geneva, World Medical Association's International Code of Medical Ethics, UNESCO Declaration on Bioethics and Human Rights, Nuremberg Code, Declaration of Helsinki, CIOMS Guidelines and the ICH Good Clinical Practice Guidelines. The majority of these codes relate mainly to professionals and hence fall under the category of professional ethics codes, while the Declaration on Bioethics and Human Rights relates to all persons and hence it is an applied ethics code.

Published Health Research

Role of Mannose-Binding Lectin Deficiency in HIV-1 and Schistosoma Infections in a Rural Adult Population in Zimbabwe

PLOS ONE | DOI:10.1371/journal.pone.0122659

R. B. L. Zinyama-Gutsire, C. Chasela, H. O. Madsen, S. Rusakaniko, P. Kallestrup, M. Christiansen, E. Gomo, H. Ullum, C. Erikstrup, S. Munyati, E. N. Kurewa, B. StrayPedersen, P. Garred, T. Mdluluz

Background: Polymorphism in the MBL2 gene lead to MBL deficiency, which has been shown to increase susceptibility to various bacterial, viral and parasitic infections. We assessed role of MBL deficiency in HIV-1 and schistosoma infections in Zimbabwean adults enrolled in the Mupfure Schistosomiasis and HIV Cohort (MUSH Cohort).

Conclusion: Our data indicate high prevalence of MBL deficiency, no evidence of association between MBL deficiency and HIV-1 infection. However, lower plasma MBL levels were protective against both *S. haematobium* and *S. mansoni* infections and MBL2 promoter and variants LY and LL increased susceptibility to *S. haematobium* infection.

Using Geographic Information Systems and Spatial Analysis Methods to Assess Household Water Access and Sanitation Coverage in the SHINE Trial

Clin Infect Dis. (2015) 61 (suppl 7): S716-S725.doi: 10.1093/cid/civ847

R. Ntozini, S. J. Marks, G. Mangwadu, M. N. N. Mbuya, G. Gerema, B. Mutasa, T. R. Julian, K. J. Schwab, J. H. Humphrey, L. I. Zungu for the SHINE Trial Team

Access to water and sanitation are important determinants of behavioral responses to hygiene and sanitation interventions. We estimated cluster-specific water access and sanitation coverage to inform a constrained randomization technique in the SHINE trial. Technicians and engineers inspected all public access water sources to ascertain seasonality, function, and geospatial coordinates. Households and water sources were mapped using open-source geospatial software. The distance from each household to the nearest perennial, functional, protected water source was calculated, and for each cluster, the median distance and the proportion of households within <500 m and >1500 m of such a water source. Cluster-specific sanitation coverage was ascertained using a random sample of 13 households per cluster. These parameters were included as covariates in randomization to optimize balance in water and sanitation access across treatment arms at the start of the trial. The observed high variability between clusters in both parameters suggests that constraining on these factors was needed to reduce risk of bias.

Annual National Health Research Forum



The Medical Research Council of Zimbabwe (MRCZ) hosted a very successful Annual Health Research Ethics Forum on the 20th of November 2015. The theme for the Forum was ***“Improving the Quality and Quantity of Health Research”***. The forum was attended by 139 people, including researchers from outside Zimbabwe.

The keynote address entitled: **“Improving quality and quantity of health research with limited resources”**, was given by Professor Sithole-Niang on behalf of the Research Council of Zimbabwe.

She encouraged local researchers to increase on research quantity in terms of the end product of publications. Academic institutions were challenged to come up with strategies, structures and practices that promote the quality and quantity of research.

Some of the strategies were spelt as:

- A. Establishment of Research Support Centres manned by research experts, which provides following services to staff and graduate students:
 - Proposal writing consulting
 - Quantitative methods and statistics
 - Qualitative methods consulting
 - Publication writing workshops
 - Research methods training.
 - Seminars on proposal development, research conduct and publication writing.
 - Organisation of Institutional research days and awarding of prizes to outstanding researchers and students.
- B. Institutional research excellence awards
- C. Strengthening Peer & Ethics review mechanisms
- D. Close monitoring of research – from approval to publication
- E. Establishing a formal research mentoring mechanism

Other presenters included:

Prof. S.Rusakaniko: Improving the impact of students’ research: Going beyond students dissertations.

Prof. P. Ndebele: Research quality and ethics issues: The MRCZ perspective

Tertiary Institutions

The following tertiary institutions also gave presentations on their experiences in addressing research quality and quantity strategies, issues and challenges.

Prof. E. Gomo : UZ College of Health Sciences

Dr. P. Makoni : NUST

Prof. C. Masimiremba : AIBST

Mrs. Makuyana : BUSE

The institutions shared the following strategies:

- Faculty research focused workshops,
- Setting up research clusters on health issues,
- Awarding incentives for presenting during Annual Research Day,
- Encouraging health related research travel grants and subscribing to Research Africa and Pivot
- Partnering with international organizations
- Staff is encouraged to publish in institutionally accredited journals.
- Participates in National exhibitions such as Research and Intellectual Outputs, Science, Engineering and Technology (RIE– SET).
- Research Strategic plan is complimented by the Extension strategic plan for community engagement and research.

Meet the Regulators Session: MRCZ, RCZ, MCAZ, NBA

There was also a special session for researchers to meet with the research regulators. This gave the researchers an opportunity to iron out issues and get clarifications they needed.

The highlights of the discussion sessions are as follows:

- Researchers need to be familiar with submission requirements
- Regulators from time and again should invite researchers for collegial interaction to strengthen up some regulatory issues
- Need for grooming of young researchers
- Researchers suggested that regulators should review regulatory fees downwards
- MRCZ and MCAZ are currently working towards e-submission in order to improve efficiency

The Forum ended with institutions being encouraged to prioritize dissemination of research findings to local stakeholders even after results have been published in international journals.

THANK YOU TO THE 2015 MRCZ REVIEWERS

MRCZ would like to appreciate the following individuals who most generously agreed to review proposals for us between January and December 2015. The assistance and expertise of these professionals promotes and maintains the high quality of ethics & scientific review.

Prof. S. Rusakaniko
Prof. T. Chipato
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Dr. P. V. Makaya
Mr. G. Javangwe
Mr. S. Buzuzi
Prof. T Mduluza
Mr. P. Chatikobo
Dr. T. Magwali
Mr. R. Magauzi
Ms. T. Bandason
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Dr. N. Nhando
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Prof. C. Maponga
Mr. Mukanangana
Dr. F Mupambireyi
Dr. K. Charambira
Dr. T. Magure
Mrs. B. Jokomo
Dr. D Chibanda
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